

**FACULTY OF  
PHARMACEUTICAL MEDICINE**



**CURRICULUM FOR  
PHARMACEUTICAL MEDICINE  
SPECIALTY TRAINING  
(PMST)**

**December 2006**

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**FACULTY OF PHARMACEUTICAL MEDICINE**  
**PHARMACEUTICAL MEDICINE SPECIALTY TRAINING**  
**(PMST)**  
**CURRICULUM**

**INTRODUCTION**

**Pharmaceutical Medicine**

Pharmaceutical Medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of the marketing of medicines for the benefit of patients and the health of the community.

**The Faculty of Pharmaceutical Medicine**

The Faculty of Pharmaceutical Medicine of the three Royal Colleges of Physicians of the UK exists to advance the science and practice of pharmaceutical medicine by working to develop and maintain competency, ethics and integrity and the highest professional standards in the specialty for the benefit of the public.

**Specialist Pharmaceutical Physicians**

An accredited specialist pharmaceutical physician is a medical doctor who, having completed at least three years of post-qualification clinical training in approved posts, has fulfilled the requirements of the curriculum in Pharmaceutical Medicine Specialty Training (PMST) in an approved training environment and has been awarded a Certificate of Completion of Training (CCT) by the Postgraduate Medical Education and Training Board (PMETB).

The pharmaceutical physician will be registered with and certified as fit to practise by the General Medical Council (GMC).

The specialist pharmaceutical physicians will practise pharmaceutical medicine within a pharmaceutical company,

independent clinical research organisation, medicines regulatory authority, or as an independent practitioner.

Specialist pharmaceutical physicians will undertake continuing professional development.

### **Specialist Training: Purpose**

The purpose of specialist training in pharmaceutical medicine is to produce accredited pharmaceutical physicians, who are equipped with specialist knowledge and comprehensive skills and competencies to practise to the highest ethical and professional standards, for the benefit and safety of patients and the public, in the development and maintenance of medicines.

### **Specialist Training: Objectives**

- To practise pharmaceutical medicine according to the principles and standards of Good Medical Practice laid down by the General Medical Council and of Good Pharmaceutical Medical Practice by the Faculty of Pharmaceutical Medicine. To acquire and demonstrate interpersonal and management skills for the practice of pharmaceutical medicine to the highest expected levels of competency, care and personal conduct.
- To acquire and demonstrate knowledge of and competency in the surveillance of the safety of medicines during all stages of development and clinical use, with particular emphasis on the choice, application and analysis of appropriate surveillance methods, on the international regulatory reporting requirements and on the timely revisions of product information.
- To acquire and demonstrate a knowledge of and competency in medicines' regulation to the level necessary to fulfil the role of a pharmaceutical physician. Specifically, to contribute to the execution of tasks related to the national, European and/or other international regulatory systems, to the principles of clinical trial regulations, to the licensing procedures and to post-licensing monitoring for safety, efficacy and quality of medicines.
- To acquire knowledge of and competency in clinical pharmacology and other supporting disciplines to the level necessary to fulfil proficiently the role of a pharmaceutical physician. Contribute to investigations, judgements and decisions on the clinical pharmacology of a medicine in all phases of its research and development. Apply such knowledge

in the continuing support and extension of the clinical indications, formulations and dosage schedules, in the investigation and assessment of suspected adverse drug events, in submissions to regulatory and pricing authorities, and in product information for doctors and patients.

- To contribute clinical input to enable effective collaborative work with professional statistical and data management personnel, thereby ensuring optimal clinical study design, and effective management and analysis of clinical trial data to meet scientific and regulatory standards.
- To acquire competency to prepare a critical overview of a therapeutic area and demonstrate the relevance of developing a drug in this area. To prepare and/or discuss critically a clinical development plan to explore the safety and efficacy of a new pharmaceutical agent that will lead to its safe adoption into clinical practice after approval by national and international regulatory agencies. To oversee a programme of clinical trials that will demonstrate ethically and adequately the safety and efficacy of a new pharmaceutical agent in compliance with national and international laws, regulations and guidelines. To appraise critically and report on the evidence of safety and efficacy of a new pharmaceutical agent and assess its benefits, risks and place in the pharmaceutical armamentarium.
- To demonstrate applied knowledge of the commercial environment in which pharmaceutical marketing takes place. To demonstrate competency in applying these principles to the constructive role of the pharmaceutical physician in ensuring that marketing activities within this environment remain legal, ethical and, where appropriate, innovative. To serve the welfare of patients in providing medical support that leads to appropriate prescribing of marketed medicines.

# **1. RATIONALE FOR PMST CURRICULUM AND ORGANISATION OF TRAINING**

## **CURRICULUM**

### **Purpose**

The curriculum provides the guidance and support for the acquisition of specialist knowledge and skills to ensure the competency of pharmaceutical physicians in the practice of pharmaceutical medicine and of providing a high standard of professional service for the benefit of patients and the health of the community.

It underpins the Pharmaceutical Medicine Specialty Training (PMST) programme for the award of a Certificate of Completion of Training (CCT) in pharmaceutical medicine.

### **Development and consensus**

The development of the curriculum for postgraduate training in pharmaceutical medicine began over 30 years ago, and has adopted and developed the best and most appropriate educational practices, with the curriculum being updated regularly.

Pharmaceutical Medicine Specialty Training (PMST) – *formerly Higher Medical Training (PMST)* – implemented since 2003, comprises a specialty knowledge base and a practical, competency-based, curriculum.

### **Specialty Knowledge Base of PMST**

The specialty knowledge base of pharmaceutical medicine is assessed by professional examination leading to the Diploma in Pharmaceutical Medicine.

From 1976 the three UK Royal Colleges of Physicians awarded the Diploma in Pharmaceutical Medicine. In 1994, five years after the creation of the Faculty, responsibility for the Diploma examination was transferred to the Faculty. Possession of the Diploma allows pharmaceutical physicians to apply to become Members of the Faculty.

## Educational basis

The Diploma examination has always been conducted by a Board of Examiners chosen from senior physicians working in pharmaceutical companies, regulatory authorities, universities and hospitals, who together bring experience of pharmaceutical medicine and of related specialties, such as clinical pharmacology and toxicology. An important contribution from the beginning has been the ongoing experience of some examiners in other postgraduate examinations.

At the outset, the importance of the Diploma was threefold [ref.1].

First, it required that medical graduates sitting the examination would have undergone a two-year period of postgraduate training and experience in pharmaceutical medicine after completing at least two years in general medical training following full registration with the General Medical Council (GMC) or an equivalent body in another country.

Second, it adopted a format that was similar to the written and oral parts of other diploma examinations in the UK.

Third, the three Royal Colleges of Physicians and the Joint Committee on Higher Medical Training (JCHMT) had endorsed and promoted the training and the examination. Thus, it had credibility and complied with the current attitudes/behaviour on postgraduate training following the report of the Royal Commission on Medical Education (1968).

## Training courses

The creation of a part-time postgraduate training course in pharmaceutical medicine was a parallel activity.

The JCHMT began in 1975 the planning of the two-year training course. The regulations for obtaining the Diploma mandated periods of dedicated study on a training course or courses that was equivalent to a total of eight weeks full time [viz "...part-time study throughout these two years or not less than 12 months of part-time study if the candidate has had at least six months in a post with experience of clinical pharmacology or therapeutics approved by the Board of Management" and "... will have undergone a period of study equivalent to eight weeks whole-time... that should normally include two one-week periods of residential training"].

The Joint Advisory Committee (JAC) of the Association of the British Pharmaceutical Industry (ABPI) and the Association of Medical Advisers in the Pharmaceutical Industry (AMAPI, later BrAPP) together with the University of Wales Institute of Science and Technology (UWIST) designed a two-year programme that began in the autumn of 1976. It was a modular design comprising periods of 2-4 days on 10 occasions during the two-year cycle [ref. 2].

The Postgraduate Course in Pharmaceutical Medicine, the so-called Cardiff course, directed from the Department of Pharmacy, had a curriculum of 14 topics initially, which reflected the Diploma syllabus. Liaison between the UWIST course organisers and the Board of Examiners was encouraged and, more importantly, the course director invited speakers from a wide spectrum of industry, university, hospital, government and other organisations.

In 1985, the Board of Examiners set up a Working Party to review thoroughly the Cardiff course and, among many ideas, proposed separating first- and second-year students and encouraging "mock examinations".

Other training courses dealing with one, some or all modules are now available in the UK and other European countries.

### **Curriculum content choice**

#### Diploma examination syllabus

The curriculum has been regularly reviewed and modified in order to reflect current practice and expectations.

The original syllabus of 14 short paragraphs, each containing key elements of the topics, was approved in 1975. These paragraphs were expanded in 1983 by the Joint Advisory Committee (JAC), which also oversaw the Cardiff curriculum.

Teachers on the course, who judged the level of knowledge of the attendees, were constantly expanding the taught curriculum in order to meet their real needs. The JAC and the Board of Examiners monitored this dynamic process and in the 1983 revision of the curriculum consolidated these improvements.

In 1989, the Faculty of Pharmaceutical Medicine was inaugurated but there was a deliberate decision to maintain the Board of Examiners as a separate entity, under the aegis of the Royal College of Physicians of Edinburgh, during the Faculty's formative stage when proposals for a Membership examination were being debated.

It was finally decided that possession of the Diploma would grant Faculty Associateship status.

A Curriculum Working Party was formed in 1989 by the Board of Examiners and reported to a joint meeting of the Board and the Faculty's Qualifications and Examinations Committee. The proposals were endorsed and the Working Party was asked to develop a comprehensive modular syllabus and a related modular training programme suitable for tuition on approved courses. Its second report in November 1990 presented a proposed revision of the syllabus, which would comprise 18 modules, and these were also suitable for training module curricula that could be "mixed and matched" into training blocks. In fact, the revised syllabus was edited into 12 sections by amalgamating those on drug development and those on clinical trials. The new syllabus was agreed in December 1990 and became effective for the examination held in November 1992.

In 1994, the Board of Examiners created Working Parties to formalise its operational procedures (1995) and to issue guidance notes for candidates (1996).

The syllabus in pharmaceutical medicine was revised in 1998 and again in 2003 with revision on that occasion of the regulations, operational procedures and guidance notes for the Diploma examination. The 2003 syllabus is now separated into nine sections, the scope and content of which are largely unchanged from that prior to 2003 but the presentation has been updated to bring them in line with recent developments in PMST and to take account of advances and changes in the practice of pharmaceutical medicine.

The first six sections listed correspond to the practical PMST training modules. In addition, 'Discovery of New Medicines' is considered an essential area of knowledge for physicians entering a career in pharmaceutical medicine. Similarly, 'Therapeutics' has always been included in the syllabus but its importance to the practice of all areas of pharmaceutical medicine is emphasised by its designation as a separate section. The final section on 'The Role of the Medical Department' emphasises the roles and organisation of what is the main workplace and centre of operations for pharmaceutical physicians.

The Board of the Faculty has approved another Diploma syllabus revision in March 2006; in the main relating to changes in the regulations and procedures for the examination.

## Diploma Examination

At its inception the examination adopted the conventional format of those for other postgraduate medical diplomas in the UK, such as child health and public health. Over the 30 years, the format has changed somewhat, but it has always comprised a written and an oral part. It has always been held once a year.

In 1976, the written part (three hours) comprised three sections. The first one dealt with pharmaceutical medicine and the second with clinical pharmacology and therapeutics; each required two essays. The third offered 20 short questions on a general syllabus. It was changed in 1978 with greater emphasis on the general paper, which tested factual knowledge, reducing the short questions from 20 to 15, allocating more time (two hours), with a corresponding shortening of the time for the other two parts and only one question to be answered in each.

In 1983, the second written paper (clinical pharmacology and therapeutics) was changed from an essay format to "short notes" format. It was felt that essays took considerable time to write and read, dealing with one topic, and that candidates whose native language was not English were often at some disadvantage with an essay format. Indeed, there had been earlier decisions that recognised problems for overseas candidates, such as reducing questions on specific British practice (e.g. UK drug regulations).

At the beginning of this first 10-year period, a paper on the Diploma was published [ref. 3] and, by the end of the period, other events were contributing to a greater awareness of the specialty. In 1984, a new journal called *Pharmaceutical Medicine* was launched, an article on the discipline appeared in *The Lancet* [ref. 4], and a textbook was published [ref. 5].

In 1989, as mentioned earlier, the examination syllabus was extensively revised. The idea of a multiple choice question (MCQ) paper had been mooted several years before. The Board of Examiners was presented with a detailed proposal based on the London College computer-based system for marking the MRCP (Part 1) examination, used by other professional examinations, including the diplomas in tropical medicine and child health. Candidates sitting the Diploma examinations in 1990 and 1991 were invited to complete a "mock" MCQ paper. Based on this two-year evaluation, it was decided that another paper with 25 MCQs would be a good

discriminator and it was introduced in 1992, replacing the section on clinical pharmacology and therapeutics.

A Working Party on the Diploma Examination was set up in December 1993 to look at ways to increase standards and reported back a year later. It recommended that the essay questions should present a problem-solving scenario and that an idealised response should be available to assist even marking between examiners. Similarly, oral questions should aim to assess the use of knowledge in a more practical manner and to probe a candidate's appreciation of issues. It also favoured dropping numerical marks and instead categorising candidates in each part of the examination (i.e. good, adequate, borderline pass, borderline fail, fail). More importantly, only adequate or good passes in the other three parts could compensate for one "borderline fail". It suggested that the award of the Diploma with Distinction should enhance standards. All these recommendations were adopted.

Thus, there was major re-appraisal of the Diploma examination in this period with substantive revision of the syllabus and changes in assessments, aiming to provide an objective evaluation of candidates' factual knowledge and ability to apply it. In parallel, the Cardiff postgraduate course had adopted a modular style and completed its first cycle based on the revised syllabus. Another textbook directed at the examination candidates was published [ref. 6]. The Society of Pharmaceutical Medicine was formed in 1987, providing another forum for pharmaceutical medicine in the UK that included non-medical members. It initiated the *Journal of Pharmaceutical Medicine* in 1991 that was merged with *Pharmaceutical Medicine* in 1997 to form the *International Journal of Pharmaceutical Medicine* in which the Faculty and the Society had sections.

### Specialty recognition and Higher Medical Training

The Faculty was now pursuing specialty recognition. It consolidated the Diploma examination as the specialty knowledge base of a programme that, together with practical competency-based modules, would secure specialist status for successful candidates. There was a need to create a series of documents dealing with the constitution of the Board of Examiners, role specifications for its officers and operational procedures for the Diploma examination, including appeals.

In 1996, the new regulations, agreed in 1994, came into effect. The main requirement was that a candidate should pass all four

parts of the examination. A different panel of examiners dealt with questions in each section of the written examination. Attention was focussed on the MCQs, bringing the bank of questions up to date, and the traditional negative marking was retrospectively compared with a modified Angoff procedure, used to decide the pass mark and grade boundaries, and used in practice since 2001. Negative marking continued until 2004, the last year of its use. Since 2003 the Angoff procedure has also been used for setting grade boundaries for the Short Answer Question Paper. The oral examination was modified so that real-life scenarios are dealt with, by assessing a scientific paper.

The final integration of the knowledge base with practical modules in PMST (*formerly HMT*) led to the Diploma curriculum being reduced from 12 to nine modules, as mentioned above. Thus, the Diploma examination is the summative assessment of the Specialty Knowledge Base. It can be taken for the first time after a minimum of two years from taking up a post in pharmaceutical medicine and enrolment into PMST.

### **Agreement on specialty knowledge base curriculum**

The Syllabus in Pharmaceutical Medicine has always fallen under the Board of Examiners for the Diploma in Pharmaceutical Medicine, initially reporting to the JCHMT and the three Royal Colleges of Physicians of the UK (1975-89), to the Royal College of Physicians of Edinburgh (1989-94) and since 1994 to the Board of the Faculty of Pharmaceutical Medicine.

Reviews of both the syllabus in Pharmaceutical Medicine and the curricula of the course(s) were undertaken by working parties of the Board of Examiners (1983 and 1989). The Board of Examiners reported in 1983 to the JCHMT and the three Royal Colleges of Physicians and in 1989 to the Board and Qualifications and Examinations Committee of the Faculty of Pharmaceutical Medicine.

### **Practical competency-based training in PMST**

#### Early Developments

The Faculty from its inception in 1989 adopted a plan to form a two-tier examination system for Associateship and Membership.

As late as 1992, it was formally proposing that an Associateship assessment comprising written and oral sections would replace the

Diploma examination, which currently allowed entry to Associateship. Entry to Membership would be examined by presentation of a dissertation and would normally require the candidate to be already an Associate of the Faculty. Thus, the objectives were directed at Faculty entry at these two levels.

The entry criteria for Associateship were significantly weakened. The main requirement was two-year in-post training. Academic training was not mandatory but was recommended and might be on a full-time, distance learning, or day or block release basis.

The Board of Examiners in 1992 expressed its reservations about the Associateship examination. A year later the Faculty then proposed a twice-yearly two-part Diploma examination. The two-part examination policy was at variance with other professional examinations and with European Commission (EC) policy on specialist examinations. The Board voted against both elements.

The Diploma requirements and examination were not changed and the responsibility for it was transferred from the Edinburgh College to the Faculty in the following year.

Meanwhile, the Membership by dissertation proposal was adopted [ref. 7]. However, the number of applications for this route was small in a 5-year period and few completed it despite the Board of Examiners' guidance to candidates and supervisors. It was never designed to act as an exit examination for judging overall professional competency and knowledge and could not qualify for specialist recognition. It was eventually abandoned.

#### Pharmaceutical Medicine Specialty Training (PMST) (formerly Advanced HMT)

The advent of specialist medical training in the UK for clinical specialties leading to granting of a Certificate of Completion of Specialist Training (CCST-UK) offered pharmaceutical medicine an opportunity to achieve equivalent recognition as a listed specialty and for pharmaceutical physicians to gain a CSST-UK.

The Faculty of Pharmaceutical Medicine and the JCHMT of the three Royal Colleges of Physicians of the UK worked closely together to propose, pursue and oversee recognition of pharmaceutical medicine as a medical specialty and the development and implementation of a specialist-training programme. The JCHMT in 1995 established a Subcommittee in Pharmaceutical Medicine of the Specialist Advisory Committee in Clinical Pharmacology and Therapeutics (SSAC) and the Faculty a Specialist Training

Subcommittee of its statutory Education Committee reporting to the Board of the Faculty.

The first step was designing a programme of Specialist Medical Training and gaining approval from the Specialist Training Authority (STA). This was aided by the existence of the Diploma and its academic pedigree. The Faculty prepared and issued in 1997 a consultative document [ref. 8]. The existing provisions for the Diploma, which identified a training programme, existing courses and an exit examination, already met the basic training requirements.

Pharmaceutical Medicine Specialty Training was designed around six modules with continuous assessment. It would be an individualised (*ad personam*) approved programme in order to match local opportunities for direct (on-the-job) training, reflecting the nature of the pharmaceutical company and its research, development and marketing portfolio, and for indirect training through interactive courses.

The next step was obtaining recognition of pharmaceutical medicine as a listed specialty in Schedule 2 of the European Specialist Medical Qualifications Order 1995.

This was achieved 17 April 2002 after the Secretary of State for Health signed the Order, which was acceded to by Parliament.

### **Curriculum content choice**

#### Delphi exercise

The Faculty produced in 1997 draft outlines for six modules in the Curriculum and then commissioned the University of Keele to undertake a Delphi exercise to determine their content. The attraction of the Delphi process is its employment of an iterative process, which is an adaptation of the Delphi forecasting technique, and has been applied in health services research [ref. 9]. It provides a survey technique for decision-making among isolated anonymous respondents. In a multi-stage process, each stage builds on the previous one aiming to guide group opinion to think through complex problems and to produce specific ideas of high quality. It had been applied to undergraduate and postgraduate medical courses [refs. 10, 11].

The purpose of the exercise was finding out from a group of experts in each particular field if the proposed competencies were those one

would expect in a specialist pharmaceutical physician. More importantly, each competency was categorised on the basis of three levels of ability:

- (a) being able to perform the task alone and unsupervised,
- (b) performing the task as part of a team, or
- (c) having an understanding of the underlying principles.

In addition, a weighting factor was applied so that a rank order of competencies was obtained. Then in a second phase the previous statements and new ones proposed by the expert panel were re-assessed.

A panel of correspondents for each module was drawn from Fellows, Members and Associates of the Faculty and from other experts in the field. The six panels were more or less the same size (range 27-35). There were a total of 364 statements. These were then assembled to form six curricula and the level of competency was given for each or for a group of related activities.

The penultimate curricula were assessed by a taskforce in the Faculty, the Curriculum Steering Group, established for the purpose by the Specialist Training Subcommittee, and final editing and juxta-positioning of related topics was undertaken.

The style and outcomes of each Delphi exercise on the six modules were analysed at the University of Keele and each was published between December 1999 and April 2000 [refs. 9-13].

### **Agreement on PMST (formerly HMT) curriculum**

The curriculum for PMST comprised the specialty knowledge base (*formerly Basic HMT*) and workplace-centred practical competencies (*formerly Advanced HMT*) and this was approved by the SSAC and the JCHMT as fulfilling the requirements for a specialist training programme. In addition, the Specialist Training Subcommittee, the Education Committee and the Board of the Faculty approved it as fulfilling the breadth and depth of content for a specialist training programme in pharmaceutical medicine.

Following submission of the curriculum to the Specialist Training Authority (STA), as part of the application for specialist recognition and listing of the specialty, the curriculum was approved by the STA.

It was further approved by the STA in 2003 as fulfilling the requirements for a competency-based education and training programme in pharmaceutical medicine.

The PMST curriculum has been the recent innovation. It has benefited from new educational techniques. Few medical specialties have been so original in deciding the curricula for training of their future specialists. The Delphi exercise and its implementation must rank as one of the biggest and most ambitious consultation exercises ever mounted in defining a higher education programme in a medical specialty [ref. 14].

### **Teaching & learning methods**

Teaching and learning methods in pharmaceutical medicine have developed to satisfy the training and continuing education requirements of postgraduate doctors working in an industrial and commercial setting in local and international multidisciplinary teams with a requirement for both general and very specific learning material.

During their career doctors in pharmaceutical medicine may move jobs, institutions and even countries within a competitive industry. Yet, it remains imperative that these pharmaceutical physicians, working ultimately for the benefit and safety of patients, maintain and demonstrate professional standards of competency, care and conduct throughout their careers and are required to acquire and maintain transferable skills through which to do so.

Learning methods include:

- a. apprenticeship (experiential) learning;
- b. structured postgraduate courses in pharmaceutical medicine; university based;
- c. interactive structured courses;
- d. problem- and case-based scenarios;
- e. national and international symposia and conferences;
- f. self-directed and distance learning (journals, textbooks and internet);
- g. reflective commentary;
- h. formal training at local, national, international (themed) courses and study days;
- i. in-company training programmes;
- j. self-assessment;
- k. small-group seminar learning with peers. Teachers are

- experts & thought leaders from industry, regulatory bodies, university;
- I. one-to-one teaching and learning.

Teaching and learning methods in pharmaceutical medicine have developed over the past 50 years to meet the needs of doctors working in a dynamic, rapidly developing research-based industry.

Teaching has moved from the familiar didactic lectures in a classroom setting to a reliance on experts, scientists from industry and academia, clinicians from hospital medicine and general practice, and on senior pharmaceutical physician peers to present, share and discuss the latest research and its impact in the clinical setting and on drug development and therapeutic monitoring.

Research seminars, national and international symposia, topic and themed meetings organised either inside a company or through the industry's trade, professional and academic allied organisations has become the standard for imparting information and forming principles and practices.

Basic education and training takes place in short modular courses from one to three days rather than long residential or full-time programmes, so that the requirements of everyday work are not unduly disrupted. These structured education and training programmes are supplemented increasingly by pre-course reading and research and post-course assignments and assessments, also increasingly by distance learning through correspondence or the internet.

### **Role of teachers & registrars in curriculum development**

As described above the specialty knowledge base in pharmaceutical medicine has been accrued over a period of 30 years. Its formal syllabus and derived curricula have been compiled, updated and delivered by experts and professionals working in the field.

Registrars, both past and present, have contributed to the development of the curriculum, both in keeping knowledge and skills up to date in a rapidly developing research-based field, and in moulding its delivery to appropriate learning strategies for adult, postgraduate education.

## **Curriculum & stage of learning**

The PMST curriculum provides education and training for pharmaceutical physicians who have joined the specialty of pharmaceutical medicine after at least four years of post-qualification clinical training. Prior to gaining a post in pharmaceutical medicine, physicians have had little or no experience of or exposure to the principles and practices involved in the discovery, development, evaluation, registration, monitoring and medical marketing of medicines.

The curriculum is appropriate for registrars preparing for practice and a career in pharmaceutical medicine, and, following training, it is possible for a pharmaceutical physician to practise in several different ways: as a clinical research physician in early- or late phase clinical development involving healthy volunteer subjects or patients in clinical trials; as a medical adviser involved in the post-licensing phase of medicines' development; as a medical assessor in a medicines regulatory body; or as an independent consultant practitioner.

The curriculum provides specialist training across the breadth of pharmaceutical medicine. It thus lays the ground also for eventual sub-specialisation in areas such as exploratory development of medicines, medicines' regulation, pharmacovigilance, or special interests in the field of pharmaceutical medicine, such as medical-marketing, legal, communications, management and business development.

Pharmaceutical physicians, in working towards the award of a CCT, are prepared for competent and safe practice across the breadth of the specialty within a medical department or pharmaceutical body conducting a range of activities in the field of drug development and maintenance. They will be able particularly to recognise the limits of their knowledge and experience for their stage in career and know when to refer issues to colleagues, seniors and those with greater expertise and experience. It is essential that the curriculum enables all registrars to be able to practise to this level from a minimum time of four years after entering the specialty.

The curriculum is broad ranging and flexible within programme and will enable registrars to develop special interests whilst gaining experience and competencies through continuing professional development to further their expertise over time.

## **Curriculum and specialty**

The curriculum covering knowledge, practical competencies and generic aspects of PMST is designed for training of pharmaceutical physicians who enter the specialty of pharmaceutical medicine after at least three years of post-qualification clinical training. It is appropriate for doctors working in pharmaceutical companies, clinical research organisations or regulatory bodies to achieve the knowledge and competencies necessary for an accredited specialist in pharmaceutical medicine.

The curriculum in PMST is also appropriate for those doctors who are already established as pharmaceutical or regulatory physicians but have not to date undertaken or completed formal education and training in pharmaceutical medicine to become an accredited specialist (CCT holder).

## **Link of curriculum to stages of education and training**

The curriculum for PMST covers a 4-8 year period of specialist training for those eligible pharmaceutical or regulatory physicians who have joined pharmaceutical medicine following a period of clinical training and experience.

Doctors will have completed the Foundation Programme (F1 and F2 posts) and at least one year of post-foundation clinical training in a basic specialist training programme (ST1) before embarking on specialist training in pharmaceutical medicine (PMST).

For PMST there is no restriction on the specialty from which pharmaceutical physicians come to join pharmaceutical medicine. Doctors may join pharmaceutical medicine after acquiring clinical training over at least three years post-qualification (graduation) in approved posts offering clinical care, including acute clinical care and broad experience in prescribing and monitoring the effects of medicines.

They may additionally have acquired postgraduate scientific and medical degrees and diplomas. Doctors may enter pharmaceutical medicine after a variable period in another specialist training programme in any area of clinical practice.

Following successful completion of specialist training and acquisition of a CCT to become an accredited specialist in pharmaceutical medicine, the curriculum will have prepared the pharmaceutical physician to:

- a. continue with their continuing professional development (CPD) in pharmaceutical medicine to remain up to date and maintain their place on the specialist register;
- b. engage with appraisal and revalidation; (s/he will also be eligible to revalidate their certification to practise on the UK general medical register - under criteria still to be published).
- c. review their practice in the light of Good Pharmaceutical Medical Practice;
- d. identify their learning needs and goals to develop further specialised or sub-specialty practice (to date there is no sub-specialty accreditation available in pharmaceutical medicine).

### **Curriculum and programmes**

Each pharmaceutical physician enrolled in PMST undertakes a personalised (*ad personam*) course of training, involving acquisition of the specialty knowledge base and a balance of competencies from the PMST curriculum spread between in-work experience and course-based or other learning modalities.

Thus, each personalised course of education and training (as set out in JCHMT Form B) represents a programme of training.

The demonstration of the standard for acquisition of the Specialty Knowledge Base (part of PMST) is in the successful outcome of the examination for the Diploma in pharmaceutical medicine.

The acquisition of competencies in the practical component of PMST depends on the method to achieve them, either by in-work experience or through structured approved module courses, other in-house or external courses, or other learning modality.

It is expected that registrars will demonstrate competencies across the breadth of pharmaceutical medicine as laid down in the PMST curriculum. For each programme, a minimum of two operational modules (from medicines regulation, clinical pharmacology, statistics and data management, clinical development, healthcare marketplace and drug safety surveillance) will determine the combination of competencies to be achieved through in-work experience.

Each *ad personam* PMST programme of training must be approved by PMETB prior to enrolment (issue of a National Training Number – Industry [NTN-I]).

## **ORGANISATION OF TRAINING**

### **Overview of Pharmaceutical Medicine Specialty Training (PMST)**

Specialty training in pharmaceutical medicine (PMST) may begin after gaining a post in pharmaceutical medicine and after completion of the Foundation Programme (F1 and F2) and one year of basic specialist training (ST1) in any medical specialty, for example Core Medical Training (CMT) of the Royal Colleges of Physicians, or its equivalent in other medical specialties.

The nature of the clinical training prior to specialty training in pharmaceutical medicine must include acute clinical care of patients and broad prescribing experience. The specialties in which this experience is gained are not critical and pharmaceutical physicians come from a wide variety of medical and surgical disciplines.

The programme of PMST consists of the Specialty Knowledge Base (leading to the Diploma in Pharmaceutical Medicine), and practical competency-based training in an individualised (*ad personam*) programme centred on an approved workplace training environment.

Practical PMST comprises a modular programme in six fields of practice in pharmaceutical medicine that accompanies and / or follows acquisition of the Specialty Knowledge Base. The six modules are Medicines Regulation, Clinical Pharmacology, Statistics and Data Management, Clinical Development, Healthcare Marketplace and Drug Safety Surveillance.

A seventh module covers Generic aspects of pharmaceutical medicine including Interpersonal and Management Skills, and Good Pharmaceutical Medical Practice. The generic module in pharmaceutical medicine continues from the Generic Module for the Medical Specialties delivered during clinical training with its emphasis on individual patient care within the NHS. The generic module in pharmaceutical medicine encompasses the principles of Good Pharmaceutical Medical Practice and interpersonal and management skills relevant to the ethical and professional work of a pharmaceutical physician practising outside the NHS.

Practical PMST training with continuous and performance-based assessments enables registrars to demonstrate the breadth and depth of learning and experience that they have achieved in acquiring competencies in pharmaceutical medicine.

Throughout PMST, registrars should acquire and maintain a thorough knowledge of the principles and practices of the management of diseases in the therapeutic areas in which they are working. They should acquire investigational skills in those areas of applied clinical research covered by the training programme. They should also acquire a thorough understanding of the administration and management of those organisations in which they work or with which they are affiliated within pharmaceutical medicine.

Registrars will exhibit professionalism in all their activities.

Registrars will be mindful of the safety of patients, and of healthy and patient volunteer subjects.

Registrars are expected to be competent in all aspects of the curriculum.

### **Entry criteria to PMST**

The requirements for entry to specialist training in pharmaceutical medicine are:

1. Registration with The General Medical Council (Limited or Full) at entry. Full registration is required on completion of PMST prior to obtaining a CCT.
2. A minimum of three years of clinical training in approved training posts following medical qualification, which will include clinical care of patients, including acute care, and the prescribing and monitoring the effects of drugs. This will be satisfied in the UK by completion of the Foundation programme (F1 and F2) and at least one year of basic specialist training [ST1] (e.g. Core Medical Training, CMT1 or the equivalent in other disciplines), or the equivalent if qualified outside the UK.

Fixed Term Speciality Training Appointments (FTSTA) may also contribute to post-Foundation clinical training.

The post-Foundation competencies required for entry to PMST relate to any specialty training programme and the successful RITA review (RITA-C) at the end of one year (ST1 or equivalent).

3. Appointment through a transparent system of competitive interview(s) to a post within the pharmaceutical industry, the regulatory authorities, or independent clinical research organisation wherein a Faculty-approved training programme can be undertaken. Approval of both the employing organisation (JCHMT Form A) for training and the training programme (JCHMT Form B) will be required for enrolment.
4. The possession of a scientific qualification (e.g. BSc) and/or postgraduate medical or scientific diploma or degree (e.g. MSc, PhD, MD, MRCP, MRCPPath) is not essential but is desirable.
5. Registration with the Faculty as an Associate member (Training) is essential.

### **MMC (Modernising Medical Careers) and transition to PMST**

Following the implementation in August 2005 of Modernising Medical Careers (MMC) by the four UK Health Departments the requirements for clinical training prior to entry to specialist training programmes changed.

The introduction of a Foundation Programme (F1 and F2) over two years replaced the Pre-registration house officer posts and one year of post-registration Senior House Officer posts. Entry to specialties then followed (from August 2007) with specialties with run-through training programmes requiring completion of basic specialist training over two years (ST1 and ST2).

#### **1. Medical graduates who qualified before 2005:**

Those doctors who qualified before 2005 and received provisional registration with the General Medical Council before 1 August 2005 will need to demonstrate successful completion of the following clinical training requirements or demonstrate equivalence to them before entry to higher specialist training in pharmaceutical medicine:

- One (1) year as Pre-Registration House Officer (PRHO)
- Two (2) years post-registration experience of General Professional Training in approved training posts at Senior House Officer (SHO) level, which would normally involve direct patient care and experience of prescribing and

monitoring the effects of drugs. Approved training in a range of specialties is highly recommended but is not required.

## 2. Medical graduates who qualified in or after 2005:

Those doctors who qualified in or after 2005 and received provisional registration with the General Medical Council on or after 1 August 2005 will need to demonstrate successful completion of the following clinical training requirements or demonstrate equivalence to them before entry to higher specialist training in pharmaceutical medicine:

- Completion of the Foundation programme (two years: F1 and F2)
  
- A minimum of one year of Basic Specialist Training (ST1) in training programmes in any medical specialty or in a fixed term specialist training appointment (FTSTA), which would normally involve direct patient care, including acute care, and experience of prescribing and monitoring the effects of drugs.

3. Programmes for Pharmaceutical Medicine Specialist Training (PMST) will continue to be approved by the PMETB as a separate stage in the enrolment process.

4. Medical graduates whose post qualification training does not completely fall within either of the above models, including those who qualified and/or trained outside the United Kingdom, will be assessed for eligibility for entry to PMST by the SAC-PM. Successful applicants will be required to demonstrate that their qualifications and clinical training are equivalent to the current entry requirements, and subject to approval by the PMETB.

5. Doctors entering PMST before 31 July 2007 will follow the PMST (*formerly PMST*) curriculum approved by JCHMT, STA and PMETB of 2003. Doctors entering PMST from 1 August 2007 onwards will follow the curriculum approved by JCHMT and PMETB of 2007. Doctors may switch from curriculum 2003 to curriculum 2007 with prior agreement of the SAC in Pharmaceutical Medicine.

## **EEA or Overseas Doctors**

The entry requirements for doctors trained in the EEA or overseas are the same as those outlined above with the following amendments:

1. The basic medical qualification must be recognised by and be registrable with the GMC. Limited or full GMC registration will be required for enrolment into PMST, and full GMC registration will be required for a recommendation of a CCT.
2. Clinical training must have been supervised to the same extent as approved posts in the UK and prospective entrants must be able to provide evidence of suitable knowledge and experience, and the equivalence of competencies acquired in the Foundation Programme and post-Foundation clinical training up to ST1. This is subject to approval by the Lead Postgraduate Dean.
3. Appointment to posts must be consistent with UK employment law and good practice in selection and recruitment. The applicant must be in post in the UK prior to enrolling for PMST.

### **Overseas Diplomas and the Specialty Knowledge Base**

Diplomas in Pharmaceutical Medicine offered by the University of Brussels (Belgium) and the University of Basel (Switzerland) have been recognised as equivalent to the Diploma in Pharmaceutical Medicine (UK). Possession of either the Belgian or Swiss Diploma is considered to demonstrate the specialty knowledge base of PMST, and is acceptable for the UK CCT PMST programme.

### **Duration of Training**

The PMST programme will take a minimum of four and a maximum of eight years (full-time equivalents). The Specialty Knowledge Base follows the syllabus for the Diploma in Pharmaceutical Medicine examination. Passing the Diploma examination is required before a CCT can be recommended. The Specialty Knowledge Base ensures a breadth of knowledge appropriate to a specialist in pharmaceutical medicine.

### **Generic Curriculum**

This specialty curriculum is complementary to the generic curriculum which applies to all 28 physicianly specialities. The generic curriculum follows the headings of good medical practice and runs through from core training to CCT. Trainees should read and understand both their specialty curriculum and the generic curriculum. Both curricula should be seen as integrated so that generic competencies are acquired at all stages of specialty training. Some generic components are also further expanded and deepened

for some specialties (eg palliative medicine). When planning specialty programmes, deaneries and trainers should ensure that both specialty and generic competencies can be acquired and assessed.

### **Flexible Training**

Registrars who are unable to work full-time are entitled to opt for flexible training programmes as per EC Directive 93/16/EEC:

- i. Part-time training shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities to a period of at least half of that provided for full-time registrars;
- ii. The competent authorities shall ensure that the total duration and quality of part-time training of specialists are not less than those of full-time registrars.

The above provisions must be adhered to in pharmaceutical medicine.

### **Research and critical appraisal**

Trainees who wish to acquire extensive research competencies, in addition to those specified in the generic element of the curriculum, may undertake a research project as an ideal way of obtaining those competencies, all options can be considered including taking time out of programme to complete a specified project or research degree. Time out of programme needs prospective approval from the SAC and the support of the Postgraduate Dean. Funding will need to be identified for the duration of the research period. A maximum period of 3 years out of programme is allowed.

### **The Training Team**

The core training team for PMST in pharmaceutical medicine comprises the registrar, the Educational Supervisor (ES) and the Senior Specialty Adviser (SSA). These work together to define programme content, facilitate availability of learning opportunities and resources, assess and appraise the outcomes and control quality of the programme delivery in order to meet standards for the CCT.

Other teachers and trainers may be involved throughout a training programme, for example delegated in-company educational supervisors for reasons of expertise or additional help, lecturers and seminar leaders on structured postgraduate courses or PMST modular courses.

The role of all teachers and trainers is twofold; to impart knowledge, expertise and the fruits of experience to the registrar; to encourage and facilitate learning and acquisition of competencies by the registrar.

### Senior Specialty Adviser (SSA)

The SSA has responsibility for overseeing the PMST programme followed by registrars within a training environment.

The role of SSA is a joint appointment of the Faculty and Lead Postgraduate Dean (PGD). The SSA will normally be a Fellow of the Faculty, experienced at a senior level in pharmaceutical / regulatory medicine as well as in staff supervision, appraisal and assessment, and is committed to continuing professional development in general with a particular emphasis on PMST.

The SSA must undergo induction and training, organised by the Faculty, into PMST, the background to responsibilities of the SSA and the expected duties and activities in undertaking the role. The SSA is responsible to the Director of Education and Training (DET), acting on behalf of the Faculty, and the PGD. The SSA has a duty of responsibility, diligence and care to the JCHMT and the Specialist Advisory Committee in Pharmaceutical Medicine (SAC-PM).

The SSA is assigned to a training environment (company; institution) to advise the organisation on PMST and registrars on their PMST programmes, and to oversee (quality control) their progress and achievements.

### Principal Educational Supervisor (PES); Educational Supervisor (ES)

Each registrar has a Principal Educational Supervisor (PES) who must be a registered doctor and an experienced pharmaceutical physician who is normally a Member or Fellow of the Faculty of Pharmaceutical Medicine. The PES will normally be the registrar's medical manager and work on the same site. S/he will normally be familiar with and oversee the registrar's work.

The PES supervises on a regular basis and through personal contact a registrar undertaking a PMST programme in an approved training environment.

The specialist registrar should identify the PES in the preparatory stages of enrolment. The SSA has the responsibility for meeting the nominated PES and approving the choice on behalf of the Faculty and Postgraduate Dean (PGD).

If the PES does not work on the same site as the registrar, the SSA must be assured that regular contact with the registrar will be adequate.

In some circumstances, with approval of the SSA, a PES may delegate overall educational supervision or supervision of certain training modules to an Educational Supervisor (ES), not necessarily medically qualified, whilst retaining overall responsibility for supervision of training.

These circumstances include but are not confined to the following: when the PES is to be absent for any reason for a period in excess of four weeks; where the registrar is seconded, as part of their job, to another site or overseas; when supervision of a specified PMST Module is outside the experience of the PES for supervision.

*(Where possible, the generic single term Educational Supervisor [ES] will be referred to throughout this document.)*

During the course of PMST, it may be necessary to replace the ES, for example because the registrar or ES changes jobs or company so that the prime responsibilities of educational supervision can no longer be fulfilled. A new ES will be appointed with the approval of the SSA on behalf of the Faculty and PGD.

The ES must undergo induction and training in the responsibilities, skills and processes of supervision of a registrar in pharmaceutical medicine; for example, the conduct of educational and performance appraisals and assessments of performance and competency. The Faculty, along with the SAC-PM and PGD, will offer or facilitate any appropriate training that it considers necessary or which is requested.

The ES ensures the availability of and access to components of training as set out in the curriculum and detailed in the registrar's *ad personam* PMST programme (JCHMT Form B).

In particular the ES is responsible for ensuring access to the content of the generic module (Interpersonal and Management Skills; Good Pharmaceutical Medical Practice).

The ES is responsible for ensuring that the PMST programme fulfils the principles and standards laid down in Good Pharmaceutical Medical Practice (GPMP).

The ES oversees the education of a registrar to ensure that s/he is making the necessary progress. The ES may also be involved with the registrar's teaching, training, assessment and appraisal as well as assisting with professional and personal development.

The ES provides the registrar with educational supervision during the PMST programme. The ES should be in regular contact with the specialist registrar on at least a weekly basis. More formal meetings, with a written record, should occur in the early stages of training at least monthly and might be more often. In the later stages, contact might be less frequent, and the level of supervision may be less depending on the acquisition of competencies and experience of the registrar.

The ES and registrar should undertake formal educational appraisals on a 4-monthly basis and a formal annual performance appraisal for PMST prior to the annual RITA review.

During the preparatory stages for enrolment, the ES must participate in the enrolment meeting(s) with the registrar and SSA to complete JCHMT Form B. It sets out the full PMST programme which, when approved, is transferred to the Training Record and becomes the registrar's *ad personam* PMST programme.

The ES should keep the SSA informed about: significant problems that arise in provision of educational components; registrar experiencing difficulties in achieving educational objectives; performance not reaching the required standard; problems relating to the professional and personal development of the registrar, as they relate to the PMST programme. Such issues should be discussed with the specialist registrar in the first place and remedial measures adopted as soon as possible. It may be necessary, with the registrar's permission, to raise such matters with the SSA and / or PGD prior to the annual RITA review.

The ES will be involved in assessments and appraisals of PMST registrars:

- a. PMST meetings / advisory / educational (ongoing);

- b. educational appraisals;
- c. annual performance appraisal ('summative assessment');
- d. performance and competency assessments (as necessary for PMST curricular items).

Sections c. and d. above will form part of the Record of In-Training Assessment (RITA) annual review. Confidential aspects of appraisals, notably of b. above may be lodged in a separate section of the Training Record by mutual agreement between registrar and ES, and not presented for RITA review or other external scrutiny, except under exceptional circumstances (e.g. Appeals).

Adequate records should be maintained by ES of interactions with registrars, including competency assessments and appraisals. These records will be needed for the RITA process, notably the annual Review meeting with the PGD (or as delegated by the PGD).

The ES is responsible to the Faculty and the Postgraduate Dean (PGD) for monitoring a registrar's performance.

### **Individual Programmes in PMST**

PMST training follows seven practical modules, which are underpinned by the specialty knowledge base and depth of applied knowledge and competency in practice that is appropriate to a specialist in pharmaceutical medicine.

Three of the advanced modules, including the generic module (incorporating Interpersonal and Management Skills and Good Pharmaceutical Medical Practice), must be completed through in-work experience. The remaining four modules may be completed in work or by means of Faculty-approved interactive taught courses. They may also be acquired through a mix of in-work experience and supplementary short courses, either internal or external to the training organisation.

In-work modules may begin prior to passing the Diploma examination, but some taught courses would require evidence of specialist knowledge at a level equivalent to the Diploma prior to enrolment on the course.

### **Exemption from Training**

A maximum of one Module of PMST may be exempted from training, as follows:

a. possession of an accredited Diploma or Degree in the subject of the module which, to the satisfaction of the SAC, covers the module curriculum and demonstrates the registrar's competency in the module.

b. a portfolio of acquired prior experience covering the curriculum of the module, with evidence which, to the satisfaction of independent assessors appointed by the SAC, demonstrates the registrar's competency in the subject of the module.

An exempted module applies to the training only, not to the assessment of competency which may require to be undertaken as part of prospective PMST to the satisfaction of the SAC.

### **Location of Training**

To enrol in PMST, to acquire a CCT-UK, doctors must be resident in the UK.

A minimum of 50% of the 4-year programme must be undertaken in the UK.

Following enrolment, PMST may be undertaken overseas, with agreement of the SAC in Pharmaceutical Medicine. In order for training to be undertaken outside the UK, the training environment must be approved by the SAC (JCHMT Form A) and the individual programme also approved (JCHMT Form B) by the SAC and by the PMETB.

The SSA and ES must also be trained and approved by the Faculty and SAC.

### **Enrolment into PMST**

The JCHMT writes to the applicant registrar to confirm eligibility to enrol and list in their letter all the documents required for enrolment.

The SSA should establish with the registrar and / or ES if the SAC has previously approved a Form A for the organisation. If so, the SSA should enquire whether the training opportunities still apply to the post held by the registrar and if there have been any significant changes to them.

The enrolment meeting should be primarily between the SSA, registrar and ES, as they will liaise throughout the PMST programme and have defined responsibilities. The meeting should normally be held at the site where the registrar works.

The SAC has already agreed the eligibility of the registrar for PMST and the ES has been selected on the basis of appropriate experience. The SSA should explore any divergences from these requirements, agree alternative arrangements for supervision, and explain these to the JCHMT.

It is important that the company Medical Director or immediate line-manager for the registrar meets the SSA at this stage. Issues such as appraisals, assessments, study leave and costs can be discussed.

If the SAC has not already agreed a Form A for an earlier application by another registrar in the same organisation and locality, the SSA should meet a senior person in Human Resources or the Training Department. They can confirm the supervised training and evaluations that will be available in post.

The SSA must verify certificates of university degrees and other professional qualifications on behalf of the JCHMT/SAC-PM.

### Training opportunities

JCHMT Form A describes the on-the-job training opportunities and related assessments and appraisals available to the registrar in their workplace, mainly as part of their work experience or as in-house courses.

It is expected that job training and experience (in-work Modules) will be available for a minimum of three modules in the PMST curriculum, including Module 7 (Interpersonal and Management Skills & GPMP; the Generic Module).

The availability of projects and processes in work to enable the registrar to demonstrate competencies in real-life, alone or as part of a team, should be evaluated. This is particularly the case where modules of the curriculum in PMST will be selected as the two (core) operational in-work modules. Exceptions to availability of topics and items within these modules in the workplace should be agreed

and ratified by the SSA. In-house mini-courses and assessments will usually be substituted and / or supplemented by outside courses.

Amendments to training already approved in an earlier Form A require that a new Form A be submitted to the JCHMT and the Faculty with a covering letter of explanation.

### Individual registrar programmes

JCHMT Form B describes the personalised advanced training programme foreseen for the registrar, which must be completed in full prior to enrolment. It may be prepared as a draft before the meeting.

It will include the in-work (in-post) modules and proposed in-house courses shown in the company's Form A.

For those module core items and any non-core items that cannot be completed in-work, proposals must be made in Form B regarding taught mini-courses either in-house or external.

External module training courses, organised by a provider and approved by the Faculty and SAC-PM are available from the Faculty for use by the registrar, ES and SSA in planning PMST and completing Form B.

In the approval process, it must be expected that the SAC will wish to re-assure itself that the PMST programme is balanced across the modules and that the curriculum items are covered by reasonable project proposals, assessment methods and chances of completion.

Accordingly, the SSA should inquire into these aspects and agree how in-house appraisals and assessments will be made, how appropriate feedback to the registrar will be achieved, and how relevant documentation will be made available to the Faculty and JCHMT.

The SSA should explain that a registrar has a confidential channel through the SSA for guidance on any aspect of their PMST programme.

If the SSA is unsure whether Form B can be completed fully prior to submission to the JCHMT, guidance should be sought from the programme director (DET) in the first instance.

The SSA should agree any exceptions to the above criteria and should explain the reasons for the discrepancies in writing to the JCHMT and the Faculty.

## **Taught and interactive courses in PMST**

### Module courses

For each of the six specialist operational modules approved interactive courses are available. Independent course providers under contract with the Faculty offer these.

The SAC-PM through the PMST (*formerly PMST*) Subcommittee of the Faculty approves each course. The course programme must be mapped against the requirements of the module curriculum.

The course should have within it a variety of teaching and learning methods so that registrars may demonstrate competency in the topics / items covered.

These would include lectures, seminar and group discussions, short and long case studies involving interactive team-working, problem-solving scenarios, critical review, opportunities to demonstrate transferable skills (chairmanship, team-leadership, team-working, negotiating, presentation, time management, interpersonal skills).

There will be assessments of competency related to applied knowledge and competences (simulated activity). For example, these could be observe and score situations, critical review of imperfect documents, MCQs and written assignments.

The courses are quality assured by a Board of Examiners QA panel assigned specifically to each course. These report back through their convenor to the Board of Examiners QA panel convenors group.

Module courses are not restricted to one provider. They are normally run at least on an annual basis.

### Other taught courses

There are available many meetings and courses both within companies and outside. These are available to PMST registrars, when considered by registrar and ES to offer coverage of a module topic or item.

Such courses and meetings are not quality assured by the Faculty, and assessment of competencies as a result of participation must be made by the ES as part of the in-work programme.

### **The Training Record**

A Training Record will be maintained by the registrar, remaining the property of the registrar and produced at the annual RITA review meetings. It will be counter-signed by the ES to confirm satisfactory fulfilment of the required training experience and the acquisition of the competencies in PMST.

The Training Record is designed to:

- a. provide a guide to the PMST programme;
- b. create a record of the experience and competencies acquired, and the achievements attained;
- c. be a record of progress, both factual and reflective;
- d. cross-refer to an archive of evidence of performance and competency from assessments, appraisals and other sources that have been acquired over time;
- e. be a reference for regular review of progress, e.g. performance appraisals & RITA reviews, and to plan future training goals;
- f. integrate with other educational aims and requirements for demonstration of competency, for example, revalidation for maintaining a licence to practise, and for aspects of continuing professional development (CPD).
- g. reflect the description and content of the registrar's job(s), as well as changes to job, location or educational supervision, all of which might affect the nature of the PMST programme and the progress towards the CCT.
- h. emphasise registrar duties and responsibilities in respect of managing the PMST programme, including maintaining the Training Record, producing it for review (RITA) or audit.

### **Training Plans**

A Training Plan should be prepared by the Registrar and ES, with advice as necessary from the SSA, for a suitable period ahead, for instance 6-12 months, as a practical guide for all involved in the training.

The Training Plan should include, where appropriate and relevant to the period, items of modules in which training will be undertaken,

including in-house and external courses, assessments, educational and performance appraisals, and preparatory plans for RITA reviews.

It should give estimates of the planned start and completion dates.

It should be updated / renewed following a review of achievements during, for example, an educational appraisal, annual performance appraisal or RITA review.

As a result of appraisals and reviews, revision of the Training Plan and even the overall PMST programme (JCHMT Form B) might be necessary.

### **Evidence of competency**

The proper collection and recording of evidence of attainment and assessment of competencies in PMST by the registrar is an important aspect of demonstrating progress and completion of training.

Regular checks and verification of the appropriateness and veracity of this evidence are made, recorded and authenticated by the ES, as well as the processes of its collection, collation and storage. In addition the evidence of competency may be validated as necessary by the SSA or independent assessor, notably prior to a RITA Review, in particular the PYA. This is also essential at the time of pending change of ES or employment, together with an end-of-employment report on the registrar's attainments and progress to date.

The programme of PMST is designed and approved for each registrar. This personalised (*ad personam*) programme must be reviewed at intervals and also, if necessary, be altered and approved. Such reviews need evidence of competencies reached so far. The evidence must firstly be collected, collated and stored in the Training Record and, secondly, summarised in the Performance / Competency Assessment Record ('Training Log'). In this way, a personalised record of progress is available for the mandatory annual RITA review.

If the registrar is going to change employer or workplace location, it is important that attainments achieved to date are fully documented, authenticated by the ES, and entered in the Training Record before the registrar relocates, because access to original records may be difficult or impossible later.

In these circumstances, an interim Performance / Competency Assessment Record (Training Log) is also required from the registrar and current ES.

The confirmation of the evidence of attainment of competencies (modular topics / items) of the PMST curriculum, and the related assessment of performance, competency and working knowledge is relevant in particular to two circumstances in PMST:

- a.** preparing for annual, PYA and final RITA reviews;
- b.** change of employer, workplace site, or Educational Supervisor.

The evidence of competency and its evaluation can result from both workplace-based activities (in-work modules and topics / items), including in-work assessments as a result of 'mini' internal or external courses, or from external approved module courses, where assessments are conducted by course providers and outcomes given to the registrar / ES after adjudication (evidence provided as part of this assessment, if appropriate, may be returned to the registrar after adjudication).

The emphasis, however, is on evidence collected in the workplace as a result of in-work modules and part-modules (topics / items).

### The evidence

#### Original records

During PMST, a large number of original in-house documents will be generated. These may comprise reports written by the registrar alone or as a member of team. These may be bulky and / or confidential. In this case evidence retained in the registrar's Training Record may be sampled.

In many instances, a front sheet of a report or a certificate of attendance and assessment at a taught course may suffice as a sample. The ES should validate the evidence that is presented. The Training Record, including this verification, should be brought to the RITA Review by the registrar. The full original documents (see above) need not be brought to the review.

#### Retention of copies

It is recommended that copies of the originals be held in a separate location (archive) until the annual RITA/PYA Review is completed and the module in question signed off as complete.

The annual RITA review also effectively endorses the evidence presented in the Training Record and that retained in archive.

### Validation

For the above reasons, it is essential that the registrar provide adequate sampled evidence of the work done as part of the Training Record, if necessary in a separate folder. This information ought to be filed under module topics / items and thereby cross-referenced.

Evidence of the projects or tasks and of their assessment must be cross-referenced to the curriculum Modules and their Items/Topics.

This evidence might comprise reports, publications or other documentary evidence resulting from a real-life project or task, if necessary appropriately sampled to maintain corporate confidentiality (e.g. front sheets of protocols or regulatory documents etc). It might also be evidence from a simulated assessment e.g. a written assignment.

The evidence should be collated on an ongoing basis, and in such a way that it can be presented to third parties during or after the PMST programme as required (e.g. in an annual RITA Review, a PYA, a final RITA or an audit). Its existence and veracity must be assured by the ES in signing the Performance/Competency Assessment Record ('Training Log') in the Training Record.

Evidence contained in the Training Record is the property of the registrar, and should accompany the registrar throughout the PMST programme, including a change of workplace or employer.

## **Assessment**

### Assessors

Assessors should be appropriately trained in conducting performance and competency assessments of in-work and / or taught course modules during PMST.

Assessment of a registrar's performance and competency during in-work training will be the responsibility of the PES. Some assessments may be delegated to others, who are better placed and competent to judge the registrar in particular tasks.

Assessment of a registrar’s applied knowledge and competency during an external taught interactive module course will be conducted by the course provider and / or others, as determined by the course provider.

Assessment of a registrar’s applied knowledge and competency during in-house or external mini-courses, which provide additional training for items from in-work modules, will usually be conducted outside the course by the ES as part of the assessment of the in-work module.

### Assessments of performance and competency

Assessments of performance and competency during PMST will be conducted according to current guidance from the Faculty and the SAC-PM.

Registrars undertaking an in-work module will use their actual work experience to demonstrate their performance and competency, whereas those doing a taught module course will rely on simulated situations.

The expected Competency Levels are:

#### **Competency Level 1:**

Fully competent to perform the task or activity unaided or as part of a team.  
(In real-life or through simulated activity.)

#### **Competency Level 2:**

Understanding of underlying principles and practices relating to a task or activity or body of applied knowledge.

The Assessment Level of performance / competency in undertaking a task can be made within the following rubric (Miller’s pyramid):

DOES	Can demonstrate performance / competency in undertaking the task in real life
SHOWS HOW	Can demonstrate competency through simulations of the task
KNOWS HOW	Knows how to apply knowledge of the task

KNOWS	Possesses knowledge of the subject / task*
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\*Assessment of Specialty Knowledge Base is the remit of the examination for the Diploma in Pharmaceutical Medicine.

Within this framework of competency assessment, the registrar will be assessed on items within a module in terms of applied knowledge, skills and attitudes / behaviour.

The assessments relating to 'attitudes / behaviour' considers how a skill / competency was achieved. A validated assessment tool for this purpose is the Multi-Source Feedback assessment (MSF; '360° assessment').

Assessors will also consider the degree of the following attributes that have been applied to the task and how these might influence the overall assessment of performance / competency: judgement, initiative, insight and supervision need.

The outcomes of performance and competency assessments will be recorded in the Training Record, which is the property of the registrar, who must maintain it and keep it up-to-date.

The Record of Performance / Competency Assessments is a template for recording progress in PMST (training log).

The outcome of the assessment for each curriculum item is recorded in the training log using the following code:

1A	Competency Level 1, Achieved, Real-Life, Alone / Unaided
1B	Competency Level 1, Achieved, Real-Life, Part of Team
1C	Competency Level 1, Achieved, Simulated, Alone or Part of Team
1D	Competency Level 1, Requires more experience / improvement
2C	Competency Level 2, Achieved
2D	Competency Level 2, Requires more experience / improvement

The training log for the item of the module is signed and dated by registrar and PES / ES.

The Educational Supervisor's comments on an assessment of performance and competency may be made on the ES Report Form, as part of the Training Record. Comments may cover details of the task / activity of the module item and assessment method, including how performance / competency was achieved. Comments should also refer to deviations from the Training Plan and programme (JCHMT Form B) in arriving at a judgement on attained performance / competency to reach the required standard for the CCT.

### Assessment of Good Pharmaceutical Medical Practice

Generic knowledge, skills and attitudes / behaviour governing competency, care and conduct in professional practice are common to all medical specialties and appropriate for all practising doctors. In pharmaceutical medicine, such generic matters are described in Good Pharmaceutical Medical Practice (GPMP).

GPMP is based on the Good Medical Practice (GMP) document produced by the General Medical Council. GPMP does not supersede GMP but complements it.

All registrars must meet the objectives of GPMP and, while no timescale is offered for acquisition and demonstration of these competencies, they must all be attested to before completion of PMST and the award of a CCT.

The GPMP objectives also form the basis of annual appraisals leading to revalidation of the licence to practise and retention on the General Medical Register.

Assessment of GPMP should be undertaken at intervals, usually annually, and be recorded on the GPMP Assessment Form of the Training Record.

Assessment and progress in GPMP should be appraised as part of the annual performance appraisal. For this the PES / ES may prepare a report on progress in GPMP using the form for the purpose in the Training Record (Section 6).

### Assessments

The SSA will ensure that the ES is conversant with the methods and standards of workplace assessment. Reports of assessments from in-work modules will form part of the registrar's Training Record.

The SSA will inspect records of all assessments as part of the preparation for the annual RITA review meeting.

If any serious issues arise about the conduct and outcomes of assessments, the SSA in consultation with the DET and PGD will request the SAC to appoint an appropriate expert panel to conduct an on-site inspection of procedures.

### **Appraisal**

Progress through and successful completion of PMST is dependent on the demonstration of performance and competency in the skills and tasks comprising the PMST curriculum to a standard appropriate for the award of a Certificate of Completion of Training (CCT).

It is recognised that good educational progress towards successful episodes of assessment must be facilitated by regular meetings of registrar and Educational Supervisor to provide feedback and agree new training goals. Some but not all of these meetings are arranged by agreement between registrar and ES more formally in order also to produce a written record of progress, either confidential or otherwise as determined. Such formal meetings are referred to as Appraisal.

The elements in the process to acquire and verify evidence of competency are:

1. Assessment of performance and competency.
2. Regular appraisals to review educational achievement and goals, and progress against the PMST Training Plan and, as necessary, elements of the registrar's Personal Development Plan. This is termed Educational Appraisal.
3. Annual appraisal to review achievements against the PMST curriculum and Training Plan. This is termed Annual Performance Appraisal.

Progress through PMST is verified independently through annual Record of In-Training Assessment (RITA) review meetings, and the Penultimate Year Assessment (RITA PYA), organised by the Postgraduate Dean.

Since normally the ES will be the registrar's medical manager in the workplace, meetings between them should be on a regular and continuous basis. The term 'regular' is not defined, but this is usually daily, weekly or fortnightly as circumstances permit or demand. Records of these informal meetings may or may not be kept routinely, and they constitute the normal currency of educational supervision, which provide opportunities for immediate on-the-job feedback.

On at least a monthly basis there should be a more formal meeting between registrar and ES, following which a short report should be made and lodged in the Training Record.

On a four-monthly basis it is recommended that there be a formal Educational Appraisal, which follows the outline set out below. On an annual basis, normally preceding the RITA review meeting, there will be an Annual Performance Appraisal, which follows the outline set out below.

### *Educational Appraisal*

To carry out an Educational Appraisal, the registrar and ES should meet privately on a four-monthly basis.

The appraisal meeting should be conducted in dedicated time, and be prepared for in advance.

Educational appraisals are meetings of registrar and Educational Supervisor which are formative and developmental. The registrar is able to show and discuss deficiencies, and both registrar and ES engage in a constructive learning exercise.

The educational appraisal provides the opportunity for:

- a. Reflective self-appraisal by the registrar;
- b. Review of achievement against goals in the current Training Plan;
- c. Constructive feedback from the ES, both positive and negative, at the appropriate time for executable action;
- d. Mutual agreement on the next set of training goals and objectives, and their context;
- e. The production of a written summary of the revised Training Plan;
- f. Adaptation as necessary of the Personal Development Plan (relates to employment appraisal);

- g. Arrangement to meet again to review progress made and to set new goals.

The Educational Appraisal should be written up by the ES and the report agreed with the registrar. The report should be held on file or distributed only as agreed.

The written revised Training Plan should not be deemed to be confidential and may inform later performance appraisals and RITA review meetings.

#### Annual Performance Appraisal

The process of performance appraisal involves regular episodes, usual annual, of formally reviewing the registrar's performance in training against minimum standards of progress defined for pharmaceutical medicine by the PMETB and the Royal Colleges of Physicians (SAC-PM / JCHMT).

The annual Performance Appraisal (sometimes termed summative assessment) is a judgemental process, which depends on the production of auditable written evidence of performance drawn from a range of sources, which are best used by combining different methods in parallel.

These methods include:

- a. Educational Supervisor reports on specialty knowledge, referenced to the Syllabus in Pharmaceutical Medicine (Specialty Knowledge Base);
- b. records and reports of assessments of directly observed performance and competency in Items of the PMST module curricula;
- c. written reports of assessments and judgement of programme against the aims of Good Pharmaceutical Medical Practice;
- d. documented evidence of other educational endeavour in cumulative Personal Development Plans or portfolios, e.g. courses, presentations, publications, teaching;
- e. elements of personal development planning;
- f. performance against personal objectives is reviewed in a confidential interview (Educational Appraisal) and new goals are set.

Annual Performance Appraisal has the following characteristics:

- a. it is formal, judgemental, open, honest and documented, with the full knowledge of the registrar as to methods and criteria;
- b. it regularly measures progress against external standards laid down by the PMETB, the body which advises the General Medical Council on the admission of doctors to the specialist register;
- c. it provides written evidence, which can be substantiated or challenged, of appropriate progress in PMST through acquisition of knowledge, skills and professional behaviour;
- d. it should be reliable, valid in content, acceptable to assessors and participants, predictive in value, non-discriminatory and cost-effective;
- e. it is compiled by the sharing of judgements by Educational Supervisor(s), other trainers and colleagues (a process known as triangulation);
- f. it should have positive effects on the educational progress of PMST registrars, and thus be acceptable to them.

The Annual Performance Appraisal is open to formal appeal.

### **Evaluation of Progress in PMST**

The two processes of Educational Appraisal (formative assessment) and Annual Performance Appraisal of PMST registrars are separate but interdependent.

The appraiser and chief assessor are most often, but not necessarily, the same ES, an individual and probably medical manager who will know most about the registrar professionally and as a person.

The ES is expected to appraise regularly, honestly and openly the registrar in all the positive and negative aspects of his/her progress and performance, and only in this way can be expected to arrive at a fair assessment of the registrar.

The required detached judgement of progress will be made annually in the RITA review by the RITA panel, which provides the registrar, the PGD and the JCHMT (RCPs) with a final decision on progress.

Both processes of Appraisal and RITA should provide mechanisms to remedy any deficiencies, which might have been agreed in appraisal or defined by assessment.

Annual performance appraisal is likely to share much in common with company/management appraisal and with appraisal for Revalidation. For this reason it is permissible for PMST annual performance appraisal to be conducted at the same time as company / revalidation appraisals, and for the written record to be made in a way which avoids duplication and is acceptable to the common processes and aims of the three appraisals.

## Evidence of Competency and the RITA Review

### Purpose

The purpose of the annual RITA is to review the in-training assessments of the previous year and thus evaluate the registrar's progress and achievements in PMST. This review is based initially on summaries of the evidence that will be submitted at the RITA meeting that the Panel members receive and read some days before.

It is imperative that summary documentation, that the Panel requests prior to the meeting (via the FPM), is complete and that the presentation of corresponding evidence at the RITA meeting allows ease of inspection. Panel members formulate their questions before the meeting, and, at the end of the meeting, the Panel decides if progress is satisfactory or if some remedial steps are needed.

### Nature

During the half-hour interview, the Panel will focus on uncertainties and concerns arising from their prior reading. They may examine the Training Record, which is a key element in this process. It registers the competency achieved in the Module undertaken and, more importantly, it must provide an authenticated explanation of the activity performed and of the assessment made. An individual Module Item/Topic may be chosen for closer interrogation in order to judge whether the Training Record contents are adequate and complete and, more crucially, to ascertain whether an on-the-job activity, the contribution made to it and the evaluation, fulfil the standards for the level and assessment of competency awarded.

The most likely and regular event in which the nature of the evidence of competency may be questioned is the annual RITA Review.

In preparation for a RITA Review:

1. The ES, together with the registrar, must ensure that evidence of competency and its assessment is appropriately collected, logged, cross-referenced and archived. This evidence should be at the declared level of attainment as signed in the Performance/Competency Assessment Record (Section 6 of the Training Record).
2. The SSA, at a site visit prior to a RITA Review, should authenticate that the appropriate evidence has been collected and checked, and furnish the registrar (and ES) with a signed record to this effect. This Authentication Record should be lodged by the registrar in the Training Record and presented at the RITA Review.

### Record of In-Training Assessment (RITA)

The Record of In-Training Assessment (RITA) is a formalised yearly review of a registrar's progress towards achieving a Certificate of Completion of Training (CCT).

Progress in PMST, as judged through the RITA process, depends on meeting defined criteria set down by the Faculty and SAC-PM (JCHMT) on behalf of the PMETB.

The RITA process is conducted by an appropriately constituted RITA Panel under the auspices of the lead Postgraduate Dean (PGD) for Pharmaceutical Medicine, who is responsible for quality assuring the training, assessment, appraisal and review of registrars to ensure that they meet the CCT standards laid down by the PMETB.

The records of assessments in training will be reviewed at the annual RITA review meetings together with the Educational Supervisor's assessment and appraisal reports. Based on these an appropriate RITA form will be issued, indicating continuation of the training programme and any remedial training required.

The RITA is an important process in gaining specialist certification and can be considered a regulatory aspect of evaluating progress, rather than a developmental or judgmental encounter.

### Preparing for annual RITA Review

Following PMST enrolment, a practical Training Plan for a period ahead (e.g. 6-12 months), based on JCHMT Form B, should be

prepared by the registrar and ES with advice from SSA and others as required. It should be signed by both and incorporated into the Training Record. It will be updated at intervals.

All Training Plans should be lodged in the Training Record and can be used to assess progress towards training objectives. The Training Plan should be taken along to the meeting by the registrar.

Prior to the RITA Review certain documents from the Training Record will be requested by the RITA Panel and will need to be submitted in advance as per the Faculty's request.

The Summary Report (Specialty Knowledge Base and Practical Modules of PMST) is an important document that the ES prepares for the RITA Review, using the form in the Training Record.

At the time of the RITA Review, the Training Record must contain at least the following records:

- a. Current CV
- b. Educational Supervisor's Summary Report for RITA Review
- c. Record of Assessments (Training Log)
- d. Educational Supervisor's reports on:
  - i. Postgraduate training leading to the Diploma in Pharmaceutical Medicine
  - ii. PMST Assessments (Modules 1-7)
- e. Annual Performance Appraisal Report, including GPMP Record / Report
- f. Other documents / records as applicable
  - i. Training Plans
  - ii. Educational Appraisals (as agreed and if applicable to progress in PMST)

Prior to the RITA Review, the registrar and ES should meet and ensure that the documentation for the RITA is up-to-date and ready for submission and / or scrutiny. Any forms provided by the PGD in readiness for the RITA review should be completed at this time.

#### Role of Educational Supervisor and the RITA review

It is the responsibility of the ES in preparing the report for the RITA Panel to share information regarding any lack of attainment of goals and / or skills expected at the respective stage of training.

It is not the responsibility of the ES to make the judgement on progress in PMST, which is the responsibility of the RITA Panel.

### The RITA Panel

The RITA Panel for pharmaceutical medicine will normally comprise:

- a. Postgraduate Dean (or Representative) – Chair;
- b. A minimum of one, but normally two, Senior Specialty Advisers (SSAs) not connected with the registrar;
- c. Director of Education and Training (or Deputy DET);
- d. Education Administrator (in attendance).

An independent external representative (Faculty Assessor) will supplement the RITA Panel for Penultimate Year Assessments.

### The RITA Review meeting

RITA Review meetings will usually occur around the anniversary of PMST enrolment.

It is likely that RITA Review Panels will meet at least once each month, usually in London, and, exceptionally, regionally.

The registrar will normally be expected to attend the RITA panel meeting, at the discretion of the Postgraduate Dean.

The registrar may be accompanied by his/her ES or SSA.

The RITA Review meeting will have the following agenda:

- a. Introductions
- b. Check of registrar's personal details
- c. Check of projected CCT date
- d. Review of documentation on attainment and progress in PMST programme (pre-read)
- e. Decision on which RITA Form (C, D, E, F, G) to award
- f. General discussion on achievements and future educational / training needs; feedback on training environment, courses and projects, including opportunity for confidential comments

The annual RITA Review will conclude with a satisfactory progress grading (Form C) or a recommendation for targeted training (Form D) or for intensified supervision or repeated experience (Form E). Within the last two categories, there may be a stated or implicit rejection of competencies granted, due to incomplete evidence or

slack assessments. In the latter situations, the Senior Specialty Adviser (SSA), possibly with another appointed person, would audit the site procedures and records.

The RITA Form will be filed at the Faculty, and a copy sent by the Faculty to the registrar and JCHMT. The RITA Form must be filed in the Training Record.

### Penultimate Year Assessment (PYA)

The PYA is a special RITA interview at the end of the penultimate year of training.

An independent external representative (Faculty Assessor) is invited to attend the PYA Review Panel. A Faculty Assessor must not be involved in PMST in any capacity; he or she may come from Pharmaceutical Medicine or a related specialty such as clinical pharmacology and/or may be a Fellow of one of the Royal Colleges of Physicians. The PYA aims to ensure that planned training in the final year and the evidence of achievements throughout PMST will fulfill the requirements for a CCT.

Prior to the PYA, the registrar, with input from ES / SSA as appropriate, must complete the Summary of Training Experience for Penultimate Year Assessment (PYA), which lists all activities and achievements in PMST, using the form in the Training Record.

The ES's Summary Report for RITA Review will also be prepared as for an annual RITA Review meeting.

### The RITA Forms

Seven forms are related to the RITA process:

Form A	Up-to-date core information about the registrar
Form B	Changes to core information
Form C	Record of satisfactory progress
Form D	Recommendation for targeted training
Form E	Recommendation for intensified supervision or repeated experience

Form F	Record of out of programme experience
Form G	Final record of satisfactory progress

(Forms D&E are Stage 1 & 2 of 'required additional training', respectively.)

The RITA D is not a 'failure' but rather indicates the need for obtaining additional training. The RITA E indicates that the registrar has failed to make adequate or satisfactory progress in PMST, and as with a RITA D, demands remedial activity.

### RITA and the award of Certificate of Completion of Training (CCT)

The culmination of training will be the award of a CCT by the PMETB. The JCHMT will send a form to the Registrar approximately six months prior to the completion date for confirmation by the Postgraduate Dean / Senior Specialty Adviser / Programme Director that the Registrar has completed training or is about to do so. This should be completed and returned to JCHMT by the Registrar with a current copy of their CV and RITA G Form.

The JCHMT will send a CCT application form approximately six months in advance of the CCT to those Registrars who are confidently expected to complete on time. This form should be submitted to the PMETB by the Registrar not less than one month before the completion date. The JCHMT will in turn confirm to the PMETB the satisfactory completion of training and the PMETB, if it accepts the Registrar's eligibility, will forward the certificate (CCT) and a letter for the Registrar to send to the GMC to obtain an entry in the Specialist Register.

### Appeal against RITA Panel decisions

A registrar may disagree with the RITA Panel and, in this situation, there is an established appeals process, which can be discussed with the Faculty and the Director of Education and Training.

### Quality control

The SSA will be expected to check that the quality assurance adopted for in-house courses complies with that recommended by the BoE panels.

Reports on assessments from external taught courses will be provided to the ES and registrar, and will form part of the registrar's

Training Record. Reports that are less than 'satisfactory' for a competence (skill, task) on an external taught course will be considered by the ES (with the SSA as required) to determine the course of action for the registrar to achieve demonstration of competency.

The SSA will ensure that the ES is conversant with the methods and standards of workplace assessment that the BoE panels have recommended.

Reports from assessments from in-work modules will form part of the registrar's Training Record.

The SSA will inspect records of all assessments as part of the preparation for the annual RITA review.

If any serious issues arise about the conduct and outcomes of assessments, the SSA in consultation with the DET and PGD will request the SAC to appoint an appropriate expert panel to conduct an on-site inspection of procedures.

#### Changes to programme

During PMST, unforeseen changes may occur, necessitating decisions at various levels.

The foreseen PMST in-house training may change or new external courses may be preferred.

The registrar may change location within the same or merged organisation in the UK that may necessitate appointing a new ES.

The registrar may take up an appointment in another organisation in the UK that will require review and possible revision of the PMST programme (Form A and Form B) as well as a new ES, and possibly a change of assigned SSA.

The registrar may move overseas, either in the same or a new organisation, and arrangements to establish a revised PMST and suitable supervision and review must be made. Whilst 50% of training can be undertaken overseas, this must be prospectively approved on an ad personam basis by the SAC and the interpretation should be exception rather than the rule.

The ES may also change for several of the above reasons.

In all these circumstances, the SSA, DET and FPM must be notified so that the appropriate steps can be taken.

The SSA may also need to be re-assigned as a result of some of the above changes or on account of his or her completion of the four-year appointment.

### Evidence of competency and change of employer

#### Interim reviews

Apart from the annual RITA/PYA Reviews, there may be an interim end-of-employment or relocation assessment. Evidence of competency gained in the present post must be authenticated by the current Educational Supervisor and logged in the Training Record.

Similarly, a Performance / Competency Assessment Record should be completed in order to conclude and verify that period of PMST, because others cannot do so retrospectively.

It is important that there is a record of continuity of attainment of competencies and progress throughout the PMST programme, together with the continuation of collection and collation of evidence of such attainments and their assessment.

Changing job, site or employer during PMST might result in a change in ES, as well as a change in Form A, and an adjustment of Form B and the training plans. During such change the record of continuity might be diminished or lost.

#### End-of-employment ES report

Prior to the planned change in workplace (move to another company; change of company site, including moving overseas) it is essential that the Registrar's ES prepares an End-of-Employment Report which authenticates what the Registrar has achieved so far (Items completed, levels of competency achieved); this report should be lodged by the Registrar in the Training Record, and be presented at the annual RITA Review.

The SSA (or new SSA), on behalf of the Registrar, should ensure that such an End-of-Employment Report can be prepared, and verify that it is lodged in the Training Record prior to the subsequent RITA Review.

## **Quality Control & Quality Assurance in PMST**

Quality Assurance of Pharmaceutical Medicine Specialty Training is the sum total of those organised arrangements made to ensure that the training programme meets the requirements of the curriculum and the standards laid down by the Specialist Advisory Committee in Pharmaceutical Medicine of the JCHMT with the Faculty of Pharmaceutical Medicine to meet the requirements of the PMETB for the issue of a Certificate of Completion of Training in Pharmaceutical Medicine.

Of necessity, quality assurance arrangements apply to the training environment, the roles, responsibilities and activities of registrars, their trainers and all personnel involved in PMST, in-work projects, evidence of competency, taught courses, assessments, appraisals and reviews.

### *Quality Assurance of training environments*

The quality assurance of training environments / sites is under the direct responsibility of the PMETB.

Quality control of training environments / sites to ensure availability and delivery of training to standards appropriate for a CCT in pharmaceutical medicine and laid down by PMETB, will be carried out by the SAC-PM.

### *External Taught Courses*

An External Taught Course aims to provide training in all or some of the items in a PMST Module that would normally be obtained from on-the-job experience. As a substitute for the latter, it has weaknesses and strengths.

A course cannot simulate the length of time, variety of disciplines, number of people, and focus of attention usually given to a single project in work. Even so, the project may or may not provide the registrar with full coverage of all the items in a Module, simply because some did not arise or other people dealt with them.

The External Taught Course can draw upon several historical and / or simulated scenarios, so giving a wider perspective. More importantly, it can produce a balanced and thorough coverage of all issues likely to be met in future real-life projects. However, it suffers from the limited amount of time available compared with in-work experience; days rather than months.

For all the foregoing reasons, inspection of External Taught Courses is mandatory in order to ensure high standards throughout, both in the nature and extent of the training given and in the assessments made of the registrars.

A panel from the Board of Examiners (BoE) of the Faculty, comprising experts in that particular field, will assess the quality of such external courses, organised by independent bodies (providers).

This BoE quality inspection will assess the content and delivery of an external course and will judge assessments undertaken by the provider to assess the performance and competency of registrars.

Each BoE panel will thereby establish the principles, practices, processes and methods for assessment of registrars in the particular field covered by a PMST module.

Such standard setting will provide an important template for an existing course and future external courses, which in turn may establish new standards that regular quality assurance inspections ought to identify.

The BoE panels will give advice on assessments to providers who are planning new courses or companies organising mini-courses in the workplace.

Reports on assessments from external taught courses will be provided to the ES and registrar, and will form part of the registrar's Training Record.

The Senior Specialty Adviser (SSA) will be expected to check that the quality assurance adopted for in-house courses complies with that recommended by the BoE panels.

### *In-Work Training*

The assessments being applied to simulated scenarios on a course attempt to reflect those made during on-the-job experience.

In the latter situation, the Educational Supervisor [usually the line-manager] together with others will judge, over a period of time in the workplace, the performance and competency of a registrar in doing a particular task. Their assessment in a real-life situation is a pivotal evaluation of the registrar's fitness to practise. It also judges ability to work alone and / or as part of a team.

The quality assurance standards set by each BoE panel for courses must be adopted for internal assessments of registrars so that there is comparability. Such benchmarking will be a fundamental feature. The BoE panels can and will advise companies.

Senior pharmaceutical physicians in the company and especially those on the site, together with the registrar's Educational Supervisor, will be responsible for setting and monitoring in-house standards.

## **2. CONTENT OF LEARNING**

### **Specialty specific content**

#### **Specialty Knowledge Base**

The specialty knowledge base is derived from the Syllabus in Pharmaceutical Medicine and prepares the registrar for the examination for the Diploma in Pharmaceutical Medicine. The Syllabus is set out below. Learning commences from taking up a post in pharmaceutical medicine, and formally from the time of enrolment into PMST.

As mentioned above, courses are available which present a curriculum for the specialty knowledge base derived from the Syllabus. These are usually delivered over a 2-year period.

The Diploma examination may be taken for the first time after two years in a post in pharmaceutical medicine, and repeated as necessary. The examination is offered on an annual basis.

#### **Practical Competencies**

The curricula for the modules of PMST are set out below in terms of the applied knowledge, skills and attitudes/behaviour necessary to demonstrate competency in the items of the modules.

#### **General professional content**

The content of the generic module (Module 7) in pharmaceutical medicine is set out below and includes both interpersonal and management skills and the elements of Good Pharmaceutical Medical Practice.

#### **Sequence of Learning**

Acquisition of the Specialty Knowledge Base and training in practical modules of PMST may be undertaken concurrently.

#### **Content and the Learning experience**

Whilst the specialty knowledge base and the practical modules of PMST may be undertaken at the same time, there is a tendency for there to be an emphasis on acquiring the specialty knowledge base and the Diploma in Pharmaceutical Medicine prior to completing the majority of items of practical competencies of PMST.

## **CONTENT OF CURRICULUM**

### **PART A**

#### **SPECIALTY KNOWLEDGE BASE**

Pharmaceutical Medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of the marketing of medicines for the benefit of patients and the health of the community.

The Faculty of Pharmaceutical Medicine is responsible for ensuring and maintaining standards in the discipline and, as such, has developed a curriculum for higher medical training to equip specialists with the comprehensive skills and competence increasingly demanded by the industry for the public good.

The Syllabus for the Diploma in Pharmaceutical Medicine and the Curriculum for the practical Modules of PMST follow this section.

#### Training Programme

Pharmaceutical Medicine Specialty Training (PMST) comprises the Specialty Knowledge Base which follows the syllabus of the Diploma in Pharmaceutical Medicine, and a practical component, which builds on and applies this knowledge following seven curriculum modules. The details of both the Specialty Knowledge Base and the practical modules of PMST are outlined below.

#### Specialty Knowledge Base

The syllabus in Pharmaceutical Medicine forms the curriculum for basic higher medical training leading to the Diploma in Pharmaceutical Medicine. This is composed of nine sections:

1. Medicines Regulation
2. Clinical Pharmacology
3. Statistics and Data Management
4. Clinical Development
5. Healthcare Marketplace
6. Drug Safety
7. Role of the Medical Department
8. Discovery of New Medicines
9. Therapeutics

The first six sections listed correspond to the practical modules of PMST and present the specialty knowledge base for these modules of PMST.

In addition, 'Discovery of New Medicines' is considered an essential area of knowledge for physicians entering a career in pharmaceutical medicine.

Similarly, 'Therapeutics' has always been included in the syllabus but its importance to the practice of all areas of pharmaceutical medicine is emphasised by its designation as a separate section.

The content of the syllabus is listed under the separate sections below. There is a considerable degree of overlap and some topics appear under more than one section though it is not intended to imply that any topic is restricted only to that section under which it is listed. The order of listing does not reflect importance.

## **1. Medicines Regulation**

- The general principles of medicines regulation
- Medicines regulation in UK, EU, USA, Japan
- Activities and contribution of International Conference on Harmonisation
- Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices
- Clinical Trials regulations – IND, CTA, EU Directives etc.
- Common Technical Document, Overviews
- Reporting of adverse drug reactions, periodic safety update reports
- Product information – Summary of Product Characteristics, Patient Information Leaflets
- Licensing – MAA, NDA, abridged applications, updating and maintaining licences
- Orphan drugs
- Provisions for and use of unlicensed medicines
- Drug abuse and dependence
- Non-prescription drugs and reclassification of Prescription Only and Pharmacy only medicines
- Codes of practice, industry self regulation, advertising
- Fraud and professional misconduct
- Patents, legal issues, parallel imports
- Ethics and Ethics Committees
- Pharmacopoeias

## **2. Clinical Pharmacology**

### Pre-clinical development to support testing in humans

- Safety testing – acute, subacute toxicology, genotoxicology, reproductive toxicology, topical irritation and hypersensitivity, safety pharmacology, immunotoxicology

- Pharmacokinetics and metabolism
- Pharmaceutical Development - formulations, manufacture and supply of materials, labelling and presentation, stability and storage, purity, compatibility, disposal

#### Exploratory Clinical Development

- Assessment of preclinical data
- Planning of studies in Exploratory Development
- Populations for exploratory studies - healthy volunteers and patients
- Ethics – principles, peer review, informed consent, Declaration of Helsinki
- Regulation
- Studies - objectives, design, conduct and analysis, choice of site
- Tolerability and safety
- Use of biomarkers and pharmacodynamic endpoints, dose-response
- Pharmacokinetics, ADME and pharmacokinetic/pharmacodynamic models
- Interpretation of study design, analysis and results

#### Clinical Pharmacokinetics

- Concepts – half-life, volume of distribution, clearance
- Bioavailability and Bioequivalence
- Drug-Drug and Drug-Disease Interactions (Extrinsic factors)
- Studies in different populations (Intrinsic factors)
- Pharmacogenetics
- Population pharmacokinetics
- Applicability of pharmacokinetics to dosage regimen and study design

### **3. Statistics and Data Management**

*The purpose and fundamentals of statistics*

#### Trial design, hypothesis testing, power

- Pre-trial decisions and specification
- Risk factors, confounding variables
- The null hypothesis, Type I and II errors, significance, power

#### Measurement and types of data

- Standardisation
- Variations in biometry in population, in disease

#### Data collection and management

- Options for data collection (manual and electronic)
- Creation, maintenance and security of databases, software validation and archiving

- Data management from clinical trials: corrections, computer capture, verifications and extraction
- Within-trial decisions, data management, extraction and manipulation

#### Types of analysis

- Analysis of efficacy end-points and of safety
- Paired and non-paired tests, parametric and non-parametric tests, confidence limits
- Handling of rating and visual analogue scales, patient diaries and laboratory values

#### Interpretation of study design, analysis and results

Assessment of violations, withdrawals, errors, bias

Statistical principles and issues in report writing: data manipulation, transposition, merging

Clinical interpretation of trial

Final report writing and formatting for registration dossier and publications

### **4. Clinical Development**

#### Planning and Organisation

- Organisation and operation of project teams
- Objective and target setting
- Integrated project planning
- Requirements for licensing of new medicines
- Budgeting and costs control

#### Regulation and Ethics

- EU Directives
- ICH – Good Clinical Practices
- Ethics – principles, peer review, informed consent, Declaration of Helsinki
- Regulatory review
- Indemnity
- Confidentiality and Data Protection

#### Clinical Trials

- Planning of Clinical Trial programme – use of preclinical and Phase I data
- Study types and designs
- Documentation - protocols, reports, source documents, case report forms, study master file, investigator's brochure
- Contractual arrangements with investigators and contract research organisations
- Study conduct
- Quality control and quality assurance

- Adverse Events and Serious Adverse Events – definitions, collection, reporting, assessment, coding
- Interpretation of study design, analysis and results
- Formulations, manufacture and supply of materials, labelling and presentation, stability and storage, purity, compatibility, disposal
- Data management and statistical analysis
- 

## **5. Healthcare Marketplace**

- Quality of Life
- Marketing structure and competition, price negotiations,
- National and local formularies.
- Product information, advertising and claims
- Product support and promotion
- Product life-cycle management
- Product liability
- Codes of practice including the MHRA Blue Guide
- Principles and practice of marketing
- Measurement of healthcare, governmental policy and third-party reimbursement
- Principles of health economics
- Pharmacoepidemiology
- Competition, in-licensing, co-marketing

## **6. Drug Safety**

### Preclinical

- *In vitro* and *in vivo* testing.
- Toxicology: dose-range finding, GLP studies, requirements to support exposure in humans, safety testing of topicals, immunotoxicity, genotoxicity, carcinogenicity, reproductive toxicity
- Safety Pharmacology
- Studies of drug metabolism to predict interactions
- Implications of findings to studies in humans

### Clinical Trials

- Adverse Events and Serious Adverse Events – definitions, collection, reporting, assessment, coding, ICH and CIOMS

### Adverse Drug Reactions

- Classification of Adverse Reactions, idiosyncrasy, accidents
- Mechanisms, predisposing factors in health and disease
- Dosage, Cumulation, Interactions
- Assessment of evidence and management

- Reporting
- Carcinogenicity and Genotoxicity
- Prevention

### Regulation

- Dear Dr Letters and Withdrawal of products
- SmPCs and PILs
- Drug abuse and dependence
- Non-therapeutic drug use
- Life and Storage Safety of Medicinal Products

### Pharmacovigilance

- Methods and ethics of adverse event monitoring, post-marketing surveillance, spontaneous reporting, Safety Assessment of Marketed Medicines, Periodic Safety Update Reports
- Benefit-risk assessment
- Issue and Crisis management

### Pharmacoepidemiology

- Databases
- Signal generation
- True and apparent incidence and prevalence data

Sensitivity and specificity of indices

## **7. Role of Medical Department**

- Clinical Research
- Regulatory submissions
- Pharmacovigilance
- Quality Assurance
- Information services
- Data Management
- Financial control
- Legal compensation
- Crisis management

## **8. Discovery of New Medicines**

- The philosophy behind and organisation of research
- Disease target identification and selection
- Patenting new active substances
- Receptor-based approaches, agonists, antagonists, enzyme inhibitors, genomics, proteomics
- Lead optimisation and candidate selection of molecules for exploratory human investigation
- *In vitro* and *in vivo* testing of new compounds

- Relationship between animal and human pharmacology

## **9. Therapeutics**

- Management of common acute and chronic diseases
- Major drug classes including biologicals
- Measurement of drug effects
- Adverse drug reactions
- Benefit: risk
- Drug interactions
- Prescribing for particular populations e.g. children, elderly, pregnant and breast feeding women, patients with renal or hepatic impairment
- Controlled drugs and drug dependence
- Overdosage and treatment of poisoning
- Patient compliance and information
- Therapeutic Drug Monitoring

**PART B**

**PRACTICAL COMPETENCIES IN PMST**

## **MODULE 1**

### **MEDICINES REGULATION (RGN)**

#### **AIM**

**To acquire knowledge of and competency in medicines regulation to the level necessary to fulfil the role of a pharmaceutical physician. Specifically to demonstrate the competency to execute tasks relating to the conduct of clinical trials, the licensing procedures, post-licensing monitoring for safety, efficacy and quality of medicines in fulfilment of the national, European and / or other international regulatory requirements.**

**ITEM: RGN 1****OBJECTIVE:**

**The registrar will be able to explain the legislative framework supporting the development and registration of medicines and the monitoring of their safety, efficacy and quality.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>1.1</b> Describe The Medicines Act 1968 and related Statutory Instruments (SI). Describe European Regulations, Directives &amp; Guidelines relating to medicines' development and monitoring. Describe the ICH process and the significance of ICH Guidelines.</p> <p><b>1.2</b> Define the requirements for development and registration of medicines.</p>	<p>Identify, retrieve and assemble documents from all available sources in order to be informed about and to undertake specified regulatory tasks.</p> <p>Discuss the distinction between Regulations, Directives and Guidelines and their implementation.</p>	<p>Recognises the need for the pharmaceutical physician to maintain close contact with the regulatory affairs department.</p> <p>Understands the requirement for physician consultation and participation in appropriate discussion meetings.</p> <p>Recognises that there are regional differences in requirements and participates in meetings and calls upon appropriate resources to address these differences.</p>	<p><b>Assignment:</b> Identify, retrieve and assemble documents from all available sources in order to be informed about and to undertake a specified regulatory task.</p>

<b>ITEM: RGN 1 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>1.3</b> Describe the operational procedures at major national regulatory agencies (e.g. Medicines &amp; Healthcare products Regulatory Agency (MHRA), the European Medicines Agency (EMA), the US Food &amp; Drug Administration (FDA) and The Pharmaceuticals and Medical Devices Agency, Japan (PMDA).</p>	<p>Discuss the relationship between EMA and national regulatory authorities of the EU.</p>	<p>Recognises the need for the pharmaceutical physician to interact with different regulatory authorities. Endeavouring to find a common ground whenever possible, and advancing solutions for differences that cannot be reconciled.</p>	
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<p><b>1.4</b> Describe differences between the EU, US, Japanese Regulations and European requirements for medicines development in the context of the ICH guidelines and their implementation.</p> <p>Describe the registration of pharmaceutical products in international markets.</p>	<p>Discuss the impact of harmonised and non-harmonised requirements on drug development and registration processes.</p> <p>Differentiate between the requirements for registration of drugs in different regulatory regions.</p> <p>Discuss how and why these requirements have evolved.</p> <p>Discuss how these differences may be accommodated.</p> <p>Initiate and participate in dialogue with different regulatory authorities.</p>		

**ITEM: RGN 2****OBJECTIVE:**

**The registrar will be able to describe and undertake post-marketing safety monitoring and reporting procedures.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>2.1</b> Describe Adverse Drug Reaction reporting systems (including specially targeted spontaneous reporting schemes).</p> <p><b>2.2</b> Describe the drug safety reporting requirements that operate under different jurisdictions.</p> <p><b>2.3</b> Submission of reports from marketed products, from clinical trials on marketed products and in registration dossiers for products already on market elsewhere.</p>	<p>Ability to advise on setting up appropriate post-marketing safety studies, and assess how to conduct market research ethically and safely.</p> <p>Distinguish non-serious from serious safety signals that are likely to be of greatest concern to the regulators and impact the life cycle and use of the drug.</p> <p>Set up systems to ensure that all reports originating from various sources are centrally gathered and assessed.</p> <p>Ability to assess drug safety issues.</p> <p>Initiates internal company meetings and if necessary, a dialogue with the regulators.</p>	<p>Recognises the need for pharmaceutical physicians to maintain close collaboration with the drug safety department.</p> <p>Recognises the strengths and limitations of in-house systems for assembling safety databases.</p>	

<b>ITEM: RGN 2 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>2.4</b> Describe the obligations of the Marketing Authorisation Holder (MAH) with respect to drug safety reporting.	<p>Collate data from various sources and prepare a safety report (real or hypothetical) for submission to a regulatory authority.</p> <p>From collated safety data identify new safety signals that may concern regulatory authorities or indicate how such signals might be identified.</p> <p>Regularly scan literature to track drug safety issues.</p>		
<b>2.5</b> Describe the strengths and limitations of various kinds of reports and approaches to identifying safety issues.	<p>Is able to commission reports that deal with specific safety issues at the request of regulatory authorities.</p> <p>Ability to write or review safety reports in consultation with experts and regulators to evaluate new signals.</p>		
<b>2.6</b> Describe the further investigation and assessment of drug safety alerts.	<p>Discuss the regulatory approaches to investigation and assessment of drug safety issues.</p> <p>Follow up novel reports for additional details to assess causality.</p>		

<b>ITEM: RGN 2 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<p><b>2.7</b> Describe risk minimisation strategies.</p>	<p>Identify risk factors and institute measures to promote safe and effective use of medicines.</p> <p>Has endeavoured to find common patterns in drug usage and link these with the safety and known properties of the drug.</p> <p>Devises and writes a risk management plan for a specified product (real or hypothetical).</p>	<p>Understands the requirement to propose measures to minimise risk and evaluates critically the effectiveness of these measures.</p>	<p><b>Assignment:</b> Draft a report for management on risk minimisation for a product (real or hypothetical).</p>

**ITEM: RGN 3****OBJECTIVE:**

**The registrar will understand the significance of Periodic Safety Update Reports (PSURs), and participate in their preparation and review.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>3.1</b> Describe CIOMS and the history of Periodic Safety Update Reports (PSURs).</p> <p><b>3.2</b> Describe the legal requirements for PSURs.</p> <p><b>3.3</b> Describe the contents and format of PSURs.</p> <p><b>3.4</b> Describe periodicity of submission of PSURs.</p> <p><b>3.5</b> Explain the possible outcomes from the review of a PSUR.</p>	<p>Understand template to enable an efficient review of a PSUR.</p> <p>Identify critically all known safety information.</p> <p>Assess the contents of a PSUR in the context of current prescribing information for a product.</p> <p>Identify and appraise the significance of new signals that may emerge from PSURs</p> <p>Update prescribing information to promote safe and effective use of medicines.</p>	<p>Recognises that PSURs are a vital means of reviewing proactively the safety of marketed products.</p> <p>Realises that PSURs enable different authorities to be provided with the same comprehensive information on the safety of the drug from all sources.</p>	<p><b>Outcome:</b> Draft, submit and review of outcomes of a PSUR; impact on prescribing information.</p>

**ITEM: RGN 4****OBJECTIVE:****The registrar will be able to prepare and review ethically acceptable product-related literature.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>4.1</b> Describe Regulations, Guidelines, Formats and Contents relating to writing:</p> <ul style="list-style-type: none"><li>- Summary of Product Characteristics (SmPC);</li><li>- Patient Information Leaflets (PIL);</li><li>- Technical Leaflets;</li><li>- Package Labelling;</li><li>- Advertisements.</li></ul> <p><b>4.2</b> Describe data required to support the contents of these documents.</p>	<p>Analyse and discuss the similarities, differences and relationship between these documents, and the legal basis of and requirements for their Formats and Contents.</p> <p>Write and /or review these documents.</p> <p>Ensure that all product-related literature is consistent with the terms of the Summary of Product Characteristics and complies with regulations.</p>	<p>Recognises the significance of these documents.</p> <p>Values the Summary of Product Characteristics as a legally binding document that impacts the contents of other product-related literature.</p> <p>Understands the need to regularly scrutinise these documents for accuracy and their effectiveness in promoting safe and effective use of medicines.</p>	
<p><b>4.3</b> Describe voluntary codes of practice in the context of product-related literature.</p> <p>Discuss penalties for breaches.</p>	<p>Maintains familiarity with procedures and proceedings of the appropriate responsible bodies for codes of practice.</p>		

<b>ITEM: RGN 4 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<b>4.4</b> Describe issues associated with prescribing information, which is different in different countries.	Understand geographical differences in pattern of drug usage and in the global need for clear and comprehensive prescribing information.	Recognises the hazards associated with different standards of maintaining accuracy of prescribing information.	

**ITEM: RGN 5****OBJECTIVE:****The registrar will be able to advise on unlicensed uses of medicines and ensure patient safety is paramount.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>5.1</b> Describe legislation that allows for provision of unlicensed medicines for specific uses.</p> <p><b>5.2</b> Describe the types of unlicensed use, including compassionate use / named patient supplies / clinical trial supplies.</p>	<p>Differentiate between use of medicines when off-label and when unlicensed, and between the various types of unlicensed medicines.</p> <p>Discuss conditions attached to the use of various types of unlicensed medicines to protect patients.</p> <p>Conducts scientific arguments supporting the availability of medicines for unlicensed use.</p>	<p>Recognises why unlicensed use is often necessary.</p> <p>Consults and discusses with regulatory affairs department when requested to make available unlicensed medicines.</p> <p>Identifies personal role in compliance.</p>	

<b>ITEM: RGN 5 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>5.3</b> Describe sources of unlicensed medicines and impact of internet advertising and pharmacies.</p>	<p>Discuss the duties of the supplier and the prescriber with respect to unlicensed medicines.</p> <p>Discuss procedures for gaining approval for provision of unlicensed medicines.</p> <p>Review applications for making available unlicensed medicines and liaise with regulators.</p> <p>Discuss the risks of internet advertising and procurement of medicines.</p>	<p>Maintains regular contact with the prescriber to protect the patient.</p>	
<p><b>5.4</b> Describe safety monitoring requirements and procedures during unlicensed use of medicines.</p>	<p>Discuss how to avoid unauthorised use of unlicensed medicines.</p>	<p>Adopts a responsible approach to the availability and the use of unlicensed medicines.</p>	
<p><b>5.5</b> Describe differences between off-label and unlicensed medicines.</p> <p>Describe measures to promote the use of medicines as approved.</p> <p>Describe penalties for promoting off-label use of medicines.</p>	<p>Critically appraise requests for making available unlicensed medicines and advise on how these requests are dealt with.</p>	<p>Objectively balances the risks and benefits of making available unlicensed medicines and illustrates the risks associated with the use of unlicensed medicines.</p>	

<b>ITEM: RGN 5 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<p><b>5.6</b> Describe country-specific provisions in respect of provision of unlicensed medicines (e.g. the Specials [manufacturing] licence in the UK).</p>	<p>Describe attitudes / behaviour of different regulatory agencies in respect of provision of unlicensed medicines.</p> <p>Review applications from different countries for making available unlicensed medicines and maintain a dialogue with the regulatory agencies concerned.</p>		

<b>ITEM: RGN 6</b>			
<b>OBJECTIVE:</b> <b>The registrar will be able to describe procedures for marketing authorisations, and contribute to writing and/or review Clinical Overviews for a variety of drug applications.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>6.1</b> Describe the structure of the Common Technical Document (CTD). Describe the contents of a registration dossier.</p>	<p>Discuss regulatory evaluation and approval processes. Understand the rationale behind CTD and its relationship to data normally required for registration.</p>	<p>Displays an understanding of how the procedures have evolved.</p>	
<p><b>6.2</b> Describe national procedures in major EU Member States.</p>	<p>Discuss differences in approval procedures operating in EU Member States.</p>	<p>Participates in strategic meetings to influence in-house approaches to submission of applications.</p>	
<p><b>6.3</b> Describe European centralised, decentralised &amp; mutual recognition procedures for Marketing Authorisation, and the: - significance of Rapporteur(s); - significance of Reference Member State (RMS).</p>	<p>Differentiate between the different European procedures for applications and discuss their advantages and disadvantages. Discuss the statutory requirements for different European procedures.</p>	<p>Appraises the advantages and disadvantages of different procedures with regard to specific therapeutic classes of drugs. Expresses views on the impact, if any, of different procedures on success rates.</p>	

<b>ITEM: RGN 6 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>6.4</b> Describe clinical development guidelines and the significance of scientific advice from regulators.</p> <p>Describe scientific advice procedures.</p> <p>Describe the role of advisory bodies.</p>	<p>Discuss the value and timing of scientific advice.</p> <p>Write and / or review briefing package for scientific advice.</p> <p>Review scope of scientific advice by selected therapeutic areas.</p> <p>Participate in scientific advice meetings.</p>	<p>Recognises the advantages and disadvantages of scientific advice.</p>	<p><b>Assignment:</b> Draft a briefing package for scientific advice on a product (real or hypothetical).</p>
<p><b>6.5</b> Describe the structure and contents of a Clinical Overview.</p>	<p>Write and / or appraise Clinical Overviews especially for a new drug application (or variations, line extensions, abridged documents).</p>	<p>Recognises the significance of a well-written Clinical Overview.</p>	<p><b>Assignment:</b> Draft a Clinical Overview on a product (real or hypothetical).</p>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<p><b>6.6</b> Summarise US FDA procedures.</p> <p>Have a working knowledge of Japanese procedures.</p>	<p>Identify procedural needs specific to each regulatory region.</p> <p>Discuss the major differences between various regulatory zones, especially the EU and the US.</p>	<p>Recognises the impact of differences between different regions, and the merits and demerits of these differences.</p>	
<p><b>6.7</b> Appeal or arbitration procedures.</p>	<p>Discuss differences in appeal procedures operating in EU Member States.</p>		

**ITEM: RGN 7****OBJECTIVE:**

**The registrar will be able to describe the legal framework for clinical trials and requirements in different regions and problems associated with global drug development.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<b>7.1</b> Describe European Clinical Trials (CT) Directive.	Discuss the impact of European CT Directive on academic research.	Recognises the need to regulate clinical trials.	
<b>7.2</b> Describe the contents of the Investigators Brochure (IB).	Discuss the data required before a clinical trial in man can be conducted.	Recognises that for safety of subjects, the data requirements vary depending on the duration of the trial and the populations studied.  Recognises that investigators need up-to-date safety information for safe conduct of clinical trials.	

<b>ITEM: RGN 7 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>7.3</b> Describe the Clinical Trials Application (CTA) System.</p> <p>Describe ICH Good Clinical Practice (GCP) and its impact upon the validity of a licence application.</p> <p>Describe the principles of GCP and reporting safety data from clinical trials.</p> <p>Describe the principles and practices of Ethics Committee review.</p>	<p>Discuss the obligations of the sponsors of clinical trials.</p>	<p>Adopts a highly ethical and scientific approach to setting up clinical trials.</p>	
<p><b>7.4</b> Describe the structure and contents of a clinical trial protocol</p>	<p>Contribute to writing protocols for clinical trials.</p>	<p>Recognises the risks associated with poorly designed clinical trials (ethical and clinical as well as regulatory).</p>	

<b>ITEM: RGN 7 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<b>7.5</b> Describe US Investigational New Drug (IND) procedures.	Discuss FDA's 'clinical hold' on INDs.	Maintains close collaboration with investigators and regulatory authorities on progress of clinical trials.	
<b>7.6</b> Summarise procedures for clinical trials in Japan.	Discuss problems associated with global drug development. Display the ability to set up multicentre international clinical trials.	Recognises the reasons for global and trans-cultural differences in procedures for regulation of clinical trials.	

**ITEM: RGN 8****OBJECTIVE:**

**The registrar will be able to describe and undertake or contribute to various regulated activities and procedures following the approval of a product.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<b>8.1</b> Describe the types of post-approval applications (abridged, generic, variation, line extensions and change of legal classification) and the requirements and procedures for these applications.	Discuss the data requirements for different types of post-approval applications. Discuss the procedures for extending the indication or target population and amending dose schedules and safety information. Explore the market potential of a product.	Recognises that a marketing authorisation is an evolving document and participates in this evolution. Recognises the limitations of pre-approval safety data. Recognises the need to monitor opportunities for and threats to a marketed medicine.	
<b>8.2</b> Differences in the requirements for renewal of a marketing authorisation in different zones.	Discuss the merits and demerits of different formulations and drug combinations.	Recognises the regulatory options to protect public safety and to promote safe and effective use of medicines.	

<b>ITEM: RGN 8 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>8.3</b> Describe pharmacovigilance requirements and activities at national, regional and international levels.</p> <p><b>8.4</b> Describe post-marketing safety studies.</p>	<p>Able to set up appropriate studies to proactively characterise specific risks.</p>	<p>Recognises that the safety of drugs in routine clinical use is frequently different from that in clinical trials.</p> <p>Recognises the strengths and limitations of various post-marketing safety studies.</p> <p>Explores ways of promoting safe and effective use of medicines.</p>	

**ITEM: RGN 9****OBJECTIVE:**

**The registrar will be able to describe the mechanisms for wider availability of medicines, and undertake or contribute to product deregulation.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency level 1</b>	<b>Competency Level 1</b>	
<p><b>9.1</b> Describe requirements and procedures for change in legal classification of medicines.</p> <p>Describe local national classification systems for availability of medicines (e.g. POM / P / GSL criteria).</p> <p>Describe Patient Group Directions.</p>	<p>Discuss the data required for change in legal classification.</p> <p>Discuss the effect of change in legal classification on:</p> <ul style="list-style-type: none"> <li>- public safety;</li> <li>- public health.</li> </ul> <p>Draft and / or critically assess an outline of a clinical overview for a legal status reclassification application.</p> <p>Discuss the safety of drugs available over-the-counter.</p>	<p>Recognises the advantages and potential disadvantages of deregulation of medicines.</p> <p>Chooses to consult relevant stakeholders when considering deregulation of medicines.</p> <p>Monitors the safety of medicines available without a prescription.</p>	
<p><b>9.2</b> Explain controls over the use and promotion of non-prescription drugs.</p> <p>Describe monitoring safety of non-prescription drugs.</p>	<p>Discuss advertising of non-prescription drugs.</p> <p>Discuss the merits and demerits of direct-to-consumer advertising.</p>	<p>Ensures that promotion of the product to the public is responsible.</p>	

**ITEM: RGN 10****OBJECTIVE:**

**The registrar will be familiar with investigation of product defects, counterfeit products, miscellaneous pharmaceutical procedures & requirements.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency level 2</b>	<b>Competency Level 2</b>	
<p><b>10.1</b> Describe regulatory requirements for dealing with product defects.</p> <p>Describe the causes of product defect and how to deal with counterfeits.</p> <p>Describe the investigation of product defects.</p>	<p>Detail batch &amp; product recall procedures.</p> <p>Evaluate whether procedures are in compliance with GLP or GMP standards.</p>	<p>Recognises the significance of inspections.</p> <p>Relates product defects to failure in standards.</p> <p>Consults with regulatory authorities on potential clinical significance of defects.</p>	
<p><b>10.2</b> Describe manufacturers and wholesalers licences and inspection.</p>	<p>Summarise the requirements and significance of manufacturers' and wholesalers' licences and inspections.</p>	<p>Displays an understanding of manufacture and distribution of medicines.</p>	
<p><b>10.3</b> Outline import licences and parallel import licences.</p>	<p>Discuss the requirements and procedures for parallel importation of medicines.</p>	<p>Contributes to the evaluation of the risks, benefits and economic impact of parallel importation of medicines.</p>	

<b>ITEM: RGN 10 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>10.4</b> Describe Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).	Discuss why GLP and / or GMP standards are necessary and summarise these standards.	Recognises the sources of defects in manufacturing and distribution of medicines.	
<b>10.5</b> Describe the background to regulation and content of pharmacopoeias.	Discuss why pharmacopoeial standards are necessary.	Displays knowledge of the problems arising from failure to comply with pharmacopoeial standards.	
<b>10.6</b> Describe the regulation of herbal medicines.	Discuss regulatory procedures for approval of herbal remedies.	Recognises the established use of herbal remedies, their risks and benefits in the context of diseases and other medicines to treat these.	

## **MODULE 2**

### **CLINICAL PHARMACOLOGY (CLP)**

#### **AIM**

**To acquire knowledge of and competency in clinical pharmacology and other supporting disciplines to the level necessary to fulfil proficiently the role of a pharmaceutical physician. Contribute to investigations, judgements and decisions on the clinical pharmacology of a medicine in all phases of its research and development. Apply such knowledge in the continuing support and extension of the clinical indications, formulations and dosage schedules, in the investigation and assessment of suspected adverse drug reactions, in submissions to regulatory and pricing authorities, and in product information for doctors and patients. Recognise the need to obtain external or internal expert advice on unusual or unfamiliar findings or on particular aspects outside one's own knowledge or experience.**

<b>ITEM: CLP 1</b>			
<b>OBJECTIVE:</b>			
<b>To be able to exercise judgement of non-clinical pharmacology and toxicology firstly in deciding to evaluate a new drug candidate, secondly in the initial choice of dosage, and thirdly in planning a progressive development programme leading to marketing authorisation.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>1.1</b> Be conversant with the principles and purposes of pre-clinical tests of a candidate drug's pharmacology and toxicology.</p> <p><b>1.2</b> Be conversant with the pre-clinical data currently required for early human studies and of long-term toxicology required for the perceived clinical uses.</p> <p><b>1.3</b> Be familiar with the clinical significance of in vitro and in vivo animal pharmacology and, for example, of P450 studies.</p> <p><b>1.4</b> Be familiar with standard animal toxicology study designs and toxicokinetics.</p>	<p>Ability to understand the evidence of a candidate drug's potential value from pre-clinical studies in various species, either whole animal or isolated organ and tissue models, and in models of disease.</p> <p>Relate longer-term animal toxicology to the potential therapeutic indications and dosages.</p> <p>Use preclinical metabolism data to identify necessary clinical drug interaction studies.</p>	<p>As a therapeutic/development team member, contributes to the stepwise decisions being made based on pre-clinical pharmacology and toxicology from the perspective of therapeutic needs and patient safety.</p> <p>Recognises the benefits and pitfalls of extrapolating preclinical data to the predictions of drug effects in man.</p> <p>Communicates the relevance of the preclinical data to others working on the drug's development.</p>	<p><b>Outcome:</b> Evidence of attendance at and contribution to meetings with preclinical scientists and/or external course.</p> <p><b>Case Study:</b> Supervisor's evaluation of ability to write "Guidance for Investigator" based on preclinical data for a first-in-human study.</p>

<b>ITEM: CLP 1 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>1.5</b> Be familiar with the potential differences, particularly safety issues, of administering new biological compounds to man for the first time compared with other new chemical entities.</p>			

<b>ITEM: CLP 2</b>			
<b>OBJECTIVE:</b> The registrar will have the ability to identify and review relevant literature and other sources and to write manuscripts for publication.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>2.1</b> Thorough reading of other work in the field and of important requirements to meet clinical needs.</p> <p><b>2.2</b> Be fully conversant with all relevant publications.</p>	<p>Provide a comprehensive review of a therapeutic field and the met and unmet needs.</p> <p>Prepare a clinical development plan in conjunction with others.</p> <p>Critically review relevant publications.</p> <p>Prepare a manuscript or document as a joint author on clinical studies for submission to a peer-reviewed journal or a regulatory authority.</p>	<p>Maintains knowledge of current literature in the relevant therapeutic field and familiarity with recent advances in clinical pharmacology and therapeutics.</p> <p>Encourages other colleagues to write impartial critiques of recent publications.</p>	<p><b>Critical Review:</b> Written review of relevant clinical pharmacology in area (drug class or therapeutic indication) of registrar's interest or as a course assignment.</p> <p><b>Outcome:</b> Publication, preferably in peer review journal, of an article on any aspect of clinical pharmacology or a verbal presentation to an outside body or to a professional meeting.</p>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>2.3</b> Knowledge of relevant statistical methods and analyses.</p> <p><b>2.4</b> Understanding of pharmacokinetic analyses and modelling.</p>			<p><b>Case Study:</b> Course-based or actual analysis of data.</p>

<b>ITEM: CLP 3</b>			
<b>OBJECTIVE:</b> To have a working knowledge of the clinical pharmacology and toxicology evidence required in the stepwise regulatory approval process from initiating clinical trials to product licence approval in Europe.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level1</b>	<b>Competency Level 1</b>	
<p><b>3.1</b> Working knowledge of the relevant and current regulations.</p> <p><b>3.2</b> Working knowledge of how, in particular, the pharmacology and toxicology data necessary for Phase 1 studies must be designed, reviewed and approved in readiness for clinical trials.</p> <p><b>3.3</b> Components of clinical development plan required in Europe.</p> <p><b>3.4</b> Components of a regulatory licensing (marketing) submission required in Europe.</p> <p><b>3.5</b> Appreciation of any differences in US and Japanese regulatory needs.</p>	<p>Define the planned clinical pharmacology of the candidate drug before clinical trials are begun.</p> <p>Anticipate possible disease-related variations in drug handling in patients compared with normal healthy subjects.</p> <p>React to unexpected findings promptly and, if necessary, suspend further work while other expert opinions are obtained and the issue is clarified.</p> <p>Have an awareness of past problems in this clinical or therapeutic area that have led to regulatory refusal of trials or their modification.</p> <p>Write expert reports, clinical overviews and product information.</p>	<p>Accepts pivotal role in preparation of a development plan that requires knowledge and judgement.</p> <p>Recognises the value of liaison with other experts in related fields in the design and interpretation of studies.</p> <p>Exhibits strict compliance with regulations and guidelines.</p> <p>Understands the need to keep senior management informed.</p>	<p><b>Assignment:</b> Evaluation of clinical pharmacology report written by registrar to support:</p> <p>a. exploratory clinical studies, or</p> <p>b. confirmatory clinical studies, or</p> <p>c. product licence approval.</p> <p>The report to be prepared alone or as part of a team on a product, real or hypothetical.</p>

**ITEM: CLP4****OBJECTIVE:****To have a thorough knowledge of the design, execution and analysis of early-phase drug studies in man.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>4.1</b> Understand the purpose of and methods for investigation of a candidate drug in healthy human subjects.</p> <p><b>4.2</b> Define the objectives and limits to be applied in order to maximise the information obtained and to avoid or minimise risks to study subjects.</p> <p><b>4.3</b> Have knowledge of human pharmacokinetics, pharmacodynamics and pharmacogenetics.</p> <p><b>4.4</b> Have a working knowledge of selecting dose range and increments, of minimum effective and maximum tolerated doses.</p> <p><b>4.5</b> Be fully aware of regulatory and legal requirements in human studies.</p>	<p>Contribute to the design of human studies in order to fulfil their aims.</p> <p>Define the subsequent aims and safeguards in healthy volunteer studies and early patient trials; instil these and monitor compliance.</p> <p>Select safety measures based on pre-clinical data and related drugs.</p> <p>Check and interpret any physiological changes observed.</p> <p>Propose any dosing changes or limits for subsequent Phase 2 or Phase 3 studies.</p>	<p>Recognises one's responsibilities to study volunteers and ensure their safety.</p> <p>Imparts this ethos to others and monitor that safeguards are being applied.</p> <p>Recommends any actions needed as studies progress, such as stopping planned dose escalation or introducing new safety checks.</p> <p>Consults with other company experts in related fields and outside advisers and investigators with expertise and knowledge of clinical pharmacology.</p>	<p><b>Outcome:</b> Evidence of personal ability (real-life or simulated) to assist in the design, execution and analysis of an early-phase study.</p> <p><b>Case Study:</b> Supervisor's evaluation of registrar's ability to interpret Phase I data to support or stop clinical development (either as a real-life task or simulated).</p> <p><b>Case Study:</b> Course assessment by MCQ and / or by assigned data analysis.</p>

<b>ITEM: CLP4 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>4.6</b> Knowledge of the degree of biological variation seen in a normal population.</p> <p><b>4.7</b> The reasons and need for full screening of healthy volunteers.</p>			

<b>ITEM: CLP 5</b>			
<b>OBJECTIVE:</b> <b>The registrar will be conversant with the ethical principles and practices governing clinical research with healthy volunteer subjects.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>5.1</b> Basic principles of the protection of research subjects.</p> <p><b>5.2</b> Practical procedures in providing full information to participants and their doctors and in obtaining and recording their informed and continuing consent.</p> <p><b>5.3</b> Ethical review of studies from first-time-in-human to large-scale clinical trials.</p>	<p>Maintain these ethical principles and practices in the setting up and regular inspections of investigator sites.</p> <p>Involvement in writing and approving clinical study information sheets and consent forms.</p> <p>Ideally, have experience of Ethics Committee meetings, as an applicant and / or as a member.</p> <p>Skill in using appropriate lay language for study subjects and their relatives.</p> <p>Over-see the outcomes of site inspections and audits and make personal visits to sites as required.</p>	<p>Regards human research with new drug candidates as imposing the same and at times even greater responsibilities as those required in routine medical practice.</p> <p>Instils these principles and practices within the research organisation and local investigating teams.</p>	<p><b>Outcome:</b> Evidence of attendance at an Ethics Committee meeting one or more times as an applicant, member or observer.</p> <p><b>Outcome:</b> Personal contribution to volunteer information sheets and consent forms.</p> <p><b>Outcome:</b> Experience of site visits and audits and taking action on their outcomes.</p>

**ITEM: CLP 6****OBJECTIVE:**

**The registrar will be able to apply the principles of Good Clinical Practice (GCP) in clinical pharmacology.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>6.1</b> The ICH Good Clinical Practice (GCP) principles and practices must be known and applied throughout the development programme.</p> <p><b>6.2</b> Up-to-date procedures (e.g. ICH Guidelines) must be known and fulfilled.</p> <p><b>6.3</b> Safeguards for volunteer participants in early-phase studies and those for patients that must be followed.</p>	<p>Within the GCP framework, plan a series of clinical pharmacology investigations in a sensible stepwise sequence in order to characterise the compound's properties and to allow critical judgements to be made on its therapeutic potential and safety.</p> <p>Ensure that quality assurance checks are made and acted upon.</p>	<p>Recognises that as a team member and often the only medical graduate, the welfare of subjects in clinical studies must be paramount, as often no personal benefit for them is implied but risk is possible.</p> <p>Recognises the need for stringent adherence to procedures and maintenance of full and accurate records.</p>	<p><b>Applied Knowledge-Based:</b> Evidence of attendance at a GCP course with pass mark in course exam.</p> <p><b>Outcome:</b> Personal involvement in early-phase studies of new compounds.</p>

**ITEM: CLP 7****OBJECTIVE:**

**To be able to investigate the clinical pharmacology of a new medicine in a stepwise manner within the overall clinical development plan.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	

<p><b>7.1</b> Understand the clinical pharmacology requirements in a regulatory submission for approval of a new drug and in a Summary of Products Characteristics (SmPC).</p> <p><b>7.2</b> Apply clinical pharmacological knowledge and methodology in the development programme from choice of a candidate entity through its full characterisation and key decisions on its therapeutic potential and any limitations on its clinical use.</p>	<p>Establish in a logical and stepwise manner the main pharmacological actions of a new medicine in healthy people and in those with the target disease.</p> <p>In doing so, identify the likely dose range and, early on in the programme, measure its clinical effects (proof of concept).</p> <p>Identify further studies with other drugs in that therapeutic class aimed to determine their comparative efficacy and ADME profiles.</p> <p>Judge real and potential benefits and of the new medicine and likely safety problems to be encountered.</p> <p>Anticipate possible adverse interactions with other drugs, which are likely to be co-prescribed for other medical conditions in routine clinical practice, and of impaired ADME due to co-existing medical conditions.</p>	<p>Recognises the need to characterise in ADME studies how a new medicine is handled in the human body.</p> <p>Realises that impairment of normal ADME may be caused by the disease itself and/or other drugs likely to be given to treat the disease.</p> <p>Communicates the importance of clinical pharmacology to other members of the development team.</p>	<p><b>Outcome:</b> Evaluation by supervisor or by course teachers of ability to apply knowledge and skills and to exhibit Attitudes / Behaviour in a real-life or simulated situation.</p> <p><b>Multi-Source Feedback</b> (MSF, 360°): Within a development team. Receive peer assessment.</p>
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<b>ITEM: CLP 8</b>			
<b>OBJECTIVE:</b> The registrar will be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>8.1</b> Knowledge of the causative factors, pathophysiology and main therapeutic options in one major organ-based disease.</p> <p><b>8.2</b> Within that framework, understand the benefits and shortcomings of current therapy, and thereby identify new therapeutic needs.</p> <p><b>8.3</b> Understand how advancing knowledge, such as pharmacogenomics and pharmacogenetics, may tailor therapy.</p>	<p>Bring together scientists working on the underlying disease process, including academic and company experts on treatment options, and chemists developing new compounds that may fulfil unmet needs.</p> <p>Similarly, contribute to proposed investigations and profiling of a new theoretical agent by applying key principles of efficacy, safety and economic value.</p>	<p>As part of a research team, consults with academic and clinical experts in the therapeutic area to learn therapeutic aims, achievements and needs.</p> <p>Creates an idealised drug profile and, in doing so, recognises constraints in clinical practice and in health service provisions.</p>	<p><b>Outcome:</b> Publication in a peer review journal or in an internal company circulated memo on a therapeutic area and identification of unmet needs.</p> <p><b>Outcome:</b> Simulated exercise on a course on identification of unmet medical needs in a therapeutic area.</p>

## **MODULE 3**

### **STATISTICS AND DATA MANAGEMENT**

#### **AIM**

**To contribute clinical input to enable effective collaborative work with professional statistical and data management staff; thereby ensuring optimal study design, and effective management, analysis and reporting of clinical trial data to meet scientific and regulatory standards.**

<b>ITEM: SDM 1</b>			
<b>OBJECTIVE:</b> <b>To be able to explain the statistical principles in designing clinical studies.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>1.1</b> Explain the use of control, blinding, randomisation and other methods for the reduction of bias in clinical trials.	Select the most appropriate design structure; superiority, equivalence, non-inferiority, dose-response to meet the needs of the drug development programme.	Recognises the importance of working with a statistician in the design of clinical studies.	
<b>1.2</b> Explain the principles of power and sample size, the reduction of variation and other methods for increasing precision in clinical studies. <b>1.3</b> Outline methods for the interim analysis of clinical trial data and the management of those analyses, through an Independent Data Monitoring Committee, for the evaluation of efficacy, harm and futility.	Provide clinical input into sample size calculations, the selection of primary and secondary endpoints, choice of comparator and methods of interim analysis.		
<b>Competency Level 2</b>			
<b>1.4</b> Define case-control and cohort studies and describe their role in pharmacovigilance.			

**ITEM: SDM 2****OBJECTIVE:****The registrar will be able to provide clinical input into and review a Statistical Analysis Plan.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>2.1</b> Outline the structure of a Statistical Analysis Plan.	Review a Statistical Analysis Plan. Document the reasons for the inclusion/exclusion of patients. Identify the reasons for the inclusion of patients in samples for analysis. Plan the presentation of the results of the statistical analysis in the clinical study report.	Recognises the role of the pharmaceutical physician in the construction and review of a Statistical Analysis Plan.	

<b>ITEM: SDM 3</b>			
<b>OBJECTIVE:</b> The registrar will be able to explain the commonly used statistical principles and methods for the analysis and presentation of data in clinical studies.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>3.1</b> Explain the thinking behind statistical methods, such as the pre-specification of methods of analysis, the control of type I error and the principle of intention-to-treat to reduce bias.</p> <p><b>3.2</b> Describe the role of hypothesis testing, p-values, summary statistics, confidence intervals and modelling in the statistical analysis of data.</p>	<p>Interpret the results of a statistical analysis of data based on methods including; survival analysis, analysis of covariance, logistic regression, meta-analysis.</p>	<p>Recognises the importance of the use of appropriate statistical methodology for the correct interpretation of clinical studies.</p>	

<b>ITEM: SDM 3 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>3.3</b> Explain the principles behind statistical methods, such as the analysis of covariance and the choice of statistical test, for maximising precision when analysing data.</p> <p><b>3.4</b> Explain the methods of statistical analysis for investigating the homogeneity of the treatment effect.</p>			
<p><b>3.5</b> Explain the methods of statistical analysis for the detection of fraud and misconduct.</p>			

**ITEM: SDM 4****OBJECTIVE:**

**To understand the statistical principles for the design, conduct, analysis and reporting of clinical studies from a regulatory perspective.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>4.1</b> Outline the key principles for the design, conduct, analysis and reporting of clinical trials contained in the ICH E9 guideline 'Statistical Principles for Clinical Trials'.</p> <p><b>4.2</b> Identify the key safety questions for a Clinical Development Plan and the trials and data which relate to those questions.</p>	<p>Compile a complete list of data to be included in the integrated report of safety for a Clinical Development Plan.</p>	<p>Recognises the importance of ICH E9 in ensuring that clinical trials are designed, conducted, analysed and reported in a scientifically valid way.</p>	
<p><b>4.3</b> Identify the role of meta-analysis in the analysis and presentation of results from a series of clinical studies.</p>	<p>Identify the criteria for the inclusion of trials in a meta-analysis to answer key questions and present the results of such an analysis.</p>		

<b>ITEM: SDM 5</b>			
<b>OBJECTIVE:</b> To be able to undertake a critical review of the statistical methods used and presented in reports and publications.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>5.1</b> Describe the key statistical aspects of a clinical study that should be included in a publication or report.	Interpret the results of a statistical analysis based on commonly used statistical procedures presented in a publication or report.  Critically appraise a meta-analysis.	Recognises the need to be able to critically review published clinical studies and the importance in the publication of a full description of statistical methodology.	

**ITEM: SDM 6****OBJECTIVE:**

**The registrar will understand the principles of Case Report Form (CRF) design and clinical data management to be able to provide input to the review of clinical data.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>6.1</b> Identify the key areas where data management contributes to the clinical trial process.	List the key areas where data management contributes to the clinical trial process.	Recognises the need to involve data management in all phases of a clinical trial to ensure efficient data collection and robust data for analysis.	
<b>6.2</b> Understand the impact of poor CRF design on the conduct of the clinical trial.	Identify examples of good CRF design practice and examples of poor CRF design.	Recognises the importance of physicians contributing to reviews of CRF design.	
<b>6.3</b> Understand common issues with CRF completion at the study site and the importance of training site staff and CRAs.	Identify common problem areas in CRF completion.	Recognises the need for data management to be involved in training site staff and CRAs during study set-up.	

<b>ITEM: SDM 6 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>6.4</b> Understand the data cleaning process (relevant to both electronic and paper CRF) and where physicians should review the Data Validation plan, the clinical data, and provide support.</p>	<p>Be able to describe the data cleaning process post data-entry in a paper environment.</p> <p>Describe the typical contents of a Data Validation plan.</p> <p>List examples of areas where physicians can provide consultative advice to resolve data issues.</p>	<p>Recognises the importance of physicians participating in data review, and providing advice to teams, to ensure a clinically correct database for analysis.</p>	

<b>ITEM: SDM 7</b>			
<b>OBJECTIVE:</b>			
<b>To understand the principles of CDISC*, Electronic Data Capture (EDC) and MedDRA and their impact on data management activities. (*CDISC=Clinical Date Interchange Standards Consortium)</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>7.1</b> Understand the principles of CDISC.	Describe the principles of CDISC. List some of the benefits of CDISC. Know whether CDISC standards have been implemented in own company.	Recognises the benefits of CDISC and the need for FDA submissions.	
<b>7.2</b> Understands the EDC process and the differences in data cleaning activities and role of data management.	Describe the expectations for EDC and the actual benefits. Describe the considerations that need to be made to implement at the study site. Describe differences in study team roles (data manager and CRA) when utilising EDC compared with conventional studies.	Recognises the benefits of EDC and the differences in team roles when utilising the technology.	

<b>ITEM: SDM 7 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>7.3</b> Explain MedDRA structure, uses and support and how coding is performed.</p>	<p>Describe the MedDRA structure hierarchy.</p> <p>Perform allocation of Primary SOC to medical terms.</p> <p>Describe the roles of the individual performing coding and physician review.</p>	<p>Recognises the importance of accurate MedDRA coding in the product labelling.</p>	

## MODULE 4

### CLINICAL DEVELOPMENT (CLD)

#### AIM

**To acquire competency to prepare a critical overview of the therapeutic area and demonstrate the relevance of developing a drug in this area; to prepare or critique a clinical development plan to explore the safety and efficacy of a new pharmaceutical agent that will lead to its safe adoption into clinical practice after approval by national and international regulatory agencies. To oversee a programme of clinical trials that will demonstrate ethically and adequately the safety and efficacy of a new pharmaceutical agent in compliance with national and international laws, regulations and guidelines. To appraise critically and report on the evidence of safety and efficacy of a new pharmaceutical agent and assess its benefits, risks and place in the pharmaceutical armamentarium.**

<b>ITEM: CLD 1</b>			
<b>OBJECTIVE:</b>			
<b>To be able to describe the data required and how to obtain, analyse and apply them in order to undertake an analysis of a therapy area within the industry clinical development environment.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>1.1</b> Explain how to conduct a clinical literature search.</p> <p><b>1.2</b> Describe how to evaluate and interpret the findings in the clinical development environment.</p>	<p>Prepare a literature review of a specified therapy area.</p> <p>Write a brief report describing:</p> <ul style="list-style-type: none"> <li>a. the epidemiology and pathophysiology of the diseases that occur in this area;</li> <li>b. therapies available and their mechanisms of action;</li> <li>c. a summary of drugs under development in this area;</li> <li>d. unmet medical / therapeutic need in this area.</li> </ul>	<p>Recognises the breadth and depth of data requirements and the inherent limitations of information freely available in the public domain when making appropriate clinical development judgements.</p> <p>Works as part of a team to ensure the fullest understanding of pre-clinical, clinical and commercial data and their relevance to the therapy area review.</p>	<p><b>Outcome:</b> Literature review in defined product / therapy area: retrieval and evaluation of source material.</p> <p><b>Case Study:</b> Preparation of report on product / therapy area; diseases, therapies, drugs in development, unmet needs.</p>

**ITEM: CLD 2****OBJECTIVE:**

**To understand and be able to evaluate preclinical and Phase I data as they are applied to a Clinical Development Plan for a new drug.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>2.1</b> Describe what research, studies and data should be available to make an informed decision to proceed to clinical efficacy studies (Phase II).</p> <p><b>2.2</b> Describe the topics and the data which would explain why a drug development should not proceed further.</p> <p><b>2.3</b> Describe what types of adverse effects are likely to be encountered in clinical trials.</p> <p><b>2.4</b> Describe the Phase 1 data that would be gathered in clinical pharmacology for a potential new medicine.</p>	<p>Write a reasoned critique on whether there are appropriate data to proceed into clinical efficacy trials for a new drug (real or hypothetical).</p> <p>Evaluate the clinical pharmacology data for a new drug real or hypothetical.</p>	<p>Recognises the importance of a medical input to the evaluation of early development data, and share this with the drug development team.</p> <p>Recognises the value of healthy volunteer studies in drug development and participates actively in their evaluation.</p> <p>Consults with colleagues in the drug development team on the impact of early development data on the direction and design of Phase II studies.</p>	<p><b>Critical Review:</b> Evaluate safety aspects of preclinical and Phase I data in planning clinical development programme to demonstrate efficacy and safety for a potential new medicine (real or hypothetical).</p>

<b>ITEM: CLD 2 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>2.5</b> Justify the preclinical safety and toxicology data required for a new drug development.	Evaluate and discuss the safety and toxicology data for a new drug (real or hypothetical).  On the basis of preclinical and Phase I data, recommend, with reasons, a range of doses to be studied in Phase II.		
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<b>2.6</b> Outline the main imaging techniques used currently in clinical trials.  <b>2.7</b> Outline the main laboratory methods used in clinical trials.		Recognises the time-limitation of publications in a rapidly developing technical field.	<b>Case Study:</b> Preparation of report on main imaging techniques and laboratory parameters used in clinical trials and their applicability to the investigation of a potential new medicine (real or hypothetical)  <b>Critical Review:</b> Critique of publication of a clinical trial with particular reference to the modern imaging / lab techniques which registrar would expect to see used if the study were being set up today.

<b>ITEM: CLD 3</b>			
<b>OBJECTIVE:</b> <b>To understand and be able to construct or assess a Clinical Development Plan for the clinical development of a new drug.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>3.1</b> Describe the elements of a Clinical Development Plan, including:</p> <ul style="list-style-type: none"> <li>- the key studies required for registration;</li> <li>- the primary endpoints;</li> <li>- timelines for study and programme completion;</li> <li>- possible risks that would threaten the plan.</li> </ul>	Write a Clinical Development Plan for a new drug (real or hypothetical).	Recognises the role, value and benefit of the team approach to clinical development and recognises the contribution of others to the successful Clinical Development Plan.	<p><b>Outcome:</b> Preparation of Clinical Development Plans(s) taking into account product/therapy area, preclinical and Phase I data, safety profile and risk management, and target SmPC (real or hypothetical drug).</p> <p><b>Multisource Feedback Assessment (MSF, 360°):</b> clinical development team.</p>
<b>Competency Level 2</b>			
<p><b>3.2</b> Describe the objectives of marketing support studies.</p>			<p><b>Outcome:</b> Proposal for Phase IV study budget for drug (real or hypothetical) which would include objectives / rationale of marketing support studies.</p>

<b>ITEM: CLD4</b>			
<b>OBJECTIVE:</b> To understand the principles underpinning the development of a clinical trial protocol.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>4.1</b> Describe the required critical data in a study.	<p>Design and prepare a study protocol for a new drug (real or hypothetical).</p> <p>Write a reasoned critique of the outline protocols considering:</p> <ul style="list-style-type: none"> <li>- how they achieve the aims of the Clinical Development Plan;</li> <li>- how they comply with ethical requirements;</li> <li>- how they can be conducted in the real world;</li> <li>- how they reach achievable timelines;</li> <li>- how they can be conducted within the allocated budget.</li> </ul>	Recognises the value of carefully thought out protocols in clinical development and participates actively in their development.	<b>Outcome:</b> Medical contribution to study protocol(s) for a product / therapy area (real or hypothetical) leading to viable and robust clinical studies designed to test a scientific hypothesis through meeting primary and secondary endpoints (to satisfy scientific, ethical and regulatory standards).

<b>ITEM: CLD4 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<b>4.2</b> Describe the design of Case Report Forms (CRFs) and their key features to ensure that data is collected in a practical and unambiguous way.			<b>Outcome:</b> Preparation of training material for physician new to CLD on the design of Case Report Forms (CRFs) and their key features to ensure that data are collected in a practical and unambiguous way.

<b>ITEM: CLD 5</b>			
<b>OBJECTIVE:</b> To have a clear understanding of, and be able to apply, the regulatory and ethical aspects underpinning clinical drug development.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>5.1</b> Predict and address the ethical issues arising from clinical studies.</p> <p><b>5.2</b> Describe the principles of the Declaration of Helsinki.</p> <p><b>5.3</b> Describe the requirements of ICH Good Clinical Practice.</p> <p><b>5.4</b> Have a working knowledge of and describe:  - the regulatory requirements for clinical trials in UK, EU and USA;  - Clinical Trial Application procedures (UK).</p>	<p>Draft an informed consent form that includes all the required elements.</p>	<p>Recognises the ethical environment in which clinical trials are conducted and the contribution made by patients in agreeing to participate in clinical research.</p> <p>Recognises that clinical development is a global process regulated by differing regional frameworks.</p>	<p><b>Applied Knowledge-Based:</b>  Evidence of attendance at a GCP course with satisfactory pass mark in course exam.</p> <p><b>Outcome:</b> Preparation of informed consent documents for clinical trial(s) to meet ethical, regulatory and scientific standards, and satisfy subject/patient expectations for information, comprehensibility and clarity.</p>

**ITEM: CLD 6****OBJECTIVE:**

**To have a good working knowledge of the management and conduct of clinical trials, working as part of a team.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency level 1</b>	
<p><b>6.1</b> Describe the time required and project management skills needed to set up a study, identify, assess and recruit investigators and gain their cooperation.</p> <p><b>6.2</b> Describe how to arrange appropriate legal and ethical clearance for clinical drug trial supplies, Case Report Forms (CRFs) and other relevant materials.</p> <p><b>6.3</b> Describe the practicalities essential to the conduct of clinical trials, for example, pre-study site assessment, study start-up visits, how to start a study on time and run it to schedule, routine site monitoring visits, site close-out procedures, CRF correction, source data verification, GCP documentation, investigator payments, checks for fraud.</p>	<p>Draw up a project management plan for the clinical development of a new drug (real or hypothetical). This should include key milestones.</p>	<p>Recognises that successful drug development requires a multi-disciplinary team approach to which the physician must make timely and effective contributions.</p> <p>Consults with colleagues in the drug development team on the impact of delays to the project plan and how these may be minimised or compensated.</p>	<p><b>Outcome:</b> Contribution to project management plan(s) for multi-centre (multi-national) clinical trial.</p> <p><b>Assignment:</b> Draw up training plan for physicians new to CLD outlining CLD6.1- CLD6.7 (drug real or hypothetical) <b>or</b> Certificate of attendance at GCP course where this was covered.</p> <p><b>Assignment:</b> Draw up a project management plan for the clinical development of a new drug (real or hypothetical). This should include key milestones.</p>

<b>ITEM: CLD 6 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>6.4</b> Describe the requirements for:  - financial disclosure;  - data protection.</p> <p><b>6.5</b> Describe audit and inspection procedures applied to studies before, during and after their conduct.</p> <p><b>6.6</b> Describe why internal QA procedures are needed and the possibilities for mandated external audits and inspections.</p> <p><b>6.7</b> Outline the role and responsibilities of the QA department.</p>			

<b>ITEM: CLD 7</b>			
<b>OBJECTIVE:</b> The registrar will be able to provide a full and detailed evaluation of all suspected adverse events occurring in clinical trials.			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>7.1</b> Define and classify (describe) adverse events.</p> <p><b>7.2</b> Describe the working requirements for adverse event reporting each stage of drug development in UK, EU, USA, Japan and non-ICH countries.</p>	<p>Evaluate adverse events for severity and causality.</p> <p>Categorise and 'report' some hypothetical examples of adverse events based on patient case histories.</p>	<p>Recognises the importance of a thorough evaluation of all emerging safety data as part of the developing safety profile of a drug, in order to identify adverse safety signals early and avoid exposing patients to unnecessary risk.</p>	<p><b>Outcome:</b> Evaluation of emerging safety data and record of resulting decisions taken during the conduct of a clinical trial or study programme.</p> <p><b>Assignment;</b> draft a benefit-risk management plan for a new drug (real or hypothetical).</p>

**ITEM: CLD 8****OBJECTIVE:**

**The registrar will be able to interpret and explain the results of clinical studies and be able to create and critically evaluate clinical study reports and manuscripts prepared for publication.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>8.1</b> Explain the process involved in the preparation of manuscripts reporting clinical studies for submission for publication to a peer-reviewed journal, the key issues which must be addressed, and the typical structure of such a manuscript.</p> <p><b>8.2</b> Explain the scientific and ethical imperative to submit the results of scientific research to peer review.</p> <p><b>8.3</b> Describe the establishment and use of clinical trial registries.</p>	<p>Interpret and explain the results of clinical studies.</p> <p>Write clear, coherent and comprehensive reports of clinical research undertaken.</p> <p>Summarise the results of a programme of clinical research.</p> <p>Assess the design and conduct of studies of a drug (real or hypothetical).</p> <p>Critically review the results to determine the clinical significance of the data.</p> <p>Assess the risks and benefits of a potential new medicine.</p>	<p>Recognises the need to interpret and disseminate clinical research data within the team, company and scientific community via peer-reviewed publication in a timely and effective manner.</p> <p>Consults with colleagues on the interpretation of clinical research data.</p> <p>Recognises the need for timely and accurate interpretation of study data.</p> <p>Understands the importance of disseminating the data in a timely and effective manner.</p> <p>Recognises the impact of clinical trial data on the stock market.</p>	<p><b>Outcome:</b> Clinical study reports to meet scientific, ethical and regulatory standards (real or hypothetical drug).</p> <p><b>Assignment:</b> Draft a report to demonstrate ability to:</p> <ul style="list-style-type: none"> <li>- summarise the results of a programme of clinical research;</li> <li>- assess the design and conduct of studies of a drug (real or hypothetical);</li> <li>- critically review the results to determine the clinical significance of the data;</li> <li>- assess the risks and benefits of a potential new medicine.</li> </ul>

## **MODULE 5**

### **HEALTHCARE MARKETPLACE (HMP)**

#### **AIM**

**To demonstrate applied knowledge of the commercial environment in which pharmaceutical marketing takes place. To demonstrate competency in applying these principles to the constructive role of the pharmaceutical physician in ensuring that marketing activities within this environment remain legal, ethical and, where appropriate, innovative. To serve the welfare of patients in providing medical support to appropriate prescribing of marketed medicines.**

**ITEM: HMP 1****OBJECTIVE:**

**To demonstrate an understanding of the broader healthcare environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision making in prescribing medicines.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>1.1</b> Describe the various components of the legal and regulatory framework in which pharmaceutical medicine needs to operate:</p> <ul style="list-style-type: none"> <li>-UK Medicines Act;</li> <li>-EU Advertising Directive;</li> <li>-UK Advertising Regulations;</li> <li>-The Code of Practice for the Pharmaceutical Industry;</li> <li>-Other regulations, codes and guidelines applying to registrar's country(ies) of operation e.g. IFPMA International Code of Pharmaceutical Marketing Practices; EFPIA European Code of Practice for the promotion of medicines; WHO ethical criteria for medicinal promotion;</li> <li>-Role of the MHRA and other regulatory bodies.</li> </ul>	<p>Analyse the roles, importance relative contribution and interactions of these components in supporting the legal and regulatory framework within which pharmaceutical medicine operates.</p>	<p>Recognises the significance and authority of different levels of the law/regulation in the interpretation and operation of the legal and regulatory framework.</p>	<p><b>Assignment:</b> Legislation, directives, guidance and regulations comprising legal and regulatory framework for promotional activity.</p> <p><b>Applied Knowledge-Based:</b></p> <p>Tests on PI Code of Practice (ABPI/PICPA-based).</p>

ITEM: HMP 1 cntd			
Knowledge	Skills	Attitudes / Behaviour	Assessments
<p><b>1.2</b> Identify the key stakeholders and the main elements within the healthcare market in which the registrar works (e.g. UK NHS, Department of Health, NICE, MHRA) and in other key markets.</p> <p><b>1.3</b> Describe the contribution and decision making processes within the healthcare market in relation to prescribing:</p> <ul style="list-style-type: none"> <li>- The National Institute for Health and Clinical Excellence (NICE) or equivalent;</li> <li>- value assessments of pharmaceuticals;</li> <li>- disease management guidelines;</li> <li>- Drugs and Therapeutics Committees;</li> <li>- computerised prescribing systems (e.g. PRODIGY).</li> </ul>	<p>Evaluate the major interactions between the key stakeholders in the healthcare market.</p> <p>Interpret the interactions between the different groups and processes and how they can affect prescribing practices.</p>	<p>Recognises how these groups influence prescribing practices within the healthcare environment.</p> <p>Recognises how these interactions influence the provision of healthcare in the market.</p>	<p><b>Assignment:</b> Understanding NHS, NICE &amp; other government bodies (DoH, PPA, PPRS) and pharmaceutical industry interactions.</p> <p><b>Critical Review:</b> Analysis of key stakeholders in the healthcare marketplace and wider healthcare environment, their interactions and their influences on prescribing.</p> <p><b>Critical Review:</b> Analysis of industry key external and internal stakeholder interactions.</p>

<b>ITEM: HMP 1 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>1.4</b> Explain the principles of marketing research and profiling in the context of regulations with regard to:</p> <ul style="list-style-type: none"> <li>- competition in the healthcare market;</li> <li>- segmentation of customers and markets;</li> <li>- customer targeting;</li> <li>- methods of promotion;</li> <li>- activities of public and professional relations companies.</li> </ul>	<p>Evaluate how market research and profiling data can contribute to effective promotional activities and the constraints of regulation in this context.</p>	<p>Recognises the contribution and constraints of marketing data in the promotion of medicines.</p>	<p><b>Case-Study:</b> Observe / assess an on-the-job review of some specific market research data.</p>
<p><b>1.5</b> Describe the role of the Prescription Pricing Authority (PPA).</p>	<p>Interpret PPA data and demonstrate how it may be used in the healthcare market.</p>	<p>Recognises the role of PPA data in the prescribing environment.</p>	
<p><b>1.6</b> Outline distribution channels for medicines, including parallel importing.</p>	<p>Analyse the effects of distribution channels on the availability and cost of medicines.</p>	<p>Recognises the impact of distribution channels on availability of medicines in the healthcare market.</p>	

<b>ITEM: HMP 2</b>			
<b>OBJECTIVE:</b>			
<b>To understand the key elements involved in medical-marketing communication in the healthcare environment, to explain how relevant and legally compliant materials and activities are developed and to recognise the importance of compliance with regulation in this context.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>2.1</b> Describe the process involved in the preparation and production of legally compliant documentation to support medical marketing activities:</p> <ul style="list-style-type: none"> <li>- briefing documents;</li> <li>- presentations &amp; publications;</li> <li>- therapeutic training to medical representatives and other non-medically qualified staff;</li> <li>- materials for communications e.g. publications / presentations made by third parties.</li> </ul> <p><b>2.2</b> Explain the relevance of targeting materials to the appropriate audiences e.g. journals / conferences and ensuring consistency with commercial messages.</p>	<p>Construct medical marketing materials/documents (e.g. briefing materials, relevant publications and presentations) appropriate for the audience and consistent with commercial messages.</p> <p>Evaluate a range of medical marketing materials for scientific accuracy, legal and regulatory compliance and comprehension by the reader.</p>	<p>Recognises the importance and challenges of operating within a legal framework for medical marketing communication and the consequences of non-compliance.</p> <p>Recognises the importance of ensuring the compliance of all product-related documentation with the content of the SmPC.</p>	<p><b>Outcome:</b> Preparation and evaluation, of sales force training materials. Presentation of sales briefing / sales training materials.</p> <p><b>Outcome:</b> Detailed background research &amp; knowledge in disease management, therapy area and product area for specified disease / therapy areas / product.</p> <p><b>Outcome;</b> Input to developing core product promotional claims.</p> <p><b>Case Study:</b> Construction / evaluation of medical marketing documents for regulatory / legal compliance.</p> <p><b>Case study:</b> Evaluation promotional materials for legal / regulatory compliance.</p>

<b>ITEM: HMP 2 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>2.3</b> Identify the breadth of medical marketing activities and materials, how to determine whether they are promotional and when and how they should be assessed for legal / regulatory compliance.</p>	<p>Analyse selected materials and activities (e.g. media communications, professional and public relations, pre-launch activities) with regard to scientific, educational and promotional content.</p>	<p>Recognises the importance and consequences of differentiating medical communications as promotional within a defined therapeutic area.</p>	<p><b>Case Study:</b> Evaluating educational versus promotional content of materials.</p> <p><b>Case study:</b> Handling a complaint from a competitor company.</p> <p><b>Outcome:</b> Handling media issues.</p> <p><b>Multisource Feedback Assessment (MSF 360°):</b> sales, marketing and medical colleagues within organisation, independent medical colleagues outside the organisation.</p>

<b>ITEM: HMP 3</b>			
<b>OBJECTIVE:</b>			
<b>The registrar will be able to describe the pharmaceutical industry internal environment, structure and function, key stakeholders, the relevance of commercial drivers and how these business elements impact on the broader healthcare market.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>3.1</b> Describe the pharmaceutical industry internal environment:</p> <ul style="list-style-type: none"> <li>- structure and function of pharmaceutical companies;</li> <li>- product life-cycle management including impact of clinical studies:</li> <li>- portfolio management;</li> <li>- return on investment;</li> <li>- corporate communications and reputation.</li> </ul>	<p>Evaluate how internal business operations and drivers impact the interactions with and relationship between the pharmaceutical industry and the wider healthcare environment.</p>	<p>Recognises the relevance of the internal pharmaceutical industry environment in determining the nature of the industry's interactions in the healthcare market.</p>	<p><b>Outcome:</b> Handling media issues.</p> <p><b>Critical Review:</b> Analysis of key stakeholders in the healthcare marketplace and wider healthcare environment, their interactions &amp; influence on prescribing.</p>

**ITEM: HMP 4****OBJECTIVE:**

**The registrar will be able to describe the information required and how to analyse and apply it in order to undertake a commercial analysis of product potential for a pharmaceutical product within the industry business environment.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>4.1</b> Identify the elements involved in the commercial assessment of a pharmaceutical product:</p> <ul style="list-style-type: none"> <li>- profiling and positioning;</li> <li>- clinical data;</li> <li>- pricing;</li> <li>- products and services;</li> <li>- intellectual property (IP);</li> <li>- others, for example, health economics, costs of promotion, PPRS, reimbursement and implications of formulary listing / delisting, licensing and impact of cost of goods / royalties, break even and net present value (NPV), co-marketing, co-promotion and co-development, products and services as part of the 'augmented brand', implications of patent expiry, issues surrounding generic medicines.</li> </ul>	<p>Evaluate the commercial potential for a pharmaceutical product, real or hypothetical.</p>	<p>Recognises the breadth and depth of data requirements and the inherent limitations in the commercial analysis of pharmaceutical product potential.</p>	<p><b>Outcome:</b> Product / therapy area support – lifecycle management, strategic and operational planning.</p> <p><b>Case Study:</b> Product life-cycle planning, essential components of product strategic &amp; operational planning.</p> <p><b>Case Study:</b> Evaluation of the promotional platform for a product.</p>

<b>ITEM: HMP 4 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>4.2</b> Describe the components required for the evaluation of an in-licensing/collaboration option:</p> <ul style="list-style-type: none"> <li>- identifying candidates;</li> <li>- portfolio fit and management;</li> <li>- due diligence;</li> <li>- product efficacy and safety;</li> <li>- intellectual property (IP);</li> <li>- commercial assessment (see Topic 4.1 above).</li> </ul>	<p>Evaluate the commercial potential for an in-licensing opportunity for a pharmaceutical product, real or hypothetical.</p>	<p>Recognises the commercial potential and limitations of in-licensing and collaborative options.</p>	<p><b>Outcome:</b> Evaluation of an in-licensing opportunity including medical due diligence.</p> <p><b>Outcome:</b> Product / therapy area support – in-licensing assessment.</p> <p><b>Case Study:</b> Evaluation of an in-licensing opportunity.</p>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>4.3</b> Define the clinical and commercial aspects of a pharmaceutical reclassification:</p> <ul style="list-style-type: none"> <li>- Prescription Only Medicine (POM) to Pharmacy (P);</li> <li>- Pharmacy (P) to General Sales List (GSL).</li> </ul>	<p>Evaluate the commercial potential for a pharmaceutical product reclassification</p>	<p>Recognises the clinical and commercial implications of pharmaceutical reclassifications.</p>	<p><b>Outcome:</b> Product / therapy area support – managing a POM to P switch.</p> <p><b>Case Study:</b> Evaluation of a POM to P reclassification.</p>

**ITEM: HMP 5****OBJECTIVE:**

**To understand the need to have a knowledge of the wider competitor environment in the therapy area when evaluating the commercial opportunity for products at different stages in their development.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>5.1</b> Describe the key components of a competitive commercial product analysis for a:</p> <ul style="list-style-type: none"><li>- marketed product;</li><li>- pipeline product;</li><li>- therapy area;</li><li>- competitor product.</li></ul>	<p>Perform a competitive product analysis for a product, real or hypothetical, at two different stages in its development.</p> <p>Evaluate the promotional platform of a competitor product.</p> <p>Construct objection handling statements.</p>	<p>Recognises the value of a robust competitive commercial product analysis for products at different stages in their development.</p>	<p><b>Outcome:</b> Input to developing objection handling documents.</p> <p><b>Case Study:</b> Evaluation of the promotional platform for a competitor product.</p>

**ITEM: HMP 6**

**OBJECTIVE:**

**To demonstrate an understanding of the interface between the pharmaceutical industry and the external healthcare environment, its impact on relationships and interactions with external stakeholders and the challenges faced in balancing the commercial and professional aspects in making ethical judgements within the legal/regulatory framework.**

Knowledge	Skills	Attitudes / Behaviour	Assessments
Competency Level 1	Competency Level 1	Competency Level 1	
<p><b>6.1</b> Identify who the industry's key stakeholders are in the external environment and how the industry's activities impacts on them, including the general public.</p> <p><b>6.2</b> Describe the ethical issues which arise and approaches considered in reaching a judgement in:</p> <ul style="list-style-type: none"> <li>- the investigation and management of fraud and misconduct e.g. in clinical research;</li> <li>- particular patient use of medicines e.g. compassionate use;</li> <li>- Phase IV studies;</li> <li>- Post-Marketing Surveillance studies;</li> </ul>	<p>Perform an industry key stakeholder analysis.</p> <p>Analyse the important relationships and interactions between the key stakeholders.</p> <p>Discuss how ethical judgments are made and relevant guidelines applied in the different scenarios outlined in HMP 6.2.</p> <p>Perform ethical evaluations in the areas outlined in HMP 6.2.</p>	<p>Recognises the relevance of a stakeholder analysis and how it can contribute to the impact of developing better relationships and improving communication of the industry's activities.</p> <p>Exhibits the ability to distinguish between different ethical approaches in different situations and recognise the personal and professional challenges involved when making ethical judgements in the commercial environment.</p>	<p><b>Critical Review:</b> Analysis of industry key external and internal stakeholder interactions.</p> <p><b>Outcome:</b> Product / therapy area support – thought leader relationships and interactions.</p> <p><b>Outcome:</b> Situations and issues involving ethical judgments and approaches.</p> <p><b>Outcome:</b> development of a Data on File statement.</p> <p><b>Outcome:</b> Handling a request for compassionate use.</p> <p><b>Multisource Feedback Assessment (MSF, 360°):</b> Sales, marketing &amp; medical colleagues, external thought leaders and stakeholders.</p>

<b>ITEM: HMP 6 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<ul style="list-style-type: none"> <li>- individual patients adverse events or compassionate use);</li> <li>- open label clinical trial extensions;</li> <li>- investigator-initiated studies;</li> <li>- charging for named patient supplies;</li> <li>- giving a balanced and objective clinical / scientific view / response in keeping with company strategy and professional ethics;</li> <li>- creating a policy on patient information provided by medical information within regulation;</li> <li>- developing a Data on File statement.</li> </ul>			
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>6.3</b> Describe the roles of and relationship between the relevant trade and professional organisations, including Association of the British Pharmaceutical Industry (ABPI), British Medical Association (BMA), medical Royal Colleges, and others.</p>	<p>Discuss the function, context and relevance of the interactions between these bodies.</p>	<p>Recognises the different and complementary contribution made by the various bodies.</p>	<p><b>Critical Review:</b> Trade and professional organisation; their roles, remit, regulatory / legal authority and industry &amp; healthcare interactions.</p>

**MODULE 6 – draft (060407)**  
**DRUG SAFETY SURVEILLANCE (DSS)**

**AIM**

**To acquire and demonstrate knowledge of and competency in the surveillance of the safety of medicines during all stages of development and clinical use, with particular emphasis on the choice, application and analysis of appropriate surveillance methods, on the international regulatory reporting requirements and on the timely revisions of product information.**

<b>ITEM: DSS 1</b>			
<b>OBJECTIVE:</b>			
<b>To understand the historical background that has led to the present day pharmacovigilance regulations and systems.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>1.1</b> Be aware of the major past 'landmark' safety issues with major products (e.g. thalidomide, benoxaprofen, Vioxx) and drug classes (e.g. oral contraceptives, inhaled anti-asthma products), their investigations and outcomes.</p> <p><b>1.2</b> Understand the evolution of drug surveillance methods, of pharmacovigilance (PhV) regulations worldwide and their harmonisation, and of inter- and intra-company reporting systems for assembling and reporting adverse events.</p>		<p>Recognises the importance of these 'landmark' cases in bringing about change including increased regulation and more sophisticated reporting systems worldwide.</p>	<p><b>Applied Knowledge-based assessment:</b> e.g. test, e-learning module.</p>

**ITEM: DSS 2****OBJECTIVE:****To understand the key regulatory requirements for pharmacovigilance, both in the major regions and locally.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>2.1</b> Understand the responsibilities and liabilities of investigators, clinicians, study monitors and manufacturers in the pre- and post-marketing phases to detect, assess and report adverse events associated with medicines (in the country where registrar operates).</p> <p><b>2.2</b> Be conversant with the requirements and processes for reporting to the MHRA in the UK and to the EMEA.</p> <p><b>2.3</b> Understand the requirements for informing prescribers, investigators, ethics committees and regulatory agencies of important safety concerns.</p>	<p>Communicate and discuss this knowledge of regulations with colleagues.</p> <p>Locate the relevant sources of information on these regulations and identify any new requirements. Evaluate whether these have implications in terms of revising processes to ensure compliance.</p>	<p>Is fully aware of the broader ethical, moral and professional responsibilities of pharmaceutical physicians with regard to drug safety, e.g. the GMC description of the duties of doctors.</p> <p>Recognises the importance of adherence to these regulations and the need to stay fully aware of updates / changes to regulations and guidelines.</p>	<p><b>Applied knowledge-based assessment:</b> e.g. test, e-learning module, MCQs, essay, short answer.</p> <p><b>Critical Review:</b> Identification, retrieval and review of regulatory documents and communications in relation to legal and regulatory requirements for marketing authorisation holders in respect of drug safety &amp; pharmacovigilance.</p>

<b>ITEM: DSS 2 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>2.4</b> Understand the PhV operation of the MHRA and of the EMEA.</p> <p><b>2.5</b> Understand the PhV operation of the FDA in the USA and of its requirements for reporting.</p> <p><b>2.6</b> Outline the relevant sections of the UK Medicines Act (1968) and subsequent Statutory Instruments relating to drug safety and PhV.</p> <p><b>2.7</b> Recall the relevant ICH provisions for safety surveillance.</p>	<p>Communicate and discuss this knowledge of regulations with colleagues.</p> <p>Locate the relevant sources of information on these regulations and identify any new requirements. Evaluate whether these have implications in terms of revising processes to ensure compliance.</p>	<p>Recognises the importance of adherence to these regulations and the need to stay fully aware of updates / changes to regulations and guidelines.</p>	
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>2.8</b> Be aware of the PhV operation of the drug regulatory authority in Japan (PDMA) and its requirements for reporting.</p>			

<b>ITEM: DSS 3</b>			
<b>OBJECTIVE:</b>			
<b>The registrar will be able to carry out all medical assessments required to meet the requirements for drug safety reporting.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency level 1</b>	
<p><b>3.1</b> Define the regulations relating to the collection and reporting of suspected Adverse Drug Reactions (ADR) in local country where registrar works.</p>	<p>Review and make a medical assessment of case reports and clinical study reports in the current literature mentioning suspected ADRs and transfer relevant information to report formats for submission to relevant regulatory agencies.</p> <p>Apply ethical judgements and ensure adherence to appropriate guidelines when carrying out post-marketing surveillance studies.</p>	<p>Recognises the importance of meeting the requirements for reporting of ADRs.</p>	<p><b>Applied knowledge-based assessment:</b> e.g. test, e-learning module, MCQs, short answer, case studies, observation of presentations, review of case reports.</p> <p><b>Outcome:</b> Review of case reports: Appropriate and timely recording, assessment, follow-up, evaluation and reporting.</p>
<p><b>3.2</b> Describe the requirements regarding safety issues in the Summary of Product Characteristics (SmPC).</p>	<p>Review SmPCs of company products to ensure all safety issues are covered appropriately as regards clarity and completeness.</p>	<p>Contributes to ensuring that the SmPC appropriately reflects the safety profile of the drug in question.</p>	<p><b>Critical review:</b> Review and safety evaluation of SmPCs from company products, therapy area drug classes &amp; products.</p>

ITEM: DSS 3 cntd				
Knowledge	Skills	Attitudes / Behaviour	Assessments	
<b>3.3</b> Outline the contents of a Periodic Safety Update Report (PSUR).	Evaluate an existing PSUR. Write the overall safety evaluation section of a real or simulated PSUR.	Recognise the overall function of the PSUR in terms of updating any safety concerns re drug.	<p><b>Applied knowledge-based assessment:</b> e.g. test, e-learning module, MCQs, short answer – on requirements for PSURs &amp; PILs.</p> <p><b>Outcome:</b> Preparation of PSURs.</p> <p><b>Critical review:</b> Review &amp; evaluation of PSURs for company products in a therapy area.</p>	
<b>3.4</b> Describe the contents of safety sections of Patient Information Leaflets (PIL) and package information.	Write and be able to critically review the safety section of a PIL and package information.	Recognise how important it is to ensure that the PIL is written considering its target audience to aid compliance.	<p><b>Outcome:</b> Preparation or review of PILs for company products or in a therapy area.</p>	

ITEM: DSS 3 cntd				
Knowledge	Skills	Attitudes / Behaviour	Assessments	
<b>3.5</b> Outline product recall procedures, including communications to doctors and patients.	Evaluate and discuss issues around product recall and be able to write a Dear Doctor letter for Healthcare Professionals (HCP) and also patient communications.	Participates actively in the medical discussions around product recall.	<b>Case study:</b> 'Dear Doctor' letter(s) in respect of safety issues concerning product(s) (real or simulated).	
<b>3.6</b> Describe the role of the Qualified Person in Pharmacovigilance (QP).	Discuss interactions a QP is most likely to have with a pharmaceutical physician and the actions required by the pharmaceutical physician.	Recognises importance of the QP role.	<b>Outcome:</b> Participation in PhV activities in company and concerning products/therapy areas (real or simulated): feedback from QP.  <b>Outcome:</b> Assessment of Attitudes / Behaviour - feedback from QP.	
<b>3.7</b> Relevant pharmacovigilance sections from:  a) EU Directives and Regulations; b) ICH and CHMP Guidelines.  <b>3.8</b> Be aware of the CIOMS Working Groups and Reports I-VI.	Apply guidelines and directives and ensure compliance to them in all aspects of pharmacovigilance with particular focus on Volume 9A.	Recognises importance of these regulations and guidelines.		

<b>ITEM: DSS 4</b>			
<b>OBJECTIVE:</b>			
<b>The registrar will have a clear understanding of spontaneous reporting and signal generation methodology and be able to assess medically AE/ADR reports.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>4.1</b> Describe the characteristics that make an ADR reportable according to international guidelines.</p>	<p>Apply the definitions of adverse event, serious adverse event, unexpected / unlabelled adverse event, suspected adverse reaction and clinically significant abnormal laboratory test value; discuss the differences between them.</p> <p>Assess adverse event / reaction reports and be able to evaluate the importance of temporal relationships, concomitant medications, pre-existing or concurrent illnesses and patient characteristics.</p> <p>Formulate appropriate follow-up questions to reporting healthcare professionals and specify the data that are important in the assessment of adverse event/reaction reports.</p>	<p>Recognise the need for clear definitions and procedures / guidelines for adverse event reporting.</p>	<p><b>Outcome:</b> Handling of suspected ADR reports; evaluation, reporting, follow-up &amp; assessment.</p> <p><b>Critical Review:</b> ADR report follow-up questions developed by registrar.</p> <p><b>Case Study:</b> Application of principles and practices of adverse event and spontaneous ADR reporting, expedited and non-expedited.</p> <p><b>Case Study:</b> Medical assessment of adverse event and / or spontaneous ADR reports in relation to signal generation.</p>

ITEM: DSS 4 cntd			
Knowledge	Skills	Attitudes / Behaviour	Assessments
<p><b>4.2</b> Understand the application of epidemiological methods to spontaneous reporting.</p>	<p>Assess medically post-marketing suspected ADR reports and determine seriousness, causal relationship to suspect drug and expectedness.</p> <p>Assess medically serious adverse events (SAEs) from clinical trials and determine their causal relationship to the study drug and expectedness.</p> <p>Assess ADRs and other relevant benefit-risk information reported in the literature.</p>	<p>Recognises the importance of medical assessment of adverse events from all potential sources and its potential future use in treating or advising patients.</p>	<p><b>Applied knowledge-based assessment:</b> e.g. test, e-learning module, MCQs, short answer, questions on real or simulated ADR / SAE reports.</p> <p><b>Outcome:</b> Review of suspected ADR / SAE reports, evaluations applied to them and actions taken.</p> <p><b>Critical Review:</b> Evaluation of post-marketing suspected ADR / SAE reports in product / therapy area.</p> <p><b>Case Study:</b> Literature review and assessment of suspected ADR reports in the international literature for a product / therapy area.</p> <p><b>Multisource Feedback Assessment</b> (MSF, 360°) Medical Dept. colleagues, PhV group colleagues, EU QP feedback.</p>

<b>ITEM: DSS 4 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>4.3</b> Be aware of coding systems for drug safety (e.g. MedDRA).</p> <p><b>4.4</b> Understand the methods and applications of all signal generation methods in pharmacovigilance and the processes required for prioritisation and evaluation of detected signals.</p>			

<b>ITEM: DSS 5</b>			
<b>OBJECTIVE: The registrar will be able to interrogate a database or review published data to evaluate for signals and assess causality.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>5.1</b> Explain the major pharmaco-epidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases.</p> <p><b>5.2</b> Identify the major methods of post-marketing surveillance.</p> <p><b>5.3</b> Understand the application of the Safety Assessment of Marketed Medicines (SAMM) and the requirements for Post-Authorisation Safety Studies (PASS) in the UK.</p> <p><b>5.4</b> Understand the common causal mechanisms for ADRs.</p> <p><b>5.5</b> Understand the mechanisms of drug interactions.</p> <p><b>5.6</b> Describe the principles of causality assessment and causality algorithms to classify events as to their likely causal attribution to a particular medicine.</p>	<p>Perform relevant searches on a database.</p> <p>Critically evaluate published research data.</p>	<p>Recognises the importance of signal evaluation, causality assessment and the communication of relevant findings as a key responsibility in helping to safeguard future patients.</p>	<p><b>Outcome:</b> Communication of drug safety information to defined audiences in a timely manner.</p> <p><b>Case Study:</b> Evaluation of published research data in the context of signal evaluation and causality assessment.</p>

**ITEM: DSS 6****OBJECTIVE:**

**To understand the principles and methods of evaluation of risk and benefit balance and the principles and methods for risk management.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>6.1</b> Understand the principles and methods for risk / benefit evaluation and related decisions during pre-marketing development.</p> <p><b>6.2</b> Understand the principles and process for development of safety specifications documents.</p> <p><b>6.3</b> Be familiar with the CIOMS VI report in respect of safety in clinical trials.</p> <p><b>6.4</b> Understand the structure, roles and responsibilities of data safety monitoring committees.</p> <p><b>6.5</b> Describe the principles of risk and benefit assessment.</p> <p><b>6.6</b> Recall the CIOMS IV – Report of CIOMS Working Group IV.</p>	<p>Critically review relevant documents (e.g. protocol, PIL, safety specifications, risk management plan) for appropriate risk and benefit statements.</p>	<p>Recognises the importance of the physician’s role in risk and benefit assessment and risk management and share this with colleagues.</p>	<p><b>Outcome:</b> Review and evaluation of relevant documents in a product / therapy area e.g. protocols, PILs for appropriate risk and benefit statements and actions taken.</p>

<b>ITEM: DSS 6 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>6.7</b> Understand the principles and methods of post-marketing risk management plans (ICH E2E) and be able to provide medical input into such plans.</p> <p><b>6.8</b> Be aware of the options and mechanisms for optimising safety in relation to benefit.</p>	<p>Make appropriate medical contributions for effective risk management plans.</p>		

**ITEM: DSS 7****OBJECTIVE:****The registrar will understand the variety of regulatory actions possible to address drug safety signals.**

<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>7.1</b> Understand the key regulatory actions including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension and withdrawal.</p> <p><b>7.2</b> Explain the European procedures for reassessment of risk: benefit (Articles 31 &amp; 36 of Directive 2001/83/EEC).</p>	<p>Be able to review any of these documents before regulatory submission to ensure accuracy from a medical perspective.</p>	<p>Recognises the importance of these regulatory actions to help ensure patient safety.</p>	<p><b>Critical Review:</b> Identification, retrieval and review of regulatory agency documents and communications in relation to regulatory actions for drug restriction in the interests of patient safety.</p>

<b>ITEM: DSS 8</b>			
<b>OBJECTIVE:</b>			
<b>The registrar will understand the importance of communication of safety issues, the variety of formats required to meet audience needs and be able to contribute to the development of such communications.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>8.1</b> Outline the safety aspects of the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL).</p> <p><b>8.2</b> Understand the availability of urgent communication tools; the opportunities and pitfalls of their use.</p> <p><b>8.3</b> Understand about communications planning and the need for coordination with key stakeholders in handling a drug safety issue.</p>	<p>Contribute to the drafting of 'Dear Doctor' letters.</p> <p>Contribute to the drafting of press briefings.</p>	<p>Recognises the importance of communication of safety issues and the need for a variety of formats to meet different customer needs.</p>	<p><b>Outcome:</b> Review of key documents produced by registrar e.g. Dear Doctor letter, press briefings.</p> <p><b>Critical Review:</b> Review by registrar of safety-related documents produced (by others) in relation to product safety issue.</p>

<b>ITEM: DSS 9</b>			
<b>OBJECTIVE:</b>			
<b>The registrar will have the capability to understand an issue and establish a crisis management team, recognising the key functional areas to be represented and their roles and responsibilities.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<b>9.1</b> Explain the organisation and conduct of a crisis management team.	Identify the key individuals to be included in a crisis management team.  Identify the main steps involved in assessing and reacting to a potential crisis situation.	Recognises the need for planned procedures to be in place and the urgency required to implement these plans appropriately.	<b>Applied Knowledge-based assessment</b> e.g. test, e-learning module, MCQs, short answer, case studies,  <b>Outcome:</b> Observe & score, in-work & in-course assessments (e.g. via role play exercise); observation of registrar.  <b>Assessment of Attitudes / Behaviour / Behaviours</b> e.g. 360° feedback, observation
<b>9.2</b> Be conversant with the legal responsibilities and liabilities of pharmaceutical companies and pharmaceutical physicians in respect of drug safety issues.	Describe the appropriate response to various simulated drug safety issues.	Consults effectively with all relevant parties.	<b>Applied Knowledge-based assessment</b> e.g. test, e-learning module, MCQs, short answer, case studies,

<b>ITEM: DSS 9 cntd</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<p><b>9.3</b> Understand the role of the pharmaceutical company, the regulatory agencies, the media and the legal profession in the evolution of drug safety issues.</p> <p><b>9.4</b> Define the external factors affecting response to drug safety issues (e.g. public freedom, political agendas etc).</p>	<p>Approve product briefing documents for the media.</p>	<p>Recognises the need for appropriate training of all relevant staff in issue / crisis management.</p>	<p><b>Applied Knowledge-based assessment</b> e.g. test, e-learning module, MCQs, short answer, case studies,</p>

<b>ITEM: DSS 10</b>			
<b>OBJECTIVE:</b>			
<b>To demonstrate an understanding of the areas of progress, likely major advances and future challenges in drug safety and pharmacovigilance.</b>			
<b>Knowledge</b>	<b>Skills</b>	<b>Attitudes / Behaviour</b>	<b>Assessments</b>
<b>Competency Level 2</b>	<b>Competency Level 2</b>	<b>Competency Level 2</b>	
<p><b>10.1</b> Define the key markers of progress – examination of evidence that the output from existing safety surveillance systems has improved health.</p> <p><b>10.2</b> Outline safety aspects of gene therapy and other new technologies.</p> <p><b>10.3</b> Explain the potential for pharmacogenomics / pharmacogenetics to enhance the safety of medicines.</p> <p><b>10.4</b> Describe the CYP450 isoenzymes and their role in safety aspects of medicines' development and surveillance.</p> <p><b>10.5</b> Outline the future challenges for pharmacovigilance.</p>	<p>Evaluate how these advances may impact on drug safety surveillance in the future.</p>	<p>Demonstrates a willingness to remain abreast of advances in research and technology and apply new knowledge and learn new skills.</p>	

## **PART C**

### **GENERIC CURRICULUM IN PHARMACEUTICAL MEDICINE**

[Incorporating *Generic Curriculum for the Medical Specialties* (Federation of Royal Colleges of Physicians), *Good Medical Practice* (General Medical Council), *Good Pharmaceutical Medical Practice* (Faculty of Pharmaceutical Medicine) in Module 7 of Higher Medical Training with *Interpersonal and Management Skills*.]

All physicians registered with the General Medical Council (GMC) and working within the pharmaceutical industry are guided on the professional conduct expected of them in the GMC publication *Good Medical Practice* (GMP), and the Faculty of Pharmaceutical Medicine publication *Good Pharmaceutical Medical Practice* (GPMP). GPMP is derived from GMP for the specialty of Pharmaceutical Medicine and augments, rather than supersedes, GMP to cater for the needs of pharmaceutical physicians.

Because of the nature of their work most pharmaceutical physicians do not come into direct contact with patients, although those working in clinical pharmacology units may be responsible for the clinical care of subjects participating in clinical research studies on medicinal products.

Pharmaceutical medicine is a discipline that involves the discovery, development, evaluation, registration, monitoring and ethical marketing of medicines. The responsibility of the pharmaceutical physician within this process is to guard the interests of patients by working to standards which ensure that research studies are conducted according to Good Clinical Practice (GCP), that safety data are collected, acted upon and reported to the highest international standards and that all communication with medical professionals and patients is accurate and ethical. Delaying the entry of effective new medicines into the market is as much a public health issue as allowing unsafe ones to come onto, or remain on, the market.

The Generic Curriculum follows from the core competencies of the Foundation Programme (or equivalent), defined in Section 1 of the Foundation Curriculum (ref), which must have been attained before entry into Basic Specialist Training (e.g. Core Medical Training [CMT] of the Royal Colleges of Physicians or equivalent pre-specialty clinical training of other Colleges and Faculties, from which doctors enter specialty training in Pharmaceutical Medicine).

The competencies of knowledge, skills and attitudes & behaviour addressed in the Generic Curriculum should be maintained and built upon throughout training as they underpin the principles of *Good Medical Practice*.

Whilst the principles and topics of a generic curriculum apply throughout post-Foundation training to the end of specialty training and beyond, doctors who move from primarily clinical disciplines into pharmaceutical medicine will place greater emphasis on *Good Pharmaceutical Medical Practice* as the basis for their generic curriculum, as part of the *Generic Curriculum in Pharmaceutical Medicine*, and away from the *Generic Curriculum for the Medical Specialties* with its emphasis on clinical

care and work in the NHS. The principles of both will nevertheless continue to be relevant throughout professional life, and underpin the principles of *Good Medical Practice*.

**GENERIC CURRICULUM IN PHARMACEUTICAL MEDICINE**

**MODULE 7 OF HIGHER MEDICAL TRAINING**

**The *Generic Curriculum in Pharmaceutical Medicine* (Module 7 of Higher Medical Training) comprises *Interpersonal and Management Skills* (Items: IPM1, IPM2, IPM3) and *Good Pharmaceutical Medical Practice* (IPM4 with seven Focus Areas corresponding to those in *Good Medical Practice*)**

**AIM:**

**To demonstrate a knowledge of and competency to apply that knowledge appropriately to a number of interpersonal and management skills appropriate to the work of a pharmaceutical physician operating in a managed environment.**

**To demonstrate continuing and developing professional attitudes and behaviours relating to the application of competency, care and conduct to the work of a practising pharmaceutical physician.**

**ITEM: IPM 1****OBJECTIVE:**

**To demonstrate an understanding of the managed environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision-making in the development and commercialisation of medicines.**

KNOWLEDGE	SKILLS	ATTITUDES	ASSESSMENTS
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<p><b>1.1</b> To identify and explain the components of employment legislation that are of relevance to the operation of a Medical Department and other areas of the pharmaceutical managed environment.</p> <p>Explain the importance of relationships and interactions between Medical and other key Departments e.g. marketing, sales, R&amp;D, consumer products (Over-The-Counter medicines).</p> <p>Understand roles, responsibilities and relationships with key support functions e.g. finance, legal, human resources departments.</p> <p><b>1.2</b> Describe the elements of Health &amp; Safety Executive legislation that have importance in the pharmaceutical environment.</p>	<p>Discuss current UK employment legislation as it applies to a growing Medical Department.</p> <p>Identify differences between UK practices and those in other European and non-UK countries in the research-based pharmaceutical industry.</p>	<p>Recognises the legal framework of modern employment in the UK and its impact on the work of drug development and commercialisation.</p>	<p><b>Outcome;</b> Demonstration of the impact of employment and safety legislation and regulation on a on a managed project in an area of responsibility.</p>

<b>ITEM: IPM 1 cntd</b>			
<b>KNOWLEDGE</b>	<b>SKILLS</b>	<b>ATTITUDES</b>	<b>ASSESSMENTS</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency Level 1</b>	
<b>1.3</b> Describe the principles of financing within the pharmaceutical sector as it applies to the industry, companies, departments and projects.	Manage a budget and its accounts within a company, department or project.	Recognises the importance and impact of fiscal management in determining goals, priorities and outcomes in the pharmaceutical business environment.	<b>Outcome:</b> Presentation of a balanced budget in an area of responsibility.

**ITEM: IPM 2****OBJECTIVE:**

**The registrar will be able to demonstrate an understanding of the principles and practices of people management and leadership, and competency to apply these within their own working environment.**

<b>KNOWLEDGE</b>	<b>SKILLS</b>	<b>ATTITUDES</b>	<b>ASSESSMENTS</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency level 1</b>	
<p><b>2.1</b> Describe the general principles of people management.</p>			<p><b>Outcome:</b> Demonstration of own people management / leadership skills and impact in a departmental or project resourcing exercise (recruitment, right-sizing, team-building, change management).</p>
<p><b>2.2</b> List the principles and practices of conducting competitive employment interviews and of selecting new staff.</p>			
<p><b>2.3</b> Describe methods of performance management and appraisal, their purpose, application and outcomes.</p>	<p>Differentiate between educational and performance appraisal.</p> <p>Describe principles of effective objective setting, sources of appropriate feedback and their relative importance, and measurement of outcomes</p>		<p><b>Multisource Feedback Assessment</b> (MSF, 360°)</p> <p><b>Assignment:</b> Discussion of own performance management / appraisal systems.</p>

<b>ITEM: IPM 2 cntd</b>			
<b>KNOWLEDGE</b>	<b>SKILLS</b>	<b>ATTITUDES</b>	<b>ASSESSMENTS</b>
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency level 1</b>	
<b>2.4</b> Outline motivational techniques.	Apply motivational techniques in reaching a project outcome.		
<b>2.5</b> Describe methods used to retain and develop staff to their full potential including the role of personal development plans.	Differentiate between specialist training and management skills and how they can be complementary.  Outline appropriate specialist training and management training plans and how they can be incorporated within the pharmaceutical physician's organisational roles and responsibilities.		
<b>2.6</b> Outline the principles and common practices of managing a team in line or as a matrix.	Apply leadership and motivational skills to management of multidisciplinary teams in one of the following areas:  - in line - in matrix - local - international	Recognises the importance of management / leadership style and influence on team dynamics and reaching departmental / project goals.	

**ITEM: IPM 3****OBJECTIVE:**

**The registrar will be able to demonstrate applied knowledge and competency in a range of interpersonal and communication skills relevant to the practice of pharmaceutical medicine.**

KNOWLEDGE	SKILLS	ATTITUDES	ASSESSMENTS
<b>Competency Level 1</b>	<b>Competency Level 1</b>	<b>Competency level 1</b>	
<p><b>3.1</b> Negotiating.</p> <p><b>3.2</b> Influencing.</p> <p><b>3.3</b> Networking.</p>	<p>Use negotiating skills to reach an outcome.</p> <p>Use influencing skills to construct a committee / advisory board to meet defined objectives.</p> <p>Use networking skills to build a build a database of key influencers, opinion leaders or experts in a product / therapy area.</p> <p>Demonstrate an understanding of the importance of personal styles and preferences in approaches to interpersonal interactions and communication with colleagues and how these may be determined and acted upon (e.g. Myers Briggs and other similar psychometric methods).</p>	<p>Recognises the importance of interpersonal skills for pharmaceutical physicians to influence / drive project / team outcomes.</p>	

ITEM: IPM 3 cntd			
KNOWLEDGE	SKILLS	ATTITUDES	ASSESSMENTS
<p><b>3.4</b> Describe the critical role of IT and communications technology management in contributing to efficiency and effectiveness within an organisation.</p>	<p>Outline the principles of knowledge management and its importance in the pharmaceutical organisational context.</p>		
<p><b>3.5</b> Describe the principles applied by an effective meeting chair.</p>	<p>Chair meetings effectively to reach timely outcomes in at least one of:</p> <ul style="list-style-type: none"> <li>- development projects;</li> <li>- management projects;</li> <li>- committees;</li> <li>- speaker meetings.</li> </ul>		<p><b>Outcome:</b> Demonstration of effectively chaired meeting(s) in relation to knowledge, skills and personal style applied to the meeting topic and purpose.</p>
<p><b>3.6</b> Outline the principles of effective presentations.</p>	<p>Make effective AV presentations (in at least one of):</p> <ul style="list-style-type: none"> <li>- product related;</li> <li>- therapy area related;</li> <li>- project related;</li> <li>- case study feedback.</li> </ul>		<p><b>Outcome:</b> Evidence of effective AV presentations.</p>

ITEM: IPM 3 cntd			
KNOWLEDGE	SKILLS	ATTITUDES	ASSESSMENTS
<p><b>3.7</b> Describe the principles of effective time management.</p>	<p>Project planning and meeting allocated timelines for multidisciplinary roles.</p> <p>Relate time and time management to opportunity costs and other determinants of successful and timely project completion and outcome.</p>	<p>Recognise the importance of effective time management to meet project and personal goals.</p>	<p><b>Critical review:</b> managing a diary to time.</p> <p>Multisource Feedback Assessment (MSF, 360°) - peers &amp; managers.</p>

**ITEM: IPM 4****OBJECTIVE:****The registrar will demonstrate working to the tenets of Good Pharmaceutical Medical Practice****Focus Area 4.1: Providing a good standard of practice and care**

Pharmaceutical physicians play a key role in patient care by:

1. Having a thorough understanding of the therapeutic areas in which they work. This includes the current state of knowledge of medical science in the area, the epidemiology of the conditions of interest, the natural history of the specific diseases, the current modes of investigation and treatment and what other therapies are under investigation.
2. Designing clinical research programmes and protocols in areas of medical need working to the ICH Guidelines, regulatory requirements and the declaration of Helsinki.
3. Ensuring that they fulfil their obligations in clarifying, evaluating and reporting adverse events, whether they come from research protocols, spontaneous reports or as part of a formal surveillance programme.
4. Ensuring that documents submitted to the regulatory authorities accurately reflect the data that have been gathered in the development process. Where they have direct responsibility for writing part of the dossier, e.g. a clinical expert opinion, they do not make any statement that they know to be false or a claim that cannot be supported by the evidence. This does allow for there being different interpretations of the same data, which are reasonable until further clarification is obtained.
5. Ensuring that relevant data are made available for publication and that articles submitted to journals accurately reflect the data on which they are based and no conclusions are drawn that are inconsistent with the data.
6. Ensuring that the information provided in the Summary of Product Characteristics (SPC) is consistent with the terms of the Marketing Authorisation.
7. Ensuring that patient information leaflets are clear and can be understood by the end user.
8. Ensuring that all promotional material and representative product training is consistent with the SPC.

<b>ITEM: IPM 4 cntd</b>			
KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
Refer to PMST Modules: RGN 2,4,6 CLP 8 SDM 5 CLD 1,7,8 HMP 2 DSS 3,8	Refer to PMST Modules.	Refer to PMST Modules.	

### **Focus Area 4.2: Maintaining Good Pharmaceutical Medical Practice**

Pharmaceutical physicians are required by the nature of their job to keep themselves abreast of scientific advances that will have a major impact on the development of the new medicines of the future. They will be able to maintain this essential role by:

1. Ensuring that they remain well informed about current scientific and medical knowledge in the areas of therapeutics in which they work, by attending internal or external scientific meetings, reading relevant medical journals or by using such other means that are available and that they can demonstrate allows them to remain well informed.
2. By using benchmarking techniques, which are either internal or external, they ensure that they are maintaining the high standards required by national and international regulations.
3. By assimilating constructive feedback from their management, internal review committees, ethics committees and the regulatory authorities.

<b>ITEM: IPM 4 cntd</b>			
KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
<p>Outline the principles of adult learning theory.</p> <p>Define the principles of Continuing Professional Development (CPD).</p>	<p>Identify gaps in knowledge and plan actions to fill them.</p> <p>Translate knowledge and new learning into practice.</p> <p>Maintain a portfolio of CPD.</p> <p>Model and promote CPD within the multi-disciplinary team.</p>	<p>Strives to enhance professional competency with active involvement in CPD activities.</p> <p>Recognises the moral and professional obligation to maintain competency and be accountable.</p> <p>Reflects on all aspects of practice.</p>	
<p><b><u>Focus Area 4.3: Relationships with research subjects and patients</u></b></p> <p>Pharmaceutical physicians work with research subjects in early studies in man in Phase 1 Units, and in clinical studies with healthy volunteers and sometimes patients in exploratory clinical studies in the development phase and throughout the life-cycle of a medicine. It is unusual for pharmaceutical physicians to have direct contact with patients in the context of clinical care for an individual patient.</p>			
KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
<b>ITEM: IPM 4 cntd</b>			
Recall and build upon the competencies defined in the	Demonstrate good communication	Shows willingness to provide	

<p>Foundation Curriculum:</p> <ul style="list-style-type: none"> <li>- interview structure;</li> <li>- effective listening;</li> <li>- clarify information given by patients and research subjects;</li> <li>- use comprehensible language tailored to subject;</li> <li>- use open and closed questions appropriately;</li> <li>- gauge subjects' ideas, concerns, expectations and comprehension;</li> <li>- appropriate use of written materials and interpreters;</li> <li>- act in a courteous, polite and professional manner.</li> </ul>	<p>skills to others in team.</p> <p>Manage subject follow up effectively (e.g. with GPs).</p> <p>Accurately record details of discussions with subjects over care.</p> <p>Identify and manage communication barriers while respecting confidentiality, language, cultural differences, hearing impairment, poor literacy etc.</p>	<p>subjects with a second opinion.</p> <p>Shows willingness to provide other sources of information for subjects (printed literature, support societies etc).</p> <p>Ensures the subject is well informed and central to the discussion making process.</p> <p>Identifies significant others and recognise their role in the management of information to subjects and patients.</p>	
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**ITEM: IPM 4 cntd**

In respect of complaints and medical error recall and build upon competencies defined in the foundation programme:

- awareness of complaints procedures;
- factors likely to lead to complaints (poor communication, dishonesty etc);
- adopt behaviour likely to prevent complaints;
- deal with dissatisfied subjects;
- recognise when something has gone wrong and identify appropriate staff with whom to communicate this;
- act with honesty and sensitivity in a non-confrontational manner.

Define local complaints procedures.

Identify sources of help when advice is made about yourself or a colleague.

In respect of complaints and medical error, contribute to processes whereby complaints are reviewed and learned from.

Explain comprehensively to the subject the events leading up to a medical error.

Deliver an appropriate apology.

Distinguish between system and individual errors.

Takes leadership over complaints issues.

Recognises the impact of complaints and medical error on staff, subjects and the pharmaceutical industry.

Contributes to a fair and transparent culture around complaints and errors.

Recognises the rights of subjects and others to make a complaint.

## **Focus Area 4.4: Working With Colleagues**

### Treating colleagues fairly:

1. Pharmaceutical physicians must always treat colleagues fairly. In accordance with the law, a pharmaceutical physician must not discriminate against colleagues, including those applying for posts, on grounds of their sex, race or disability, and must not allow views of colleagues' lifestyle, culture, beliefs, colour, gender, sexuality, or age to prejudice a professional relationship with them.
2. Pharmaceutical physicians must not undermine subjects' trust in the care or treatment they receive, or in the judgment of those treating them, by making malicious or unfounded criticisms of colleagues.

### Working in teams:

Pharmaceutical research is increasingly provided by multi-disciplinary teams. Working in a team does not change personal accountability for professional conduct and the care provided. When working in a team, a pharmaceutical physician must:

1. respect the skills and contributions of colleagues;
2. communicate effectively with colleagues within and outside the team;
3. participate in regular reviews and audit of the standards and performance of the team, taking steps to remedy any deficiencies;
4. be willing to deal openly and supportively with problems in the performance, conduct or health of team members.

### Leading teams:

A pharmaceutical physician who leads a team must ensure that:

1. medical team members meet the standards of conduct and care set in this guidance;
2. any problems that might prevent colleagues from other professions following guidance from their own regulatory bodies are addressed;
3. all team members understand their personal and collective responsibility for the safety of patients, and for openly and honestly recording and discussing problems;
4. arrangements are in place to provide medical cover at all times;
5. regular reviews and audit of the standards and performance of the team are undertaken and any deficiencies are addressed;
6. systems are in place for dealing supportively with problems in the performance, conduct or health of team members.

### Arranging medical cover:

There are a few critical situations where it is necessary for a pharmaceutical physician to arrange medical cover. These include, but may not be limited

to, those working in a clinical pharmacology unit where subjects stay in overnight, those responsible for clinical trials where contact needs to be maintained for urgent action on a potentially serious adverse event. For such situations the pharmaceutical physician must make suitable arrangements for a colleague, with the necessary qualifications and experience, to cover the situation.

Taking up appointments:

It is bad practice to fail to take up an appointment that has been accepted without giving the future employer adequate time to make alternative arrangements.

KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
<p>Outline the features of an effective comprehensive handover.</p> <p>Identify the important roles played by all members of a multi-disciplinary team.</p> <p>Outline feature of good team dynamics.</p> <p>Outline the principles of effective inter-professional collaboration to optimise subject care.</p>	<p>Establish effective communication with relevant teams by means appropriate to the situation.</p> <p>Delegate to members of the medical department team and members of the multi-disciplinary team whilst maintaining appropriate supervision.</p> <p>Take responsibility as appropriate for accurate and prompt information distribution within and between teams.</p> <p>Utilise the expertise of the multi-disciplinary team.</p> <p>Communicate effectively with administrative bodies and support organisations.</p> <p>Employ collaborative negotiation to prevent and resolve conflict.</p>	<p>Fosters a supportive and respectful environment where there is open and transparent communication.</p> <p>Respects opinions and encourage open communication with all members of the multi-disciplinary team to improving learning.</p> <p>Shows willingness to participate in multi-disciplinary team meetings.</p>	<p><b>Multisource Feedback Assessment</b> (MSF, 360°)</p>

### **Focus Area 4.5: Teaching, Training, Appraising and Assessing**

1. Pharmaceutical physicians are often involved in the training of members of the company's sales team. They will ensure that they pass on only accurate and verifiable information to the sales department.
2. Pharmaceutical physicians who are responsible for training other members of the medical department will respect the professional integrity of those being trained and ensure that they are trained in the skills necessary to be able to carry out their functions.
3. Pharmaceutical physicians who have managerial responsibility for colleagues will ensure that they are adequately trained for their job function and that appraisals are carried out objectively and in accordance with company policies. Evidence of peer opinion will be obtained where available.

KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
<p>Outline adult learning principles relevant to medical education, including:</p> <ul style="list-style-type: none"> <li>- identification of learning styles;</li> <li>- construction of educational objectives.</li> </ul> <p>Describe the use of effective questioning techniques.</p> <p>Describe how to vary teaching format and stimulus.</p> <p>Outline the structure of effective appraisal interview.</p> <p>Define the work-based assessments in use.</p>	<p>Vary teaching format and stimulus, appropriate to the situation and subject.</p> <p>Provide effective feedback after teaching and promote learner reflection.</p> <p>Conduct effective appraisal.</p> <p>Demonstrate effective lecture, presentation, small group and 1-to-1 teaching sessions.</p> <p>Provide appropriate career advice or refer registrar to an alternative effective source of career information.</p>	<p>Recognises the importance of the role of the physician as educator.</p> <p>Demonstrates willingness to teach registrars and other professional colleagues in a variety of settings.</p> <p>Encourages discussions with colleagues to share knowledge and understanding.</p> <p>Shows willingness to participate in work base assessments.</p> <p>Maintains honesty and objectivity during appraisal and assessment.</p>	

<p>Differentiate appraisal and assessment.</p> <p>Identify an appropriate course of action to assist the failing registrar.</p>	<p>Participate in strategies aimed at improving subject / patient / lay education e.g. talking at support group meetings.</p> <p>Recognise the failing registrar.</p>	<p>Shows willingness to take up formal tuition in medical education.</p> <p>Recognises the importance of personal development as a role model to guide registrars in aspects of good professional behaviour.</p>	
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### **Focus Area 4.6: Professional Behaviour and Probity**

Pharmaceutical physicians usually work for a commercially driven operation. They must, therefore, be extra vigilant that their decisions and practices are not in any way influenced by any personal financial gain that could result from the movement of share price etc.

#### Writing reports and signing documents

1. Pharmaceutical physicians write the key clinical sections of final study reports. They must ensure that the document accurately reflects the data and that any publication that flows from the data is wholly consistent with the report. They must stand by the principles that all relevant reports should lead to a publication and not be persuaded by the argument that adverse data will have a negative impact on the finances of the company.
2. Pharmaceutical physicians are responsible for ensuring that advertising and promotional material are both legal and ethical. They must balance the need to make the material interesting and attractive against the need for scientific and medical accuracy. Under no circumstances must they allow statements into promotional material that are not supported by the available data.
3. Safety reporting is a key tool in the protection of public health and pharmaceutical physicians must never allow the commercial interest of a company to take precedence over the requirement to ensure that all safety data are reported to the authorities and any new adverse drug reactions are included in the prescribing information according to the legal and ethical requirements prevailing at the time.

#### Research

1. Clinical research protocols must be designed to answer genuine scientific questions and not to be promotional tools.
2. All clinical research must be carried out according to the ICH guidelines on GCP.
3. No clinical research protocol can be implemented without the approval of an independent research ethics committee.

4. In all protocols the protection of subjects must take priority over scientific interest.

Financial and commercial dealings

1. Pharmaceutical physicians must not accept gifts or hospitality that are designed to influence their professional judgement.
2. The recompense offered to investigators for carrying out a clinical trial must be commensurate with the work required and not structured in such a way as to encourage coercive behaviour.

Conflicts of interest and financial interest in commercial organisations

The areas of potential conflicts of interest are described above and pharmaceutical physicians must always declare their financial interests in their dealings with professional colleagues, the editors of scientific journals and the general public.

KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
<p>Define the concept of modern medical professionalism (ref).</p> <p>Recall and build on the competencies defined in the Foundation programme:</p> <ul style="list-style-type: none"> <li>- respect the rights of children, elderly, people with physical, mental, learning or communication difficulties;</li> <li>- adopt a non-discriminatory approach;</li> <li>- behave with honesty and probity;</li> <li>- act with honesty and integrity in a non-confrontational manner.</li> </ul>	<p>Practise pharmaceutical medicine with:</p> <ul style="list-style-type: none"> <li>- integrity</li> <li>- compassion</li> <li>- altruism</li> <li>- continuous improvement</li> <li>- excellence</li> <li>- working in partnership with members of the wider team.</li> </ul> <p>Promote awareness of the pharmaceutical physician in the best use of healthcare resources.</p> <p>Recognise and respond to unprofessional behaviour in others.</p>	<p>Recognises the need to use all healthcare resources prudently and appropriately.</p> <p>Recognises the need to improve clinical leadership and management skill.</p> <p>Recognises the situations where it is appropriate to involve professional bodies.</p> <p>Shows willingness to act as mentor and educator.</p> <p>Participates in professional regulation.</p>	

Outline the relevance of professional bodies (Royal Colleges, Faculty of Pharmaceutical Medicine, GMC, Deanery, BMA, Specialist Societies, MDU).		Recognises the right for equity of access to healthcare for minority groups.	
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**Focus Area 4.7: Health**

Whilst the risk of transmitting communicable diseases is only an issue for pharmaceutical physicians working in direct contact with patients or research subjects, conditions such as stress, depression, alcohol abuse and so forth may affect the work of others. Pharmaceutical physicians should be vigilant about these problems, both in themselves and in colleagues.

KNOWLEDGE	SKILLS	ATTITUDES & BEHAVIOUR	ASSESSMENTS
Define health problems affecting doctors and other professionals that impact work, professional behaviour and the safety of patients, research subjects and others.	<p>Show vigilance regarding health issues in self and colleagues which impact work, professional behaviour and the safety of patients, research subjects and others.</p> <p>Be willing to deal openly and supportively with problems in the performance, conduct or health of team members.</p>	Recognises that systems are in place for dealing supportively with problems in the performance, conduct or health of team members when they come to light.	

### **3 MODEL OF LEARNING**

#### **Model of learning, specialty and stage of training**

PMST is a competency-based education and training programme comprising a specialty knowledge base and practical modules covering the fields of practice within pharmaceutical medicine. The practical modules are Medicines Regulation, Clinical Pharmacology, Statistics and Data Management, Clinical Development, Healthcare Marketplace, Drug Safety Surveillance and the Generic Module comprising Interpersonal and Management Skills and the seven domains of Good Pharmaceutical Medical Practice.

Registrars acquire knowledge and skills through experiential (apprenticeship) learning on-the-job, through attendance at structured courses related to the specialist knowledge base, attendance at formal approved structured interactive courses for the advanced modules, and supplementary courses as appropriate to meet the requirements of a curricular item or topic.

#### **Balance of learning experiences**

The PMST programme is based around the workplace and much of the learning comes from experience on-the-job, governed by the individual's job description(s) and exposure to projects and learning opportunities in areas of the PMST curriculum.

Acquisition of the specialty knowledge base comes from the workplace experience, attendance at a structured course, and through other means (see below). Attendance at a structured course, e.g. the Cardiff course, is not mandatory, but the 10-module course over two years is designed to offer the equivalent of eight weeks full-time training. The outcome of acquisition of the specialty knowledge base is passing the Diploma examination, which is mandatory before completion of PMST to gain a CCT.

In PMST it is mandatory that three of the seven Modules, including the generic module, are completed in work. Thus, for a registrar, any two operational modules in fields of practice in pharmaceutical medicine form the core in-work experience.

Of the remaining four modules, all could be completed in work, if the opportunity to complete these areas of the curriculum exist in the workplace, or they could be completed on formal approved structured interactive module courses, or by a mix of in-work experience and supplementary courses provided in or outside the training institution.

In practice since 2003 the balance of learning for those completing and those planning PMST is that 74% (variance 43%-100%) of the curriculum is covered in the workplace, including some in-house meetings / seminars and 26% through external interactive module courses.

## **Achievement of knowledge and competencies**

Learning for knowledge, skills, attitudes / behaviour and expertise takes place in the workplace as part of everyday practice of pharmaceutical medicine.

The specialty knowledge base is acquired over a minimum period of two years prior to sitting the Diploma in Pharmaceutical Medicine examination. Education for this can take place in the workplace through dedicated group seminars, in-company and external lectures, meetings and conferences, self-directed and distance learning (journals, textbooks and the internet), attendance at national and international conferences and reflective commentary.

The main means to achieve the knowledge base, however, is through attendance at a postgraduate course in pharmaceutical medicine, the curricula of which are designed specifically with this knowledge base in mind and preparation for the Diploma examination.

Achievement of the competencies in PMST practical modules also takes place in the workplace as far as possible directly as part of the registrar's job. Where there are no opportunities for a topic, item or module of the PMST programme to be acquired in work, attendance on a course is necessary.

Every effort is made to achieve competencies through work experience during PMST and apart from changing job to acquire competencies, other strategies can sometimes be employed, such a job exchange or secondment to another site, overseas or to a service provider company.

Courses, where necessary, can either provide the main exposure to a particular area of applied knowledge or skill or may be supplementary to knowledge and skills acquired in the workplace.

## **4. LEARNING EXPERIENCES**

### **Diversity**

The registrar will acquire the specialty knowledge and competencies from a variety of sources and activities based around the workplace and courses devised for the purpose. The registrar will assume appropriate responsibility for self-assessment and reflection, continuing self-directed learning and maintenance of up to date knowledge in the field.

The means by which learning knowledge, as well as skills and appropriate professional behaviours are acquired include:

- a. work-based experiential learning – against job description;
- b. project-based learning – e.g. drug development;
- c. supervised one-to-one and group instruction and consultation;
- d. national and international multidisciplinary group and team project working;
- e. case and project presentation;
- f. simulated scenarios and case studies e.g. in-licensing; crisis management;
- g. document identification, retrieval and summary e.g. regulatory;
- h. web-based research e.g. literature survey;
- i. participation in feasibility studies and due diligence activities e.g. POM to P switch, in-licensing;
- j. journal clubs;
- k. research presentations;
- l. independent study;
- m. distance learning (journals, textbooks and internet);
- n. reflective commentary;
- o. self-assessment questions.

Learning in more formalised settings, for example:

- a. postgraduate courses in pharmaceutical medicine e.g. University of Cardiff, University of Surrey;
- b. revision courses and study days / weekends;
- c. PMST Module interactive courses (Faculty approved with QA) – six options covering all operational modules;
- d. in company and external short courses;
- e. department, company and industry lectures and seminars.

### **Educational Strategies**

Many strategies are described in previous sections. Physicians most frequently, though not exclusively, commence their education and training in pharmaceutical medicine in the medical department of a pharmaceutical company, or, less often, of a clinical research organisation.

Medical departments are organised in a variety of ways and few or no departments and positions exist which can be said to be representative of the industry as a whole. Positions with the same job title often vary from being highly focused to being extremely broad. Focused positions may consist of a single \ role e.g. set up clinical studies on one drug or consult on clinical studies in a therapeutic area. Broad positions usually consist of multiple roles, possible with multiple drugs, and most physicians starting their career fall into this latter category. The nature and structure of the company also play a role, since some companies are more likely than others to assign multiple roles to new pharmaceutical physicians.

Most roles assigned to physicians require medical training, though some require more scientific training, but it is the medical roles that are the most challenging and which physicians can bring to bear their medical knowledge and clinical training and experience.

Specific strategies for work-based experiential learning include:

### **Clinical pharmacology**

- Screening volunteers.
- Undertaking medical examination of volunteers, investigations and discussion with GPs.
- Obtaining informed consent.
- Study preparation.
- Dosing, applying tests, collecting results.
- Analysing data and writing reports and publications.

### **Clinical research**

- Identify, meet and interview clinicians outside the company, who are often experts, to conduct clinical trials.
- Negotiate details of the protocol and study budget with clinical investigators.
- Plan and write the clinical trials protocol.
- Lead round-table discussions with clinical investigators, monitors and consultants.
- Initiate clinical trials.
- Maintain contact with clinical investigators, and deal with problems and issues that arise during the trial.
- Edit data collection forms.
- Interpret data obtained in clinical trials.
- Extrapolate data to new situations to develop new clinical hypotheses to test.
- Create clinical strategies for developing new medicines to the point of marketing approval.
- Create clinical strategies for post-marketing studies and new indications of marketed drugs.
- Collaborate with the medical or project team developing the drug.
- Liaise with professionals in other divisions of the company as required.
- Order bulk drug and trial supplies.
- Write periodic reports of project activities and other functions.

- Interact with other physicians, statisticians, pre-clinical scientists, information specialists, computer specialists and many others on an ongoing basis.
- Approve supply of drugs to outside investigators who wish to conduct human studies.
- Critique potential in-licensing opportunities and prepare medical due diligence.

### **Marketing support**

- Review advertisements and promotional material.
- Communicate with healthcare professionals to discuss and answer questions.

### **Professional development and educational activities**

- Teach students.
- Lecture to different groups of colleagues.
- Teach sales representatives.
- Conduct research or collaborate in research projects at universities.
- Discuss the process of drug development with lay and patient groups.
- Attend seminars, courses and meetings within and outside the company.
- Present scientific / clinical drug information when relevant to various audiences.
- Read medical literature to maintain current awareness and knowledge.
- Advise company lawyers, marketers and non-medical scientists on medical perspectives.
- Improve expertise in ones own specific area.
- Consult with other physicians.

### **Medicines regulation**

- Generate regulatory submissions through written reports, summaries or evaluations.
- Report serious adverse reactions to regulatory authorities as prescribed by regulations or to regulatory personnel with the company.
- Participate at meetings with regulatory authorities.

Areas in which physicians work outside the formal medical department investigating new drugs also provide examples of learning strategies:

#### **Drug Regulatory Affairs**

Develop regulatory strategies, assemble regulatory applications and interact with regulatory agencies by letter and at meetings.

Serve as an interface for others within the company who interact with regulatory agencies.

#### **Medicines Information Services**

Interact with healthcare professionals to provide information of company's drugs regarding adverse reactions, treatment of overdose, various publications and other topics.

## **Pharmacovigilance, Drug Safety, Pharmacoepidemiology**

Assemble adverse reaction information on company's drugs.  
Prepare periodic safety update reports.  
Design, conduct and evaluate post-marketing studies.

## **Statistics and Data Processing**

Involved in numerous steps of editing data, entering data, ensuring quality.  
Evaluating and analysing data and preparing reports of the results.  
Maintain frequent interactions with statisticians, clinicians and regulatory agencies.

## **Pre-Clinical Science**

Some physicians join pre-clinical departments (pharmacology, microbiology, biochemistry, molecular biology) and conduct research relating to new drug discovery.

## **Medical Services**

This group usually has a mixture of medical, marketing and administrative tasks, with different profiles depending on the company and may include arranging courses and programmes for physician training.

## **Project Coordination**

This group oversees the project system and the matrix arm of the investigational projects in the company's portfolio. Roles combine managerial and administrative responsibilities with medical input through a wide variety of activities.

## **Other areas**

These include patents, licensing, computers and IT, education and training, commercial liaison and finance functions within the medical or R&D division.

## **5. SUPERVISION AND FEEDBACK**

### **Mechanisms for supervision**

#### Educational Supervisor (ES)

Each registrar has an ES who supervises on a regular basis and through personal contact a registrar undertaking a PMST programme in a training environment (company or institution). The ES will normally be the registrar's medical manager and work on the same site. S/he will normally be familiar with and oversee the registrar's work.

Registrars will work with a level of educational supervision appropriate to their experience and level of competency. This will be the responsibility of the Principal ES / SSA after discussion with the registrar's ES. This will be the responsibility of the training team (registrar, ES/PES, SSA).

In keeping with the principles of GMP and GPMP registrars will know that they must limit their experience to within their level of competency and seek help and support without hesitation.

The ES ensures the availability of and access to components of training as set out in the curriculum and detailed in the registrar's *ad personam* PMST programme (JCHMT Form B). In particular the ES is responsible for ensuring availability of access to the appropriate training components of PMST Module 7, Generic Module (*Interpersonal and Management Skills; Good Pharmaceutical Medical Practice*). The ES is responsible for ensuring that the PMST programme fulfils the principles and standards laid down in Good Pharmaceutical Medical Practice (GPMP).

The ES oversees the education of a registrar to ensure that he/she is making the necessary progress. The ES is also likely to be involved with the registrar's teaching, training, assessment and appraisal as well as assisting with professional and personal development.

The ES provides the registrar with educational supervision during the PMST programme. The ES should be in regular contact with the registrar on at least a weekly basis. More formal meetings, with a written record, should occur in the early stages of training at least monthly and might be more often. In the later stages, contact might be less frequent, and the level of supervision may depend less on the evolving competency and experience of the registrar.

The ES and registrar should undertake formal educational appraisals on a 4-monthly basis (two per year) and a formal annual performance appraisal for PMST prior to the annual RITA review (one per year).

The ES must be willing to undergo induction and training in the responsibilities, skills and processes of supervision of PMST in pharmaceutical medicine; for example, the conduct of educational and performance appraisals and assessments of performance and competency. The Faculty (FPM), along with the SAC and PGD,

will offer or facilitate any appropriate training that it considers necessary or which is requested.

The PES should keep the SSA, who acts on behalf of FPM and PGD, informed about: significant problems that arise in provision of educational components; registrar experiencing difficulties in achieving educational objectives; performance not reaching the required standard; problems relating to the professional and personal development of the registrar, as they relate to the PMST programme. Such issues should be discussed with the specialist registrar in the first place and remedial measures adopted as soon as possible. It may be necessary, with the registrar's permission, to raise these matters with the SSA and / or PGD prior to the annual RITA review.

The ES will be involved in assessments and appraisals of PMST registrars:

- a. PMST meetings / advisory / educational (ongoing);
- b. educational appraisals (usually four-monthly);
- c. annual performance appraisal ('summative assessment');
- d. performance and competency assessments (as necessary for PMST curricular Items).

Sections c. and d. above will form part of the Record of In-Training Assessment (RITA) annual review. Confidential aspects of appraisals, notably of b. above by mutual agreement between registrar and ES may be lodged in Section 9 of the Training Record, and not presented for RITA review or other external scrutiny, except under exceptional circumstances (e.g. Appeals).

Adequate records should be maintained by the ES of interactions with registrars, including competency assessments and appraisals. These records will be needed for the RITA process, notably the annual review meeting with the PGD (or as delegated by the PGD).

### Role of SSA & RITA process

The SSA, in an oversight (QC) role of the programmes within a training environment, will contribute to ensuring supervision of registrars through regular visits to the site and discussions with registrars, ESs and others, such as peers and managers of the registrar(s).

The RITA process too will contribute to ensuring effective supervision of the registrars. ESs are intended to accompany registrars to RITA reviews and can be questioned themselves by the RITA panel regarding aspects of supervision.

Further, at the RITA review ES reports have been presented commenting on registrar progress and achievement including assessments and appraisals.

## **Mechanisms for feedback**

Receiving regular and timely feedback on learning and performance is an essential part of the work-based experiential learning of PMST, which is, in the main, a formative, developmental process.

In training as a specialist pharmaceutical physician, a doctor must develop the ability to seek and respond to feedback from a range of individuals to meet the requirements of Good Pharmaceutical Medical Practice (and Good Medical Practice) and revalidation.

Thus feedback to the registrar on progress and achievements in PMST, including acquisition of competencies, assessments made and standards reached, strengths and deficiencies can be made on a number of occasions in different situations.

Specific details of who should give feedback and the timing in relation to training are the responsibility of the Deanery and Programme Director. Best practice guidance will be provided by the Faculty of Pharmaceutical Medicine / SAC in the form of a Guide to PMST (contained in the Training Record), regular meetings and correspondence.

Guidance emphasises the need for:

- a. an initial meeting between registrar and ES shortly after enrolment into PMST to establish learning goals and the Training Plan;
- b. regular (e.g. monthly) meetings between ES and registrar to discuss projects and learning;
- c. formative, developmental educational appraisals at 4-monthly intervals (two per year) between registrar and ES to discuss and feedback on learning, learning objectives, projects, proposals, plans, problems and personal matters; with written short reports and notes to be lodged in the Training Record, if necessary in confidence;
- d. annual performance appraisal (summative assessment) to discuss assessments, achievements and progress against the Training Plan(s) and topics and items for the new Training Plan; full write-up required by ES to be agreed and co-signed by registrar and placed in the Training Record; preparation for RITA review.
- e. feedback from the annual RITA review;
- f. feedback from the Diploma examination by the Board of Examiners if the registrar has been unsuccessful;
- g. appropriately structured written feedback (anonymised) from departmental staff, colleagues and others on competencies, attitudes / behaviour through Multi-Source Feedback (MSF, 360° assessment);
- h. structured written feedback from ES (ES Report Form) on any topic.

The results of feedback will be discussed between registrar and ES during appraisals. Evidence that feedback has been sought and responded to will form part of the annual RITA review.

The ES is normally the local medical manager of the registrar and comes into contact on a day-to-day basis, providing ample opportunity for immediate or considered feedback on performance and other matters.

The educational appraisal provides a more formal setting for feedback, both positive and negative, on progress and achievement in addressing the curriculum. The PES can incorporate feedback from other ESs who have been involved with the registrar.

A formal mechanism for feedback would be multi-source feedback (MSF) using the standard RCP tool (form) with the target group being peers and multidisciplinary colleagues of the registrar.

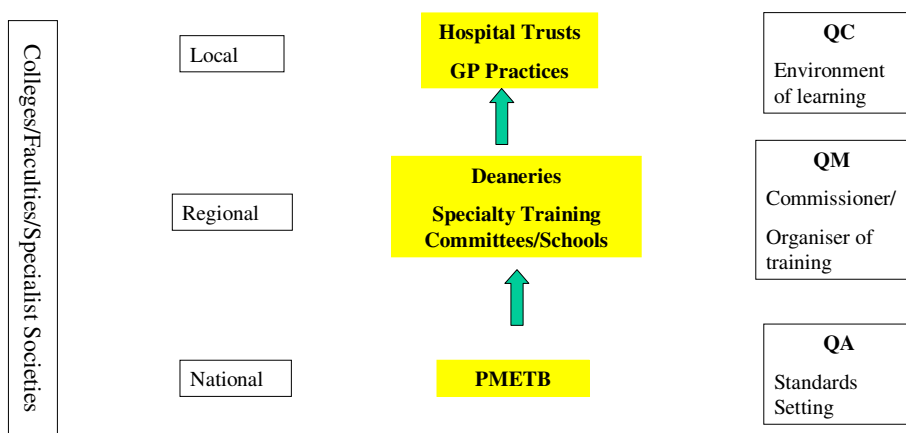
The annual RITA review offers an opportunity for formal feedback on progress and achievement in acquisition of competencies and completion of the portfolio.

## **6. MANAGING CURRICULUM IMPLEMENTATION**

**Judy – this is our text – see below**

Deaneries are responsible for quality management, PMETB will quality assure the deaneries and educational providers are responsible for local quality control, to be managed by the deaneries. The role of the Colleges in quality management remains important and will be delivered in partnership with the deaneries. The College role is one of quality review of deanery processes and this will take place within the SACs on a regular basis.

The Organisation and Quality Assurance of PG Training



**Judy – the following text is the original – should this be deleted??**

### **Use of the curriculum document by trainers and registrars**

The full curriculum will be a web-based document which will be available via the Faculty of Pharmaceutical Medicine's website. It will also be available on CD for distribution to all stakeholders in PMST as appropriate and requested. Hard copies of the curriculum can be prepared at any time from the electronic sources.

The website also allows access to all supporting material for PMST which currently includes:

- a. background and organisation of PMST;
- b. enrolment procedures;
- c. Training Record and all Report Forms;
- d. evidence grid and explanatory notes;
- e. available Module courses; timetable, providers, registration details;
- f. preparation for RITA reviews;
- g. SSA and Educational Supervisor training material;
- h. PMST Guidance and Notes for Guidance documents;

- i. PowerPoint presentations on Pharmaceutical Medicine, Faculty, background to PMST, PMST overview and procedures, Competency Assessments, Educational and Performance Appraisals;
- j. Continuing Professional Development and Revalidation; guidance and procedures;
- k. access to literature and reference material;
- l. accumulating library of projects and portfolios;
- m. links to related websites; NHS, industry, regulatory, academic bodies; curriculum content learning material; educational bodies and courses;
- n. PMST Appeal procedures (JCHMT and Faculty).

In addition past examination papers (essays and short questions only) for the Diploma in Pharmaceutical Medicine may be purchased for a small sum from the Faculty.

It is intended that the curriculum as approved by PMETB and published by JCHMT is a reference document for registrars and their educational supervisors when preparing the Training Plan(s).

The registrar's programme of in-work modular training (JCHMT Form B) and job description, together with current and upcoming projects in which the registrar will be involved will be used to plan which topics and items of the curriculum can be undertaken. These will be entered in the Training Plan for the next period of six to 12 months.

The curriculum document also details what competency level is expected for a particular topic or item of applied knowledge, skills and attitude/behaviour and also what type of assessments might be appropriate and selected through the assessment / curriculum blueprinting exercise.

It is essential that the registrar confirms the requirements of the PMST Training Plan with the ES, detailing how these are to be met at employer level and integrated into the company / workplace system and timetable, so that adequate time and resource can be provided.

The introduction of a structured competency-based training programme for PMST in medical specialties and the adoption of competency assessment procedures represents a major departure from the former approach to postgraduate training. Their incorporation in a new legal framework imposes a discipline on all those involved in the educational process. It is essential that there should be an explicit partnership between registrars and those responsible for training, so that registrars receive adequate support and guidance throughout the training period.

In turn there is a new responsibility placed on registrars to evaluate their own strengths and weaknesses and to seek out the educational opportunities that they require to correct any deficiencies.

## **Means of ensuring curriculum coverage**

Each registrar has an individualised PMST programme derived from the curriculum and mapped initially in JCHMT Form B.

The details of how the curriculum is covered in an individual training programme and workplace unit is the responsibility of the Deanery and the Programme Director. The need to show how registrars are progressing in their achievement of learning outcomes has been and will continue to be a strong stimulus to ensure that all curriculum objectives are met.

Registrars will provide feedback on their training (see Section 7) so that the training programme can be modified as necessary. This is particularly the case in event of change of job, site, company or country during the course of training, and mechanisms are in place with the Faculty and SSAs to ensure smooth transitions and continuity of training.

Such transitions over the period of PMST can raise opportunities for wider project and portfolio exposure against curricular requirements, for example through job change or promotion or a different company business profile and practices, therapy area and product portfolio or depth and breadth of registrar role and responsibility in pharmaceutical medicine practice.

### **Specialty Knowledge Base**

The outcome criterion for acquisition of the Specialty Knowledge Base is passing the examination for the Diploma in Pharmaceutical Medicine. Although not mandatory, the great majority of registrars will attend a postgraduate course that covers the curriculum.

### **PMST Practical Modules**

The applied knowledge in each modular topic of PMST is based on the Specialty Knowledge Base, which provides further assurance that the knowledge base has been covered in those areas that are part of practical PMST.

To cover the curriculum in PMST practical modules, items and topics can be undertaken either in work or through courses.

Each registrar must depict a minimum of two modules that form the core in-work modules in which the majority of items and topics will be undertaken on-the-job, and competencies demonstrated through real-life performance.

Whilst the combinations of two modules will be different for registrars these form the core requirement for the in-work experiential training of PNMST.

There is no expectation that courses, in covering the curricula, will provide the same experience as on-the-job training.

Assessments for course-work do not, by definition, assess real-life performance, but are able to assess (simulated) competency, applied knowledge and attitudes / behaviour.

In practical PMST it is expected that all curricular modules, items and topics will form part of the training.

### Generic module in pharmaceutical medicine

All items and topics of the generic module *Interpersonal and Management Skills* must be addressed during PMST.

Equally the seven domains of *Good Pharmaceutical Medical Practice* must be addressed during PMST.

### **Role of local faculty in curriculum implementation**

The centre for PMST is the workplace - pharmaceutical company, clinical research organisation, or regulatory authority.

Here the training team comprises the registrar, the ES and the SSA allocated to that training environment / site. This is the main unit for conducting the programme of PMST.

There is one Principal ES (PES) for each registrar, but some supervision for some modules, items and topics may be delegated to other ESs, whilst overall responsibility for supervision remains with the PES.

Educational Supervisors may have more than one registrar, and SSAs cover more than one site.

The ES is responsible for facilitating opportunities for training and resources so that the requirements of the curriculum can be met on-site as far as possible.

Discussion between the registrar and ES, and if necessary with the SSA, will determine which module courses and supplementary courses may be required to fulfil those requirements of the curriculum which cannot be acquired in work through real-life experience.

Other local faculty may comprise the company or unit Medical Director, Human Resources manager, local topic experts, internal and possibly external assessors, all of whom may have a role at some point during PMST for ensuring the availability, delivery and assessment of training projects and activities.

### **Responsibilities of registrars for curriculum implementation**

One of the basic principles of a competency-based workplace-centred education and training programme is that the registrar is firmly at the centre, not only as the apprentice and *raison d'être* for the programme, but as the initiator and responsible person to ensure that education and training takes place and has a successful

outcome. The curriculum for a competency-based programme puts the emphasis on learning rather than teaching.

Whilst specialty advisers and educational bodies can set curricula and lay down standards to be achieved, and educational supervisors and trainers can facilitate the availability of learning opportunities and resources, it is the registrar with the motivation, drive and enthusiasm to undertake specialist training who must ensure that the circumstances are present and appropriate for their full participation, giving them the best chance for a successful and timely outcome.

Thus, the responsibilities of the registrar for curriculum implementation and learning through utilisation of opportunities include:

- a. ensuring enrolment eligibility;
- b. selection of Educational Supervisor for approval;
- c. arranging and planning enrolment meeting with SSA and ES;
- d. completion and submission of enrolment application;
- e. preparation of Training Plan;
- f. enrolment and attendance on postgraduate training courses;
- g. planning and preparation for assessments of competency;
- h. planning and preparation for educational and performance appraisals;
- i. planning and preparation for RITA reviews;
- j. maintaining the Training Record and keeping it up to date, notably the signed-up Training Log of achieved goals and competencies;
- k. collection, collation, cataloguing and filing of evidence of competency, and ensuring its authentication / validation by ES, SSA and others as required;
- l. writing reports from self-directed learning and reflection;
- m. implementing remedial activity following appraisals and RITA reviews;
- n. maintaining communication with trainers and administrators (Faculty, JCHMT/SAC);
- o. managing transition in PMST programme (jobs, companies, countries).

One of the principles of PMST is that success should be judged by the demonstration of proficiency in the skills required by the discipline, rather than the length of time served.

Registrars require instruction, guidance and support to achieve the goals and make progress in PMST. There is a means of logging, with authentication / validation by the ES(s), the acquisition of the experience and skills, both generic and specialist, prescribed in the curriculum.

Whilst annual performance appraisal and review of assessments (RITA review) are intended to provide registrars with support and guidance, including feedback on the quality of training programmes, their primary aim is to judge whether or not the requirements of the curriculum have been fulfilled and the requisite standards achieved.

In addition, registrars must also have the benefit of a system which offers meetings with ES (Educational Appraisal) which are primarily educational, in which private

and personal matters may be raised and which are designed solely to assist registrar development and progress to meet educational needs.

### **Curriculum management in programmes**

Each registrar has an individualised programme derived from the curriculum. This is mapped out during the enrolment phase on JCHMT Form B, and this is dependent on a number of factors relating to each registrar as well as his/her workplace.

These are:

- a. exemption from one module as a result of prior training;
- b. JCHMT Form A, which states overall which parts of the curriculum are available as training opportunities at the particular site / training environment;
- c. the registrar's job description which determines the scope of his/her work and the training projects and opportunities which might present themselves in the course of work over a period of time;
- d. which modules of advanced training will be the two core modules for in-work training (the majority of topics and items to be completed in real-life as part of the job);
- e. which other modules or part modules will be completed in-work and thus which module or supplementary courses will be required;
- f. how the specialty knowledge base will be acquired – through attendance on a postgraduate course, or through work and personal study.

Following enrolment the Training Plan devised by the registrar and ES will determine what learning and projects will be undertaken during the period of the Plan (6-12 months).

The aim in PMST is for all topics / items / modules of the curriculum to be addressed during the programme, with as many as feasible being undertaken in the workplace as part of the job.

How the requirements of the curriculum are being met will be reviewed over time at formative and developmental educational appraisals, which present an opportunity for deviations and deficiencies to be addressed.

What and how much has been achieved will be reviewed at the summative annual performance appraisal in PMST.

Progress and achievement, as well as an evaluation of meeting curricular standards are assessed at the annual independent Record of In-Training Assessment reviews (RITA).

During PMST meeting the requirements of the curriculum needs to be managed actively as many factors can alter the composition of the programme as originally mapped out on JCHMT Form B.

Some of these are:

- a. non-availability of training project or activity as planned;
- b. new training project or activity not planned for;
- c. more items of modules covered in work than expected;
- d. overlap of topics and items between modules;
- e. change of job, site, company or country during PMST, with consequent exposure to new or different from planned topics and items of the curriculum.

The requirements of the curriculum for the generic module must also be managed actively throughout PMST. This requires accruing experience in interpersonal and management skills and demonstrably fulfilling the tenets of the seven domains of Good Pharmaceutical Medical Practice. These are not mainly discrete competencies of knowledge and skills but represent an approach to professional work and behaviour that develops over time and are subject to continuous assessment and appraisal to ensure that the professional standards expected of a specialist pharmaceutical physician are met.

### **Curriculum management across programmes**

Management of the curriculum across programmes as a whole is the responsibility of the Deanery, the Programme Director and the Faculty's PMST Subcommittee.

Each registrar has an individualised programme for PMST that is derived directly from the curriculum.

The acquisition of the specialty knowledge base is common to all registrars, who must pass the Diploma in Pharmaceutical Medicine examination prior to being recommended for a CCT.

The generic module is also common to all registrars and accrued competencies and behaviours must be demonstrated before a CCT can be awarded.

It is in the operational modules where individual programmes differ most including the nature and complexity of projects and activities covering identical topics and items of the curriculum. These depend on the project, the training environment / site, the involvement and engagement of the registrar, the nature of the evidence of competency and the expectations of the educational supervisor and / or other assessors towards learning outcomes.

Whilst it is accepted that no two programmes are identical in make-up, execution or outcome, it is necessary to achieve a standard of performance / competency which for a curricular item is valid, reliable and faithful to real life.

Across the varied individualised and flexible programmes, curriculum management can be approached with the following available strategies:

- a. common interpretation of curricular requirements by registrars, ESs and SSAs;
- b. regular communication across programmes by registrars, ESs and SSAs;

- c. outcomes to meet external standards set by regulation and law, international industry and company standards;
- d. application of valid, reliable, practical assessments;
- e. feedback from informal meetings and educational appraisals;
- f. formal feedback from performance appraisals;
- g. feedback from RITA reviews.

## **7 CURRICULUM REVIEW AND UPDATING**

Curriculum review will be informed by a number of different processes. For instance the SAC will be able to use information gathered from specialty heads, specialty deans and the National Health Service. It will have available to it results of the trainee survey, which will include questions pertaining to their specialty. Interaction with the NHS will be particularly important to understand the performance of specialists within the NHS and feedback will be required as to the continuing need for that specialty as defined by the curriculum. It is likely that the NHS will have a view as to the balance between generalist and specialist skills, the development of generic competencies and, looking to the future, the need for additional specialist competencies and curricula.

### **Curriculum evaluation and monitoring**

Formal evaluation of the curriculum will take place during the initial stages of curriculum implementation and during the first two years of full implementation. Evaluation will continue, as indicated from early and on-going evaluations, during the full cycle of PMST. Evaluation will continue thereafter on the same basis – on-going review, bi-annual update and full (4-year) cycle of review and update.

Evaluation will consist of:

- a. registrar questionnaire (administered through CAAM);
- b. SSA/ES questionnaire (collated at annual SSA/ES meeting);
- c. training site (educational environment) QC feedback reports;
- d. feedback from RITA reviews (including Postgraduate Dean);
- e. outcome of Diploma examinations;
- f. feedback from Board of Examiners on Diploma examination;
- g. feedback from QA Convenors Group of BoE on Module courses;
- h. feedback from Module course providers;
- i. review and feedback / commentary by lay representatives.

Details of the evaluation will include:

- a. relevance of learning outcomes to pharmaceutical medicine practice;
- b. balance of in-work experiential learning for individual programmes;
- c. balance of real-life, simulated, individual and team-based experience;
- d. balance and emphasis of material between operational modules;
- e. uptake, relevance and learning / behaviour outcomes of the generic module;
- f. opportunities for in-house and off-site course-based learning;
- g. quality, content, relevance, programmes and delivery of time-limited formal module interactive courses;
- h. quality of training in training sites / institutions;
- i. value of case studies / scenarios in learning (in-work and course-based);
- j. assessment methods and tools (validity, reliability, feasibility within training programmes; in-work and course-based);
- k. balance of competency levels reached vs. expected; extent of module items addressed / completed;

- l. balance of programme attained by nature / size of training site (large vs. small pharmaceutical companies, large vs. small CROs, MHRA and others).

Evaluation will take account of:

- a. registrar portfolios (evidence of competency) and the annual RITA reviews;
- b. developments in pharmaceutical medicine (law, regulation, drug development, medicines monitoring, technological advance);
- c. developments in pharmaceutical medicine practice (role and work of pharmaceutical physicians, clinical development, pharmacovigilance, medical marketing, codes of practice);
- d. developments in the international pharmaceutical industry (corporate organisation and location, corporate financing, status and support of education and training, industry standards, government-industry-academic interface, inter-disciplinary professional standards and practices, industry-healthcare marketplace-NHS-public interface);
- e. developments in pre-specialist clinical run-through training (by specialty and College including general practice);
- f. eligibility and uptake of overseas graduates into UK PMST;
- g. uptake and nature of international pharmaceutical medicine education and training (European CCT programmes, USA, rest of world);
- h. development of electronic portfolio and PMST programme management;
- i. movement of specialist registrars and continuing training (by job, company and country);
- j. presentation and comprehension of curriculum (by language, syntax, clarity, module overlap, repetition and redundancy, subject emphasis, competency levels, balance of material between modules);
- k. volume and extent of PMST programmes (comparison with other specialties).

Monitoring, as opposed to evaluation, will be the responsibility of the Faculty's PMST Subcommittee interacting with the registrars, Educational Supervisors and Senior Specialty Advisers. From a practical point of view, the registrar portfolios (Training Records and Training Logs) and the annual RITA reviews will be the main monitoring tools. The PMSTSC monitoring outcomes will feed into the Curriculum Review WG of the SAC-PM.

### **Schedule for curriculum review and updating**

As outlined above the schedule for curriculum review and updating can be set against timelines as follows:

Implementation of curriculum	AUGUST 2007
Review of curriculum	ONGOING
Evaluation (questionnaires, feedback)	AUGUST 2008, JUNE 2009
Updated curriculum published (half-way through the	AUGUST 2009

4-year programme cycle)	
Evaluation (questionnaires, feedback)	AUGUST 2010, JUNE 2011
Updated curriculum published (after the full 4-year cycle of PMST)	AUGUST 2011

### Registrar involvement

Registrar involvement in curriculum review will be facilitated by:

- a. feedback following appraisals, assessments, RITA reviews, Faculty meetings, QC panel site inspections with registrar interviews, meetings of CAAM (Registrars' Group) via PMST Subcommittee (PMST-SC) to Curriculum WG;
- b. registrar questionnaires (ongoing at least annual) from Curriculum WG of SAC-PM;
- c. ad hoc confidential feedback via ES / SSA to PMST-SC.

## **8 EQUALITY AND DIVERSITY**

In the exercise of these powers and responsibilities, the Royal Colleges of Physicians will comply, and ensure compliance, with the requirements of relevant legislation, such as the:

Race Relations (Amendment) Act 2000  
Disability Discrimination Act 1995 (Amendment) 2004 and Special Educational Needs and Disabilities Act 2001  
The Disability Discrimination Act 1995 (amendment) (further and higher education) Regulations 2006  
Data Protection Acts 1984 and 1998  
Age Discrimination Act October 2006

The Federation believes that equality of opportunity is fundamental to the many and varied ways in which individuals become involved with the Colleges, either as members of staff and Officers, as advisers from the medical profession, as members of the Colleges' professional bodies or as doctors in training and examination candidates. Accordingly, it warmly welcomes contributors and applicants from as diverse a population as possible, and actively seeks to recruit people to all its activities regardless of race, religion, ethnic origin, disability, age, gender or sexual orientation.

## **9. Statutory responsibilities**

The Royal Colleges of Physicians will comply, and ensure compliance, with the requirements of legislation, such as the:

Human Rights Act 1998  
Freedom of Information Act 2001  
Data Protection Acts 1984 and 1998

Deanery quality assurance will ensure that each training programme complies with the equality and diversity standards in postgraduate medical training as set by PMETB.

Compliance with anti-discriminatory practice will be assured through:

- Monitoring of recruitment processes
- Ensuring all College representatives and Programme Directors have attended appropriate training sessions prior to appointment or within 12 months of taking up post
- Ensuring trainees have an appropriate, confidential and supportive route to report examples of inappropriate behaviour of a discriminatory nature
- Monitoring of College examinations

Ensuring all assessments discriminate on objective and appropriate criteria and do not unfairly disadvantage trainees because of gender, ethnicity, sexual orientation or disability (other than that which would make it impossible to practise safely as a physician). All efforts shall be made to ensure the participation of people with a disability in training.

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## **10 APPENDICES**

### **Appendix 1**

#### **MEMBERSHIP OF THE CURRICULUM WORKING GROUP**

**Convenor:**

**Professor Peter Stonier**

**Members:**

**Dr Madhu Davies**

**Dr Brian Gennery**

**Dr Richard Kay**

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**Dr Timothy Mant**

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## **Appendix 2**

# **Diploma in Pharmaceutical Medicine; Regulations & Procedures**



**FACULTY OF PHARMACEUTICAL MEDICINE**

**of the Royal Colleges of Physicians of the United Kingdom**

**Diploma in Pharmaceutical Medicine**

**EXAMINATION REGULATIONS  
AND PROCEDURES**

APRIL 2006  
REGISTERED CHARITY NO: 1011631

## EXAMINATION REGULATIONS AND PROCEDURES

### DIPLOMA EXAMINATION

- A.1 The Diploma in Pharmaceutical Medicine (Dip.Pharm.Med) is awarded by the Faculty on the recommendation of the Board of Examiners.
- A.2 A Diploma Examination is conducted annually by the Board of Examiners at a fixed time and place announced by the Faculty.
- A.3 The Diploma candidate is required to sit a written examination and to attend an oral examination.
- A.4 Membership of the Faculty may be granted to pharmaceutical physicians who possess the Diploma and have their application approved by the Board of the Faculty (see A.52).

### DIPLOMA REGISTRATION

- A.5 The Faculty will provide a Diploma Examination pack containing all necessary forms with *Guidance Notes for Candidates and Supervisors, Syllabus for the Diploma in Pharmaceutical Medicine* and the *Examination Regulations and Procedures*.
- A.6 Candidates must complete the application form and submit it with a recent photograph for identity to the Faculty Office by the announced closing date.
- A.7 When attending the examination, candidates are required to provide photographic identity (passport, driving licence or ID from place of work) at registration on both days.

### ELIGIBILITY OF CANDIDATES

- A.8 Eligibility of candidates to sit the Diploma examination will be decided by the Board of Examiners.
- A.9 Candidates must provide evidence of full or limited registration with the General Medical Council (GMC) in the UK or possess a medical qualification recognised by the GMC and be registered in the country in which the qualification was granted or where currently working.
- A.10 When submitting the application form, candidates must provide evidence of registration as a medical practitioner by provision of their GMC registration number. Candidates not registered in the United Kingdom should provide the original or a notarised (legally validated) copy and translation of their medical registration certificate and if this does not show current registration then a certificate of good standing will also need to be produced.
- A.11 By the time of the Diploma Examination, a candidate must have completed at least two years of General Professional Training and of clinical practice involving patient care as a registered medical practitioner. Neither undergraduate clinical training nor the one-year pre-registration period as house officer (intern) for provisionally registered medical practitioners required by the GMC in the UK contribute to the two-year period of postgraduate and post-registration professional training and practical clinical experience. The Faculty complies with the conditions and the interpretations that are applied by the GMC and by the three Royal Colleges of Physicians and other Royal Colleges in determining whether a candidate's General Professional Training is sufficient.
- A.12 The minimum qualifying period of two years of full-time or equivalent General Professional Training and practical clinical experience must be met. The effect of any interruptions will be assessed when determining eligibility to sit the Diploma examination.
- A.13 In addition to General Professional Training and practical clinical experience a Diploma candidate must also have completed, by the time of the Diploma Examination, at least two years in a post

that provides practical experience and training in pharmaceutical medicine.

- A.14 The practical experience in pharmaceutical medicine may be obtained by working in a pharmaceutical company, contract research organisation or drug regulatory authority or, exceptionally, in an academic department.
- A.15 The training in pharmaceutical medicine should involve courses, distance-learning packages or other tuition or personal study. In aggregate, a combination of these should cover all elements of the syllabus. Parts 1 and 2 of this publication should be consulted on the scope of training.
- A.16 A Diploma candidate should plan a training programme with the advice of his or her Educational Supervisor.

#### **SUPERVISOR**

- A.17 Candidates must have an Educational Supervisor to assist in planning their training in pharmaceutical medicine. In addition, a Senior Specialty Adviser will be allocated to those candidates enrolling with the Faculty and JCHMT for Higher Medical Training.
- A.18 Diploma candidates should identify a person suitable to serve as their Educational Supervisor. The supervisor must be medically qualified and ideally, but not necessarily, a pharmaceutical physician who is a Member or a Fellow of the Faculty, or alternatively a suitable medical specialist with relevant experience in a local university or hospital.
- A.19 It is desirable that the supervisor should work in the same organisation and/or locality as the Diploma candidate. If a candidate is unable to identify a suitable supervisor, the Faculty may be asked to assist in finding a supervisor.
- A.20 A supervisor may be asked by the Faculty to confirm the nature and extent of training and of practical experience in pharmaceutical medicine that a Diploma candidate has received.

#### **SYLLABUS**

- A.21 The syllabus for the Diploma Examination is presented in detail in Part 2 of this document.
- A.22 A Diploma candidate should expect questions during the examination on any section of the syllabus. However, some sections comprise a greater proportion of the work of a pharmaceutical physician and, therefore, require more study and may feature in more than one part of the Diploma Examination.
- A.23 The discipline of pharmaceutical medicine is ever evolving and a Diploma candidate should be aware of important recent changes and current issues.

#### **WRITTEN EXAMINATION**

- A.24 The written examination is held during one day. The place and time are available from the Faculty about 10 months before the examination and are advertised about 3 months before the closing date for registration.
- A.25 The final selection of questions for the papers is made by the Officers and Panel Convenors of the Board of Examiners. The Board ensures that the written examination as a whole covers the syllabus appropriately. Core features of the *short answers* and guidance notes for the markers of the *essays* are checked and agreed.
- A.26 Candidates will not be allowed to leave the room within the first 15 minutes and late candidates will not be admitted to the exam after this time. Any candidate wishing to leave and return to the examination hall will be accompanied. This applies to all parts of the written examination.
- A.27 Mobile phones, calculators and other electronic devices may not be used during the exam and, if

brought into the examination hall, must be switched off and left with the Invigilator.

- A.28 The written examination comprises three separate papers with a rest period between each and consists of:

*Multiple Choice Question (MCQ) paper.* All 250 questions (50 stems each with 5 choices) should be answered in 1 hour 30 minutes

*Short Answer paper.* All ten questions should be answered in 2 hours 30 minutes

*Essay paper* with a choice of four questions of which two should be answered in 1 hour 30 minutes

## **ORAL EXAMINATION**

- A.29 The oral (*viva voce*) examination is held the day following the written examination.
- A.30 Suitable scientific papers for the oral examination are selected and topics for discussion with candidates are identified by the Officers and Panel Convenors of the Board of Examiners.
- A.31 Candidates are allocated a time for arrival and must arrive at that scheduled time. Candidates who arrive late will not be given any additional time and may not be able to take the oral examination.
- A.32 Candidates will have 5 minutes to select one of up to three published papers on which they will be examined. Approximately 40 minutes are allotted for preparation. Candidates are expected to demonstrate an ability to analyse a paper critically and to answer questions focusing mainly on design, conduct and results. Candidates will not be expected to have specialist knowledge of the particular scientific material or therapeutic area.
- A.33 The oral examination lasts 20 minutes and is conducted by two examiners, each asking questions and each adjudicating the replies for equal periods.
- A.34 An observer may be present at each table, but will take no part in the examination or in its assessment.
- A.35 Examiners will not request the candidate's company identification or confidential information.

## **ASSESSMENT**

- A.36 Candidates must attend and attempt all four sections of the examination.
- A.37 Any candidate who knows of an exceptional reason, such as a medical condition, which may affect his or her performance on any part of the examination, must inform either the Chairman of the Board of Examiners or the Education Administrator prior to sitting the examination. This information will be kept confidential. Such information passed to the Faculty after sitting the examination cannot be taken into account.
- A.38 The multiple-choice questions are marked by computer and grades are then assigned according to pre-set standards.
- A.39 Pairs of examiners mark candidates' answers in the *short answer* and *essay* parts of the written examination. Individual questions will generally be marked by a pair of examiners, each initially acting independently. The two examiners will then confer and agree a mark for each candidate on the particular question they are marking.
- A.40 The possible grades are 'Excellent', 'Good', 'Pass', 'Bare Pass', 'Bare Fail', and 'Fail'. The Board of Examiners approves the correspondence between marks and grades.

## **ADJUDICATION**

- A.41 Before the meeting of the full Board, the Officers and Panel Convenors examine any inconsistencies in a candidate's grades and re-assess the relevant papers of any candidates identified through this process.
- A.42 The Board of Examiners holds its annual meeting approximately four weeks after the examination. The adjudication of the Diploma Examination is a major item, followed by a detailed review of the overall results and of the examination procedures.
- A.43 The identity of candidates is not known to the examiners at or after adjudication.
- A.44 Each candidate's grades in all four parts are listed and each is considered in turn and a decision reached.
- A.45 An outright 'Fail' in any one part of the examination will lead to an overall fail of the examination.
- A.46 Candidates given one 'Bare Fail' may pass the examination if the grades in the other three parts are 'Pass' or higher. A 'Bare Pass' indicates precisely that and candidates with one 'Bare Fail' and one or more 'Bare Pass' grades will not pass the examination. Similarly, a candidate with two 'Bare Fails' will fail the examination. During the adjudication process, care is taken by the examiners to review papers with critical borderline grades with remarking and possible upgrading if considered appropriate.
- A.47 The Board of Examiners may award the Diploma with Distinction to a candidate who has consistently high grades (generally 'Good' or 'Excellent') in all four sections of the examination.

## **COMMUNICATION OF RESULTS**

- A.48 The Faculty will advise all candidates of the outcome in writing.
- A.49 A Diploma certificate will be provided as appropriate.
- A.50 The Chairman cannot enter into detailed discussion with a candidate but will try to be as constructive as possible in any correspondence.
- A.51 An unsuccessful candidate may resit the Diploma Examination.

## **MEMBERSHIP OF THE FACULTY**

- A.52 A pharmaceutical physician who has been awarded the Diploma in Pharmaceutical Medicine and wishes to become a Member of the Faculty must complete an application form and submit it to the Faculty Office.

## **FEES**

- A.53 The Faculty will maintain a schedule of fees, which will be included in the Diploma Examination pack with the conditions that apply clearly stated.

## **CONDUCT**

- A.54 The Faculty may refuse to register a person as a Diploma candidate and to withdraw such registration at any time if the candidate's behaviour is prejudicial before or during the examination by not complying with examination regulations or instructions.
- A.55 The Faculty may investigate any suspected dishonesty or misconduct by a candidate in relation to the Diploma Examination and may later decide to revoke the Diploma and Membership.
- A.56 Any representations by candidates on the conduct of the Diploma Examination must be made in

writing to the Academic Registrar of the Faculty. An appeals procedure exists should a candidate wish to invoke it. Please see details in Appendix A.

- A.57 The Faculty may investigate any serious professional misconduct by a Member and may decide to revoke Membership.

## **Appendix A**

### **APPEALS PROCEDURE**

Candidates may appeal against a decision of the Board of Examiners. An appeal may be based on one of the following grounds:

1. Exceptional personal circumstances; the candidate must have made the invigilator / examiners aware of such circumstances at the time of the examination. Information provided after the day of the examination shall not be taken into account.
2. Deviation from the examination procedures, which disadvantaged the candidate.

An appeal must be made in writing to the Academic Registrar, specifying the claimed grounds for the appeal. It may refer to one or more parts of the examination. The appellant should indicate whether they would wish to attend a meeting of the Appeals Panel should the Panel consider that there were adequate grounds for appeal. The appeal must be received in the Faculty office within FIVE weeks of the date of the letter informing the candidate of their examination result.

The appeals process comprises two stages conducted by a Panel appointed specifically for this purpose:

1. In Stage 1, the Appeals Panel shall meet at a pre-arranged time within TWO weeks of the deadline for receipt of appeals to consider the grounds for appeal. If the Panel considers that there are inadequate grounds, an appeal may be dismissed at this stage. If the Panel considers there are adequate grounds for appeal, it will be referred to the second stage.
2. In Stage 2, the Appeals Panel shall meet to consider whether an appeal can be upheld. If the appellant has previously indicated their desire to attend the meeting, this will be held at a mutually convenient date but no later than FOUR weeks after the first meeting of the Panel. The appellant may be accompanied by a supporter (no more than one). If the appellant has previously indicated that they do not wish to attend the meeting and the Panel consider they have sufficient evidence on which to base a decision, the second stage may be conducted at the same meeting as the first stage.

The date for the Stage 1 Appeals Panel meeting shall be fixed before adjudication of the results of the examination. The Appeals Panel will comprise:

1. A representative of one of the Royal Colleges of Physicians, who will chair the Panel.
2. The Academic Registrar\* of the Faculty. Exceptionally, this may be delegated to another senior member of the Board of Examiners who has not been intimately involved in setting or marking the relevant part/s of the examination.
3. The President of the Faculty or a deputy appointed by the President, who is a Fellow, currently serving on the Board of the Faculty.

In the period between Stage 1 and Stage 2 meetings, the Chairman of the Appeals Panel shall endeavour to collect information that may be relevant to a decision on the validity or otherwise of an appeal. Invigilators, examiners or the Chairman of the Board of Examiners may be requested to provide information in writing prior to, or orally at the meeting. The Chairman of the Panel may also request relevant written papers to be remarked by another pair of examiners if this has not already been done during the adjudication of the examination by the Board of Examiners. Having collected as much evidence as felt necessary and taken account of representations by the appellant, the Panel shall deliberate in private. It is expected that the Panel shall take performance in all parts of the examination into account when coming to a decision.

Decisions of the Panel may be to:

1. uphold an appeal and pass a candidate who had previously been deemed to have failed
2. uphold an appeal but, having insufficient evidence that the candidate is capable of obtaining a pass, may invite the candidate to retake the full examination at a future annual sitting, free of charge
3. reject an appeal

The panel shall communicate its final decision to the Appellant within ONE week of the formal meeting. No further appeal against rejection of an appeal is permitted. The decision of the Appeals Panel is final.

\*The Academic Registrar may attend meetings of the Officers of the Board of Examiners, pre-adjudication meetings, oral examinations as an observer/advisor but should not participate actively in setting or marking of papers or invigilation.