

JRCPTB

Joint Royal Colleges of Physicians Training Board



SPECIALTY TRAINING CURRICULUM

FOR

PHARMACEUTICAL MEDICINE

AUGUST 2010

(Amended 2014)

Joint Royal Colleges of Physicians Training Board
5 St Andrews Place
Regent's Park
London
NW1 4LB
Tel: 020 3075 1649
Email: ptb@jrcptb.org.uk
Website: www.jrcptb.org.uk

Faculty of Pharmaceutical Medicine
3rd Floor
30 Furnival Street
London
EC4A 1JQ
Tel: 020 7831 7662
Email: fpm@fpm.org.uk
Website: www.fpm.org.uk

Approval date: 16 December 2014

Table of Contents

1	Introduction	4
1.1	Pharmaceutical Medicine	4
1.2	The Faculty of Pharmaceutical Medicine	4
1.3	Specialist pharmaceutical physician	4
2	Rationale	4
2.1	Purpose of the curriculum	4
2.2	History and development	5
2.3	PMST entry and selection requirements	6
2.3.1	EEA or overseas doctors	7
2.3.2	Transition to PMST	7
2.3.3	Medical graduates who qualified before 2005:	7
2.3.4	Medical graduates who qualified in or after 2005:	8
2.3.5	Entry to specialty training and curricula	8
2.4	Enrolment with JRCPTB and Faculty membership	8
2.5	Duration of training	8
2.6	Less Than Full Time Training (LTFT).....	9
3	Content of Learning	10
3.1	Programme content and objectives.....	10
3.1.1	Overview of Pharmaceutical Medicine Specialty Training (PMST)	10
3.1.2	Specialty training learning objectives.....	10
3.2	Good Medical Practice	12
3.3	Syllabus.....	12
4	Learning and Teaching	63
4.1	The Training Programme	63
4.2	Teaching and learning methods.....	63
4.2.1	Balance of learning experiences.....	65
4.2.2	Achievement of knowledge and competencies.....	66
4.2.3	Educational strategies.....	67
5	Assessment.....	70
5.1	The Assessment System	71
5.2	Assessment blueprint	71
5.3	Assessment methods	72
5.4	Decisions on progress – ARCP.....	74
5.5	ARCP Decision Aid	76
5.6	Penultimate Year Assessment (PYA)	77
5.7	Complaints and appeals.....	77
6	Supervision and feedback.....	77
6.1	Supervision.....	77
6.1.1.	Educational Supervisor (ES)	77
6.1.2	Mechanisms for supervision	78
6.1.3	Role of SSA and the ARCP process.....	79
6.1.4	Mechanisms for feedback	79
6.2	Appraisal	80
6.2.1	Educational appraisal.....	80
6.2.2	Annual Performance Appraisal	80
6.2.3	Induction appraisal.....	80
7	Managing curriculum implementation	81
7.1	Intended use of curriculum by Educational Supervisors (ESs) and trainees	81
7.1.1	Means of ensuring curriculum coverage.....	82
7.1.2	PMST practical (specialty) modules	82
7.1.3	PMST common module in pharmaceutical medicine	83
7.1.4	Role of local Faculty in curriculum implementation	83
7.1.4.1	Senior Specialty Adviser (SSA) and curriculum implementation.....	83
7.1.5	Curriculum management in programmes	85

7.1.6	Curriculum management across programmes.....	86
7.1.7	Movement of trainees	87
7.2	Recording progress.....	87
8	Curriculum Review and Updating	88
8.1	Curriculum evaluation and monitoring.....	88
8.1.1	Trainee involvement.....	90
8.2	Curriculum Review	90
9	Equality and Diversity	90
10	Appendices	92

1 Introduction

1.1 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.

1.2 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.

1.3 Specialist pharmaceutical physician

An accredited specialist pharmaceutical physician is a medical doctor who, having completed at least four 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 – known as local education providers (LEPs) - and has been awarded a Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR) by the General Medical Council (GMC).

The specialist pharmaceutical physician should be registered and retain a licence to practise with the GMC, and engage in the revalidation process.

Specialist pharmaceutical physicians will practise pharmaceutical medicine within a pharmaceutical company, independent contract research organisation (CRO), medicines regulatory authority, or as an independent practitioner.

Specialist pharmaceutical physicians will undertake continuing professional development (CPD).

2 Rationale

2.1 Purpose of the curriculum

The purpose of specialty 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.

The purpose of this Pharmaceutical Medicine Specialty Training (PMST) curriculum is to define the process of training and the competencies needed for the award of a CCT or CESR, and entry on the GMC's Specialist Register in pharmaceutical medicine.

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

The PMST curriculum is appropriate for specialty training of pharmaceutical physicians who have acquired a post in pharmaceutical medicine following medical training and qualification, registration with the GMC and four years of post-qualification clinical training.

Following satisfactory completion of specialty training and award of the CCT or CESR, the pharmaceutical physician is eligible to apply for a place on the Specialist Register maintained by the GMC, to continue to practise pharmaceutical medicine as a specialist pharmaceutical physician. The specialist pharmaceutical physician will be expected to undertake CPD, and if he or she continues to hold a licence to practise, they must engage with the revalidation process.

The PMST curriculum covers the breadth and depth of operational pharmaceutical medicine in the discovery, development, registration, commercialisation and life-cycle management of medicines for the benefit and safety of patients, appropriate to the job role and career development of pharmaceutical physicians working in the medical department (or equivalent) from the start of their career in pharmaceutical medicine.

It should be noted that within the broad specialty of pharmaceutical medicine, the curriculum does not cover in detail those areas in which the senior pharmaceutical physician may develop their career over a longer period of time (e.g. medical management, medical and regulatory governance, commercial liaison, company management, international product development, medicines portfolio development, strategic business development), but aims to develop competencies, transferable skills and professional behaviours which will facilitate such career development and contribution within the sphere of pharmaceutical medicine.

2.2 History and development

This PMST curriculum was developed between 2009 and 2010 by the Specialty Advisory Committee for Pharmaceutical Medicine (SAC-PM), and the Curriculum and Assessment Working Group (CAWG) under the direction of the Joint Royal Colleges of Physicians Training Board (JRCPTB).

The PMST curriculum replaced the previous version of the curriculum dated January 2007, with changes to ensure the curriculum met the requirements set out in the GMC's 'Standards for curricula and assessment systems', and to incorporate revisions to the content and delivery of the training programme. Major changes from the previous curriculum included the incorporation of further generic competencies; the common competency framework, together with medical leadership.

The PMST curriculum was reviewed again by the CAWG in 2013 to update terminology and pharmaceutical medicine practices; include new pieces of legislation; and review and amend competency levels.

A full list of the CAWG membership involved in the initial development of the curriculum, and its subsequent revision can be found in **Appendix 1**.

The specialty knowledge base in pharmaceutical medicine has been accrued over several decades. Its syllabus and derived curricula for education and training have been compiled, updated and delivered by experts and professionals working in the field of pharmaceutical medicine (see <http://www.fpm.org.uk/trainingexams/exams/dippharmed> and **Appendix 2**).

Trainees, 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 them to appropriate learning strategies for adult postgraduate education and training.

2.3 PMST entry and selection requirements

The requirements for entry and selection to specialist training in pharmaceutical medicine are summarised below and are set out in full in the person specification on the Faculty of Pharmaceutical Medicine website www.fpm.org.uk :

Entry Criteria for PMST

- Hold a medical qualification (MB ChB, MB BS or equivalent)
- Be registered with a licence to practise with the GMC
- Registration with the Faculty as an Associate member (Training) is essential
- Hold a post in pharmaceutical medicine in the UK. 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 (JRCPTB Form A) for training and the training programme (JRCPTB Form B) will be required for entry
- Show evidence of achievement of Foundation competencies (or documentary evidence of equivalent competence) including:
 - Good clinical care
 - Maintaining good medical practice
 - Relationships with patients & subjects, and communication
 - Working with colleagues
 - Teaching and training
 - Professional behaviour and probity
 - Acute clinical care (in line with GMC standards / Good Medical Practice)
- At least 24 months' clinical experience post-Foundation (not including Foundation modules) in UK based approved training posts, or evidence of close involvement on a regular basis with the management of patients through multi-disciplinary team meetings. (A majority of doctors joining pharmaceutical medicine are physicians having completed Core Medical Training (CMT) or Acute Care Common Stem training; however, doctors can enter from any clinical specialty and will have equivalent training to CMT in other fields of medicine e.g. Core Surgical Training (CST).
- Be up-to-date and fit to practise safely

Selection Criteria for PMST

Essential:

- *Clinical Skills*
 - **Clinical Knowledge and Expertise:**
Evidence of experience of acute and continuing clinical management and care, with evidence of wide experience of prescribing and monitoring the effects of medicines (in any appropriate medical specialty); or evidence of close involvement on a regular basis with the management of patients through multi-disciplinary team meetings.
 - **Clinical Judgement:**
Evidence of capacity to apply sound clinical knowledge and judgement. Able to prioritise clinical need. Works to maximise safety and minimise risk.

Evidence of clinical knowledge, expertise and judgement would come from appraisal, satisfactory review (e.g. RITA-C, ARCP Outcome 1), reports, outcomes or equivalent record of satisfactory attainment of competencies.

- *Probity*
 - Professional Integrity and Respect for Others:
Capacity to take responsibility for own actions and demonstrate a non-judgemental approach towards others. Displays honesty, integrity, awareness of confidentiality and ethical issues.
- *Commitment to Specialty*
 - Learning and Personal Development:
Demonstrates evidence of interest and realistic insight into pharmaceutical medicine. Is self-aware, self-motivated and committed to personal and professional development. Capacity for self-reflective practice.

2.3.1 EEA or overseas doctors

2.3.1.1 Doctors with EEA-based clinical training

The entry requirements for the UK CCT PMST programme for doctors qualifying in the EEA or overseas and fulfilling UK-based clinical training requirements are the same as those outlined above for UK-qualified doctors.

2.3.1.2 Doctors with non-EEA clinical training

From 1 January 2007, doctors with non-EEA clinical training are not eligible for entry to a UK CCT programme, including PMST. Those doctors may undertake PMST training via the CESR Combined Programme (CESR CP) route. On completion of training, they will be awarded a CESR. Please visit the GMC's webpage 'Entry onto the Specialist Register with a Certificate of Eligibility for Specialist Registration or entry onto the GP Register with a Certificate of Eligibility for GP Registration' at <http://www.gmc-uk.org/doctors/aboutcp.asp> for a further description of the CESR CP process.

2.3.2 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 specialty training programmes requiring completion of basic specialist training over two years (ST1 and ST2 in clinical specialties).

2.3.3 Medical graduates who qualified before 2005:

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

- 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.

2.3.4 Medical graduates who qualified in or after 2005:

Those doctors who qualified in or after 2005 and received provisional registration with the GMC on or after 1 August 2005 will need to demonstrate successful completion of the clinical training requirements as laid out above under '2.3 Entry requirements'.

PMST programmes will continue to be approved by the GMC as a separate stage in the enrolment process.

2.3.5 Entry to specialty training and curricula

Doctors who entered specialty training before 31 July 2007 will follow the Higher Medical Training (HMT) curriculum of 2003 approved by the Specialist Training Authority (STA) and GMC (2003 curriculum). Doctors entering PMST from 1 August 2007 onwards will follow the curriculum approved by the JRCPTB and Postgraduate Medical Education and Training Board (PMETB) of 2007 (2007 curriculum). Doctors entering PMST from 1 August 2010 onwards will follow the curriculum approved by JRCPTB and GMC of 2010 (2010 curriculum).

The Pharmaceutical Medicine Virtual Deanery will require all trainees who are following the 2003 or 2007 curricula to move to the 2010 curriculum if they have not completed their training by 31 December 2015. From 1 January 2016 the Virtual Deanery will operate only one curriculum – the 2010 curriculum.

2.4 Enrolment with JRCPTB and Faculty membership

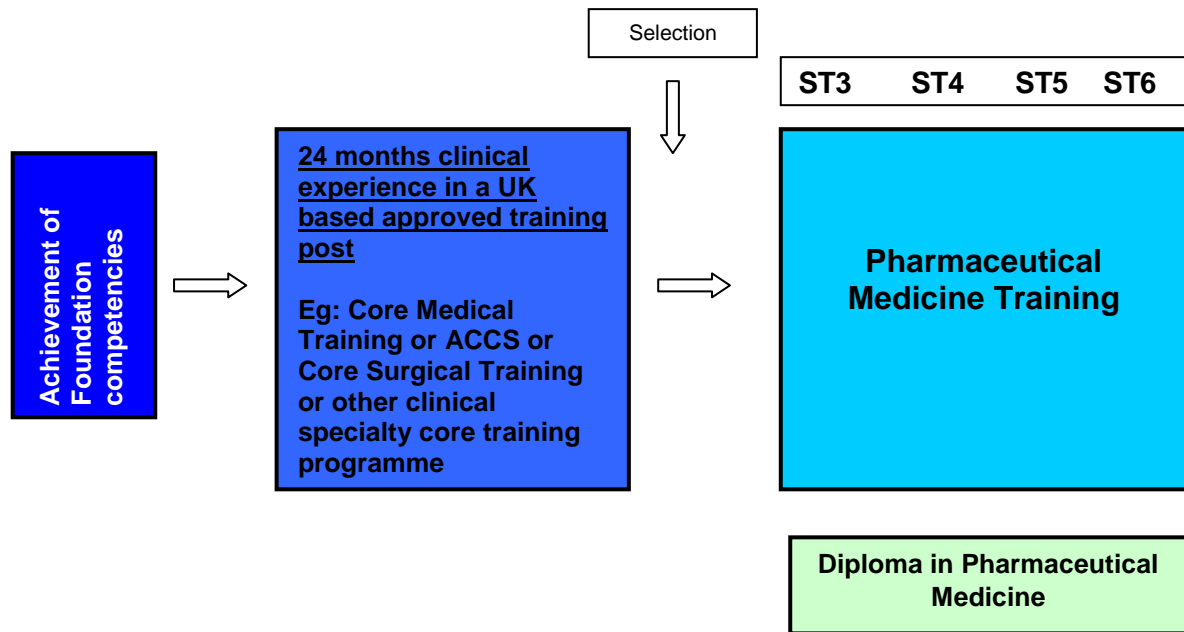
Trainees are required to register for specialty training with the JRCPTB at the start of their training programmes. Enrolment with the JRCPTB, including the complete payment of enrolment fees, is required before the JRCPTB will be able to recommend trainees for a CCT or a CESR. Trainees can enrol online at www.jrcptb.org.uk.

Trainees are required to become Associate Members (Training) of the Faculty of Pharmaceutical Medicine [AFPM(T)] prior to enrolling for PMST. Potential trainees can apply for membership via www.fpm.org.uk. AFPM(T) membership applications are evaluated by the Faculty's Education Committee and, if successful, AFPM(T) follows payment of the appropriate fee (n.b. AFPM(T) is not a Faculty post-nominal).

2.5 Duration of training

Although PMST is a competency-based programme, the duration of training must meet the European minimum of four (4) years for full-time specialty training adjusted accordingly for flexible training (EU directive 2005/36/EC). The SAC-PM has advised that specialty training in pharmaceutical medicine will usually be completed in four (4) years of full-time training.

Figure 1.0 shows the training pathway of a Pharmaceutical Medicine trainee



2.6 Less Than Full Time Training (LTFT)

Trainees who are unable to work full-time are entitled to opt for less than full time training programmes. EC Directive 2005/36/EC requires that:

- LTFT shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities.
- The competent authorities shall ensure that the competencies achieved and the quality of part-time training is not less than those of full-time trainees.

EC Directive 2005/36/EC states that there is no longer a minimum time requirement on training for LTFT trainees. In the past, less than full time trainees were required to work a minimum of 50% of full time. With competence-based training, in order to retain competence, in addition to acquiring new skills, less than full time trainees would still normally be expected to work a minimum of 50% of full time. If you are returning or converting to training at less than full time please complete the LTFT application form on the JRCPTB website www.jrcptb.org.uk.

Funding for LTFT is from deaneries and these posts are not supernumerary. Ideally therefore 2 LTFT trainees should share one post to provide appropriate service cover.

Less than full time trainees should assume that their clinical training will be of a duration pro-rata with the time indicated/recommended, but this should be reviewed during annual appraisal by their TPD and chair of STC and Deanery Associate Dean for LTFT training. As long as the statutory European Minimum Training Time (if relevant), has been exceeded, then indicative training times as stated in curricula may be adjusted in line with the achievement of all stated competencies.

3 Content of Learning

3.1 Programme content and objectives

3.1.1 Overview of Pharmaceutical Medicine Specialty Training (PMST)

The programme of PMST consists of 'The Syllabus for Pharmaceutical Medicine' (PharmaTrain Syllabus), leading to the Diploma in Pharmaceutical Medicine by examination, which must be passed prior to the award of a CCT or CESR, and practical competency-based training in an individualised (*ad personam*) programme centred on an approved workplace training environment (i.e. LEP).

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 'operational' modules are Medicines Regulation, Clinical Pharmacology, Statistics and Data Management, Clinical Development, Healthcare Marketplace and Drug Safety Surveillance.

A seventh, common module in pharmaceutical medicine continues from the Common Module for the Medical Specialties delivered during clinical training with its emphasis on individual patient care within the NHS. The common module in pharmaceutical medicine encompasses Interpersonal, Management and Leadership (IML) skills relevant to the ethical and professional work of a pharmaceutical physician practising outside the NHS.

A minimum of two specialty modules and the common IML module comprise the core practical programme and must be completed in the workplace. The remaining modules can be completed in the workplace or through approved modular interactive courses or through a mix of in-work and course-based training.

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

Throughout PMST, trainees 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.

The pharmaceutical medicine trainee will:

- a) exhibit professionalism in all their activities.
- b) be mindful of the safety of patients, and of healthy and patient volunteer subjects, and
- c) be expected to be competent in all aspects of the curriculum.

3.1.2 Specialty training learning objectives

The PMST programme is defined through its learning objectives:

- **Medicines Regulation:** To acquire and demonstrate a knowledge of and competency in medicines' regulation to the level necessary to fulfil the role of a pharmaceutical physician. To demonstrate the competency to execute tasks

relating to the conduct of clinical trials, Marketing Authorisation procedures, and post-authorisation monitoring of safety, efficacy and quality of medicines in fulfilment of national, European and / or other international regulatory requirements.

- **Clinical Pharmacology:** To acquire knowledge of and competency in clinical pharmacology and supporting disciplines to the level necessary to fulfil proficiently the role of a pharmaceutical physician. To contribute to investigations, judgements and decisions on the clinical pharmacology of a medicine in all phases of its research and development. To 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. To 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.
- **Statistics and Data Management:** 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.
- **Clinical Development:** To acquire competency to prepare a critical overview of the disease area and demonstrate the relevance of developing a product 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.
- **Healthcare Marketplace:** To be able to keep the welfare of patients and clinical trial participants at the forefront of decision-making in the promotion of medicines and design of clinical trials. To acquire knowledge of the healthcare environment in which pharmaceutical marketing takes place; To be able to apply this knowledge and Good Medical Practice to the role of the pharmaceutical physician. To ensure that marketing activities in the healthcare environment are and remain appropriate, ethical and legal.
- **Drug Safety Surveillance:** 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 principles of international regulatory reporting requirements, on the timely revisions of product information and practical methods for managing risk to patients and clinical trial subjects.
- **Common module; Interpersonal, Management and Leadership skills:** To demonstrate a knowledge of, and competency to apply that knowledge appropriately to a number of interpersonal, management and leadership 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.

3.2 Good Medical Practice

In preparation for revalidation, which was introduced on 3 December 2012, the GMC translated Good Medical Practice into a 'Framework for Appraisal and Revalidation' (GMP Framework), which provides a foundation for the development of the appraisal and assessment system for revalidation. The GMP Framework can be accessed at http://www.gmc-uk.org/doctors/revalidation/revalidation_gmp_framework.asp.

The GMP Framework covers the following domains:

- Domain 1 – Knowledge, Skills and Performance:
 - Maintain your professional performance
 - Apply knowledge and experience to practice
 - Keep clear, accurate and legible records
- Domain 2 – Safety and Quality
 - Contribute to and comply with systems to protect patients
 - Respond to risks to safety
 - Protect patients and colleagues from any risk posed by your health
- Domain 3 – Communication, Partnership and Teamwork
 - Communicate effectively
 - Work constructively with colleagues and delegate effectively
 - Establish and maintain partnerships with patients
- Domain 4 – Maintaining Trust
 - Show respect for patients
 - Treat patients and colleagues fairly and without discrimination
 - Act with honesty and integrity

The 'GMP 2013' column in the curriculum Modules (see **section 3.3**) defines which of the four domains of the GMP Framework are addressed by each competency.

3.3 Syllabus

Specialty Knowledge Base

The syllabus for the Diploma in Pharmaceutical Medicine (available at <http://www.fpm.org.uk/trainingexams/exams/dippharmed>) is 'The Syllabus for Pharmaceutical Medicine' (PharmaTrain Syllabus).

Practical Modules in PMST

In the tables below, the 'Assessment Methods' shown are those that are appropriate as possible tools that could be used to assess each competency. It is not expected that all competencies will be assessed using these tools and that where they are assessed not every tool will be used. See **section 5** for more details.

'GMP 2013' defines which of the four (4) domains of the GMP Framework are addressed by each competency. See **section 3.2** for more details.

'Competency level 1': A demonstration of full competency to fulfil the task or activity.

'Competency level 2': A demonstration of the understanding of the underlying principles for the task or activity.

Module 1

Medicines Regulation (RGN)

Aim: To acquire and demonstrate a knowledge of and competency in medicines' regulation to the level necessary to fulfil the role of a pharmaceutical physician; To demonstrate the competency to execute tasks relating to the conduct of clinical trials, Marketing Authorisation procedures, and post-authorisation monitoring of safety, efficacy and quality of medicines in fulfilment of national, European and / or other international regulatory requirements.

ITEM: RGN 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to explain the legislative framework supporting the development and registration of medicines, ensuring their safety, efficacy and quality.	PMAT, PbD, MSF, CBA, DPM	10.1, 10.3, 10.4, 10.7, 10.14	1 - 3
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The Medicines Act 1968, related Statutory Instruments (SI) and the Human Medicines Regulations 2012 as amended. • European Regulations, Directives & Guidelines relating to medicines' development and monitoring of safety and quality. • The ICH (International Conference on Harmonisation) process and the significance of ICH Guidelines. • The requirements for development and registration of medicines. • The regulatory requirements and processes of the European Medicines Agency (EMA) and major national regulatory agencies e.g. Medicines & Healthcare products Regulatory Agency (MHRA). • Regulations, Guidelines, Formats and Contents relating to writing Product Information such as: <ul style="list-style-type: none"> ○ Summary of Product Characteristics (SmPC) ○ Patient Information Leaflets (PILs) ○ Technical Leaflets ○ Package Labelling ○ Advertisements ○ Prescribing information • Penalties for breaches. • The Statutory Rights under which Regulatory Agencies perform Inspections. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To identify, retrieve and assemble documents from all available sources in order to be informed about and to undertake specified regulatory tasks. • To discuss the distinction between Regulations, Directives and Guidelines and their implementation. • To describe the relationship between EMA and national regulatory authorities of the EU. • To work with Agencies and other groups as required with regard to legal and regulatory requirements. • To describe the role and responsibility of the EU Qualified Person for Pharmacovigilance (QPPV). 			

- To describe/write and/or review the format and content of Product Information documents
- To review product-related literature to ensure it is consistent with the terms of the SmPC and any company core documents, and complies with appropriate regulations and codes of practice of appropriate responsible bodies e.g. PMCPA, EFPIA.
- To describe the circumstances under which Regulatory Agencies may order an inspection and be able to address questions raised by the Inspectorate.

Behaviours

The pharmaceutical physician:

- Recognises the need to maintain close contact and work collaboratively with the Regulatory Affairs Department.
- Promotes informed reflection on legal and regulatory issues within a team.
- Works with regulatory colleagues including, where appropriate, those in the national agencies, to advance medicinal development and patient safety.
- Seeks advice from experts and participates in appropriate multidisciplinary meetings to ensure the safety, efficacy and quality of medicines.
- Recognises the SmPC to be a legally binding document that impacts the contents of other product-related literature.
- Understands the need to regularly scrutinise the documents relating to product information e.g. SmPCs, PILs, to ensure their accuracy and effectiveness in promoting the safe and effective use of medicines.
- Recognises the importance of inspections and is well prepared for them, ensuring that records are complete and up to date.

ITEM: RGN 1 (Competency Level 2)

**Assessment
Methods**

**PharmaTrain
Syllabus**

GMP 2013

PbD, CBA, DPM

10.9

1

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- Differences between the EU and US Regulations.
- European requirements for medicines development in the context of the ICH guidelines and their implementation.
- The registration of pharmaceutical products in international markets.

ITEM: RGN 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to describe the regulations relating to post-authorisation safety monitoring and reporting procedures.	PMAT, PbD, MSF, TO, CBA, DPM	10.1, 10.6, 10.9, 10.10 – 10.13, 11.4, 10.21	1, 2
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • Adverse Drug Reaction (ADR) reporting systems, including specially targeted spontaneous reporting schemes. • Drug safety reporting requirements that operate under different legal jurisdictions. • Pharmacovigilance requirements and activities at national, regional and international levels. • How to submit regulatory reports required for: <ul style="list-style-type: none"> ○ marketed products; ○ clinical trials concerning marketed products; ○ registration dossiers for products already marketed elsewhere. • The obligations of the Marketing Authorisation Holder (MAH) with respect to product safety reporting. • The strengths and limitations of various kinds of reports and approaches to identifying safety issues. • Methods allowing for the further investigation and assessment of product safety alerts. • The underlying principles for risk minimisation strategies and periodic measurement of the effectiveness of the activities. • The role and conduct of post-authorisation safety studies (PASS). 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To describe the regulatory actions required for the reporting of safety signals and the immediate and / or future impact of those signals on the development of a product. • To recognise safety signals that are likely to be of greatest concern to Regulatory Agencies and the impact these may have on the future development or use of the product. • To participate in internal company meetings and, where required, advise on dialogue with the Regulatory Agencies to discuss post-authorisation safety signals, reports and potential studies to investigate safety. • To identify various sources of safety data required in an assessment of a (real or hypothetical) safety issue and review /prepare a report for submission to a regulatory authority. • To work in consultation with experts and regulators to evaluate new signals. • To discuss the regulatory approaches to the investigation and assessment of product safety issues and dissemination of information to regulators, investigators and clinicians. • To advise on the requirements regarding the timelines for submission of safety reports to Regulatory Agencies. • To devise an outline of, or appraise a risk management plan (EU RMP) and Risk Evaluation and Mitigation Strategies (USA REMS) for a product (real or hypothetical). 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the necessity for monitoring the safety of marketed products and having effective adverse drug reaction reporting systems. • Recognises the need for pharmaceutical physicians to maintain close collaboration with both the product safety department and Regulatory Agencies. 			

- Recognises the strengths and limitations of in-house systems for collating and interpreting safety databases.

ITEM: RGN 3 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will understand the significance of regular product Safety Update Reports to the regulatory agencies and participate in their preparation and review.	PMAT, PbD, MSF, TO, CBA, DPM	11.1, 11.4, 11.10	1, 2
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • CIOMS and the history of required Safety Update Reports; particularly Periodic Safety Update Reports (PSURs) and Annual Safety Reports (ASRs) / Development Safety Update Reports (DSURs). • The legal requirements for Safety Update Reports. • The contents and format of Safety Update Reports. • The periodicity of submitting Safety Update Reports. • The possible outcomes from the review of a Safety Update Report. • The differences between the various types of Safety Update Reports. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> • To describe the differences between the various types of Safety Update Reports. • To review and assess the known safety information for inclusion in reports. • To assess the content of Safety Update Reports in the context of current prescribing information for a product and the implications for patient treatment / prescribing practice. • To contribute to an update of prescribing information to promote the safe and effective use of medicines. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> • Recognises that Safety Update Reports are a vital means of reviewing proactively the safety of marketed products and products in development. • Realises that Safety Update Reports enable different authorities to be provided with the same comprehensive information on the safety of the drug from all sources. 			

ITEM: RGN 4 (Competency level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to offer advice on the unlicensed uses of medicines and ensure patient safety is paramount.	PMAT, PbD, MSF, TO, CBA, DPM	10.17, 10.26	1, 3
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • Legislation that allows for provision of unlicensed medicines for specific uses. • The legal issues and ethical issues of supplying an unlicensed medicine for compassionate use on a named patient basis. 			

- The legal differences between off-label and unlicensed medicines.

Skills

Demonstrate ability:

- To differentiate between a medicine when used off-label and off-licence, and between the various types of unlicensed medicines.
- To discuss the legal and ethical constraints placed on the use of various types of unlicensed medicines in protecting patients.
- To review and assess requests for making unlicensed medicines available for compassionate use or on a named-patient basis and where appropriate liaise with regulators.
- To generate reasoned scientific arguments supporting the availability of medicines for unlicensed use.
- To discuss the duties of the supplier and the prescriber with respect to unlicensed medicines.
- To discuss regulatory procedures for gaining approval for the provision of an unlicensed medicine.
- To discuss the risks and legal sanctions applicable to Internet advertising and the online procurement of medicines.
- To discuss how to avoid the unauthorised use of unlicensed medicines.

Behaviours

The pharmaceutical physician:

- Recognises why unlicensed product use may be necessary.
- Recognises the need to consult and discuss with regulatory colleagues when requested to make unlicensed product available.
- Is able to illustrate a responsible approach and an ability to balance objectively the risks and benefits of making an unlicensed medicine available.
- Adopts a responsible approach to and objectively balances the risks and benefits regarding the availability and use of unlicensed medicines.

ITEM: RGN 4 (Competency Level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

PMAT, PbD, MSF, CBA, DPM

10.17, 10.26

1

Applied Knowledge

Demonstrate knowledge of:

- Sources of unlicensed medicines and impact of Internet advertising and online pharmacies.
- Procedures for gaining approval for the provision of unlicensed medicines to healthcare professionals.
- Safety monitoring requirements and procedures during the unlicensed use of medicines.
- Measures to promote the use of medicines as approved and avoid the unauthorised use of unlicensed medicines.
- Penalties for promoting the off-label use of medicines.

Behaviours

The pharmaceutical physician:

- Demonstrates an understanding of country-specific provisions with respect to the supply of unlicensed medicines, e.g. the Specials [manufacturing] licence in the UK.

ITEM: RGN 5 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
<p>OBJECTIVE: The pharmaceutical physician will be able to describe procedures in the development of Marketing Authorisations, renewal of Marketing Authorisations and demonstrate competence in contributing to the writing and /or reviewing of Clinical Overviews.</p>	PMAT, PbD, MSF, CBA, DPM	10.3, 10.7, 10.9, 10.11 – 10.13	1
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The structure of the Common Technical Document (CTD). • The structure and contents of a Clinical Overview. • The contents of a registration dossier including the Clinical Data and an overview of the Quality and Non-Clinical Parts. • European centralised, decentralised & mutual recognition procedures for Marketing Authorisation, and: <ul style="list-style-type: none"> ○ significance of the Rapporteur(s); ○ significance of the Reference Member State (RMS). ○ Selection and role of the Concerned Member State(s) (CMS) • National procedures in major EU Member States. • Use of clinical development guidelines and the value and use of scientific advice from national and Europe-wide Regulatory Agencies. • Scientific advice procedures. • The role of advisory bodies. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To discuss regulatory evaluation and approval processes. • To describe the rationale behind the CTD and its relationship to data normally required for registration. • To write and/or appraise Clinical Overviews for a new drug application (or variations, line extensions, abridged documents). • To address questions, particularly on clinical data or content of a proposed SmPC, raised during Regulatory Agency review of new drug applications. • To differentiate between the different European procedures for applications and discuss their advantages and disadvantages. • To discuss the statutory requirements for different European procedures. • To discuss the data requirements for different types of post-approval applications. • To discuss the procedures for extending an indication or target population and amending dose schedules and safety information. • To appraise constructively the applicability and regulatory requirements of different formulations and product combinations. • To discuss the value and timing of scientific advice. • To write and/or review a briefing package when seeking scientific advice from a regulatory body and participate effectively during the scientific advice meetings or in later meetings to discuss advice received. 			

Behaviours

The pharmaceutical physician:

- Appraises the advantages and disadvantages of different procedures with regard to specific therapeutic classes of drugs.
- Recognises the advantages and disadvantages of scientific advice.
- Recognises the significance of a well-written Clinical Overview.
- Recognises that a Marketing Authorisation is an evolving document and the role of medical and regulatory professionals in its evolution.
- Recognises the need to monitor the opportunities and threats to a marketed medicine.
- Recognises their legal obligation to protect public safety and promote the safe and effective use of medicinal products.
- Recognises the need to work in teams and to develop networks to deliver required documentation, ensure it is of high quality and promotes the safe and effective use of medicinal products.

ITEM: RGN 5 (Competency level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

PbD, CBA, DPM

10.13

1

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- US FDA submissions procedures for NDA and IND.
- Appeal and arbitration procedures.
- International differences in the requirements for Marketing Authorisation renewal.

ITEM: RGN 6 (Competency level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

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

PMAT, PbD, MSF, CBA, DPM

7.4, 7.5, 10.10

1, 2, 4

Applied Knowledge

Demonstrate knowledge of:

- The European Clinical Trials (CT) Directive.
- National guidance relating to “first time in man” (FTIM) studies and the legal obligations of centres conducting FTIM studies.
- The contents of the Investigators’ Brochure (IB).
- Clinical Trials Applications (CTAs).
- National clinical trials legislation including conditions placed on study amendments, ongoing safety reports and termination.
- ICH Good Clinical Practice (GCP) and its impact upon the validity of a licence application.

Skills

Demonstrate ability:

- To discuss the impact and implications of the European Clinical Trials Directive and FTIM regulations and guidance.
- To write medical contributions to and / or constructively review the IB.
- To discuss the obligations of the Sponsors of clinical trials.
- To contribute to the writing of protocols for clinical trials.

Behaviours

The pharmaceutical physician:

- Recognises the need to regulate clinical trials.
- Adopts a highly ethical and scientific approach to setting up clinical trials.
- Recognises that investigators and regulators need up-to-date safety information for safe conduct and appraisal of clinical trials.
- Recognises the risks (ethical, clinical and regulatory) associated with poorly designed or executed clinical trials.
- Recognises the importance of close collaboration with investigators and regulatory authorities on the progress of clinical trials.

ITEM: RGN 6 (Competency Level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

PbD, CBA, DPM

10.10

1

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- US Investigational New Drug (IND) procedures.
- Problems associated with global drug development.

ITEM: RGN 7 (Competency Level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

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

PMAT, PbD, MSF, CBA, DPM

10.16

1, 2

Applied Knowledge

Demonstrate knowledge of:

- The regulatory procedures for changing the legal classification of medicines.
- Local national classification systems for availability of medicines e.g. POM / P / GSL criteria and the relevant criteria for classification.
- The role of a Risk Management Plan in product classification including the need to reevaluate the risk-benefit profile if reclassification is accompanied by changes to a product's strength, dose, route of administration, age group or indication.
- Patient Group Directions.
- Controls over the use and promotion of non-prescription medicines.
- Monitoring the safety of non-prescription medicines.

Skills

Demonstrate ability:

- To evaluate and advise on data in relation to proposed changes in legal classification.
- To assess the effect of changes in legal classification on:
 - Public safety
 - Public health
- To review constructively and/or produce an outline of a Clinical Overview for a legal status reclassification application.
- To evaluate the safety implications of making drugs available over-the-counter.
- To discuss the limitations placed on the advertising of non-prescription medicines.

Behaviours

The pharmaceutical physician:

- Recognises the advantages and potential disadvantages of the deregulation of medicines.
- Understands the need to consult relevant stakeholders when considering the deregulation of a medicine.
- Understands the importance of monitoring the safety of medicines available without a prescription.
- Ensures that promotion of the product to the public is responsible and aligned with a product's risk of misuse.

ITEM: RGN 8 (Competency Level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

The pharmaceutical physician will be familiar with the investigation of product defects, counterfeit products, and other miscellaneous pharmaceutical procedures & requirements.

PbD, CBA, DPM

10.5, 10.18 - 10.20, 10.24

1

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- The identification, investigation, management and communication of product defects including product withdrawal.
- The identification and management of counterfeit medicines including relevant communication with the Authorities.
- The impact of product defects and counterfeit medicines on public health, patient safety, and organisational reputation.
- The maintenance of a manufacturer's/wholesaler's licence and the role and remit of inspection.
- The application for and maintenance of import and parallel import licences.
- Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Distribution Practice (GDP).
- The regulation of other non-medicinal products e.g. herbals, cosmetics, devices.
- The role, use and hierarchy of Pharmacopoeias.

Module 2

Clinical Pharmacology (CLP)

Aim: To acquire knowledge of and competency in clinical pharmacology and supporting disciplines to the level necessary to fulfil proficiently the role of a Pharmaceutical Physician; To contribute to investigations, judgements and decisions on the clinical pharmacology of a medicine in all phases of its research and development; To 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; To 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.

ITEM: CLP 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to exercise judgement of non-clinical pharmacology and toxicology firstly in deciding to evaluate a new drug candidate in humans, secondly in the initial choice of dosage, and thirdly in planning a progressive development programme leading to marketing authorisation.	PMAT, PbD, MSF, CBA, DPM	1.2, 1.3, 1.5, 1.7, 3.1 – 3.11	1 – 3
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • Pre-clinical tests of a candidate drug's pharmacology and toxicology. • ICH Topic M 3, Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals. • The clinical significance of in vitro and in vivo animal pharmacology including, for example, P450 studies. • Standard animal toxicology study designs and toxicokinetics. • Animal: Human toxicity concordance, species variability. • Differences in the pre-clinical evaluation of small chemical molecules and biologics (biological medicinal products, EMA definition). 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To identify the evidence for a candidate investigational product's potential value from pre-clinical studies in various species, either whole animal or isolated organ and tissue models, and in models of disease. • To relate longer-term animal toxicology to the potential therapeutic indications and dosages. • To use preclinical metabolism data to identify necessary clinical drug interaction studies. • To interpret and evaluate the safety of an investigational product in order to mitigate risk, and plan a safe clinical development programme. 			
Behaviours			
<p>The pharmaceutical physician:</p> <ul style="list-style-type: none"> • 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. 			

- Recognises the benefits and pitfalls of extrapolating preclinical data to the predictions of drug effects in man.
- Communicates the relevance of the preclinical data to others working on the investigational product's development.

ITEM: CLP 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will have the ability to identify and review relevant literature and other sources and to write manuscripts for publication.	PMAT, PbD, MSF, CBA, DPM	2.3, 7.19, 9.22, 9.25, 12.6	1, 3
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • Readings of other work in the field and of important requirements to meet clinical needs. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> • To conduct or review a literature search concerning clinical pharmacology. • To discuss all relevant publications. • To review constructively all relevant publications. • To provide a comprehensive review of a therapeutic field and the met and unmet needs. • To describe how Phase I fits into an overall Clinical Development Plan. • To review or contribute to the preparation of a manuscript or document as a joint author on clinical studies for submission to a peer-reviewed journal or a regulatory authority. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> • Maintains knowledge of current literature in the relevant therapeutic field and familiarity with recent advances in clinical pharmacology and therapeutics. • Communicates advances in clinical pharmacology with colleagues. 			
ITEM: CLP 2 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
	PbD, CBA, DPM	5.5 – 5.11, 9.5 – 9.21	1
Applied Knowledge			
Demonstrate an understanding of the underlying principles for:			
<ul style="list-style-type: none"> • Knowledge of relevant statistical methods and analyses. • Pharmacokinetic analyses and modelling. 			

ITEM: CLP 3 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: 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.	PMAT, PbD, MSF, CBA, DPM	3.1 – 3.11	1, 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • Relevant and current regulations. • How, in particular, the pharmacology and toxicology data necessary for Phase 1 studies must be designed, reviewed and approved in readiness for clinical trials. • Components of the Clinical Development Plan required in Europe. • Components of a regulatory licensing (marketing) submission required in Europe. • Awareness of, and how to obtain advice on, US and Japanese regulatory needs. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To define or review the planned clinical pharmacology of the candidate investigational product before clinical trials are begun. • To anticipate possible disease-related variations in drug handling in patients compared with normal healthy subjects. • To react to unexpected findings promptly and, if necessary, suspend further work while other expert opinions are obtained and the issue is clarified. • To describe past problems in this clinical or therapeutic area that have led to regulatory refusal of trials or their modification. • To write or review Expert Reports, Clinical Overviews and Product Information. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Accepts a pivotal role in preparation of a development plan that requires knowledge and judgement. • Recognises the value of liaison with other experts in related fields in the design and interpretation of studies. • Exhibits strict compliance with regulations and guidelines. • Understands the need to keep senior management informed. 			

ITEM: CLP 4 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To have a thorough knowledge of the design, execution and analysis of early-phase drug studies in man.	PMAT, PbD, MSF, CBA, DPM	2.3, 2.4, 5.1 – 5.4, 5.5. – 5.13, 7.2, 8.3 – 8.11, 8.13, 8.14	1 – 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The objectives of early phase drug studies in man. The rationale, advantages and disadvantages of the use of healthy or patient volunteers in early-phase drug studies. To be aware when there is a requirement for the inclusion of special populations e.g. elderly, female in early phase studies. • The objectives and limits to be applied in order to maximise the information obtained and to avoid or minimise risks to study subjects. • Human pharmacokinetics, pharmacodynamics and pharmacogenetics. • Selecting dose range and increments relating to minimum effective and maximum tolerated doses. • Regulatory and legal requirements in human studies. • The degree of biological variation seen in a normal population. • The reasons and need for full screening of healthy volunteers. • Adaptive design. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To contribute to or review the design of human studies in order to fulfil their aims. • To define the subsequent aims and safeguards in healthy volunteer studies and early patient trials; instil these and monitor compliance. • To select safety measures based on pre-clinical data and related drugs. • To check and interpret any physiological changes observed. • To propose or review any dosing changes or limits for subsequent Phase 2 or Phase 3 studies. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises responsibilities to study volunteers in order to ensure their safety. • Imparts this ethos to others and monitors that safeguards are being applied. • Recommends any actions needed as studies progress, such as stopping planned dose escalation or introducing new safety checks. • Consults with other company experts in related fields and outside advisers and investigators with expertise and knowledge of clinical pharmacology. 			

ITEM: CLP 5 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be conversant with the ethical principles and practices governing clinical research with volunteer subjects.	PMAT, PbD, MSF, CBA, DPM	8.2 – 8.11	1 – 4
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • Basic principles of the protection of research subjects. • Practical procedures in providing full information to participants and their doctors, and in obtaining and recording their informed and continuing consent. • Ethical review of studies from first-time-in-man (FTIM) to large-scale clinical trials. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To maintain these ethical principles and practices in the setting up and regular inspections of investigator sites. • To be involved in reviewing or writing and approving clinical study information sheets and consent forms for volunteer subjects. • To participate in or have experience of Ethics Committee meetings, as an applicant and / or as a member. • To use appropriate lay language for study subjects and their relatives. • To review or oversee the outcomes of site inspections and audits and make personal visits to sites as required. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Regards human research with new drug candidates as imposing the same, and at times even greater, responsibilities as those required in routine medical practice. • Instils these principles and practices within the research organisation and local investigating teams. 			

ITEM: CLP 6 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to apply the principles of Good Clinical Practice (GCP) in clinical pharmacology.	PMAT, PbD, MSF, CBA, DPM	10.4, 10.5, 5.13	1, 2, 4
Applied Knowledge			
Demonstrate knowledge of: The ICH Good Clinical Practice (GCP) principles and practices and their application throughout the development programme. Safeguards for volunteer participants in early-phase studies and those for patients that must be followed.			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To plan or review a series of clinical pharmacology investigations, within the GCP framework, 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. To ensure that quality assurance checks are made and acted upon. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> Ensures that as a team member and often the only medical graduate, the welfare of subjects in clinical studies, whether therapeutic or non-therapeutic, is paramount. Treats all trial subjects as individuals with courtesy, empathy, compassion, professionalism and respect for their dignity. Recognises the need for stringent adherence to procedures and maintenance of full and accurate records. 			

ITEM: CLP 7 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to investigate the clinical pharmacology of a new medicine in a stepwise manner within the overall clinical development plan.	PMAT, PbD, MSF, CBA, DPM	2.1, 2.3, 5.1 – 5.13, 6.1 – 6.6, 10.10, 14.1, 14.6	1, 3
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The clinical pharmacology requirements in a regulatory submission for approval of a new medicine and in a Summary of Product Characteristics (SmPC). The application of 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. Causes of variability in human drug response. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To 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. To identify the likely dose range and, early on in the programme, measure its clinical effects 			

(proof of concept).

- To identify further studies with other drugs in that therapeutic class aimed to determine their comparative efficacy and ADME (absorption, distribution, metabolism, excretion) profiles.
- To judge real and potential benefits of the new medicine and likely safety problems to be encountered.
- To 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.

Behaviours

The pharmaceutical physician:

- Recognises the need to characterise in ADME studies how a new medicine is handled in the human body.
- 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.
- Communicates the importance of clinical pharmacology to other members of the development team.

ITEM: CLP 8 (Competency Level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

The pharmaceutical physician will be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs.

PMAT, PbD, MSF, CBA, DPM

14.1 – 14.5

1, 3

Applied Knowledge

Demonstrate knowledge of:

- The causative factors, pathophysiology and main therapeutic options in one major organ-based disease.
- The benefits and shortcomings of current therapy, and thereby identifying new therapeutic needs in one major organ-based disease.
- How advancing knowledge, such as pharmacogenomics and pharmacogenetics, may tailor therapy.

Skills

Demonstrate ability:

- To 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.
- To contribute to proposed investigations and profiling of a new theoretical agent by applying key principles of efficacy, safety and economic value.

Behaviours

The pharmaceutical physician:

- As part of a research team, consults with academic and clinical experts in the therapeutic area to learn therapeutic aims, achievements and needs.
- Creates an idealised drug profile and, in doing so, recognises constraints in clinical practice and in health service provisions.

MODULE 3

Statistics and Data Management (SDM)

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.

ITEM: SDM 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to explain the statistical principles in the design of clinical studies.	PMAT, PbD, CBA	9.5, 9.6, 9.8 – 9.12	1, 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The key principles for the design and conduct of clinical trials as contained in documents such as the ICH Guideline ‘Statistical Principles in Clinical Trials.’ • The use of control, blinding, randomisation and other methods for the reduction of bias in clinical trials. • Hypothesis testing, the null and alternative hypotheses and significance testing. • The principles of power, type II error and sample size, the reduction of variation and other methods for increasing precision in clinical studies. • The principles behind statistical methods, such as the pre-specification of methods of analysis, the control of type I error and use of intention-to-treat to reduce bias. • Statistical issues in the choice of endpoints. • The concepts of sensitivity and specificity in diagnosis. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To select the most appropriate design structure: superiority; equivalence; non-inferiority; dose-response - in order to meet the needs of the drug development programme. • To provide clinical input into sample size calculations, the selection of primary and secondary endpoints, choice of comparator and methods of interim analysis. • To understand differences in types of data and how to ensure standardisation. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the importance of working with a statistician in the design of clinical studies. • Recognises the importance of pre-trial decisions and specifications; risk factors; understanding of potential confounding variables. 			

ITEM: SDM 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to provide a clinical input into the construction and review of a Statistical Analysis Plan.	PbD, CBA, DPM	9.7, 9.21, 9.23	1, 2
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The structure of a Statistical Analysis Plan. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To review a Statistical Analysis Plan. To document the reasons for the inclusion/exclusion of patients. To identify the reasons for the inclusion of patients in samples for analysis. To plan the presentation of the results of the statistical analysis in the clinical study report. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> Recognises the role of the pharmaceutical physician in the construction and review of a Statistical Analysis Plan. 			

ITEM: SDM 3 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to explain the commonly used statistical principles and methods for the analysis and presentation of data in clinical studies; including combining data from across clinical studies as in meta-analyses.	PMAT, PbD, CBA, DPM	9.14 – 9.19, 9.21, 9.22	1, 3
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The key principles for the analysis and reporting of clinical trials as contained in documents such as the ICH Guideline 'Statistical Principles for Clinical Trials'. The role of hypothesis testing, P-values, summary statistics, confidence intervals and modelling in the statistical analysis of data. Paired and non-paired tests, parametric and non-parametric tests, confidence limits. 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. Methods for handling missing data in statistical analyses. The role of meta-analysis in the analysis and presentation of results from a series of clinical studies. To identify the criteria for the inclusion of trials in a meta-analysis to answer key questions and present the results of such an analysis. To appraise constructively a meta-analysis. 			

Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To interpret the results of a statistical analysis of data based on methods including: survival analysis; analysis of covariance; logistic regression. To assess impact of violations, withdrawals, errors, bias. To explain analysis and handling of data from rating and visual analogue scales, patient diaries and laboratory values. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> Recognises the importance of the use of appropriate statistical methodology for the correct interpretation of clinical studies. 			
ITEM: SDM 3 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
	PbD, CBA, DPM	8.17, 9.14, 9.20, 9.23, 9.24	1, 3
Applied Knowledge			
Demonstrate an understanding of the underlying principles for:			
<ul style="list-style-type: none"> Statistical methods, such as the analysis of covariance and the choice of statistical test, for maximising precision when analysing data. The methods of statistical analysis for investigating the homogeneity of the treatment effect. The methods of statistical analysis for the detection of fraud and misconduct. 			

ITEM: SDM 4 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE:	PbD, CBA, DPM	9.5, 9.6, 9.12, 9.14, 9.16, 9.20 – 9.23	1, 3
To understand the statistical principles for the design, conduct, analysis and reporting of health economic studies, non-interventional studies (such as epidemiological and observational studies), Post-Authorisation Safety Studies (PASS), studies or signal searching work using drug databases.			
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The statistical principles of benefit/risk assessments. The major pharmaco-epidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases. The processes for identifying safety signals. Patient-reported outcomes, e.g. diaries, quality of life measures. The principles used in the assessment of Health Economics. Case-control and cohort studies and describe their role in pharmacovigilance. Incidence and prevalence. Sensitivity and specificity tests. The appropriate choice and validation of measures for evaluating various subjective and objective Quality of Life measures. 			

Skills

Demonstrate ability:

- To describe the statistical principles of benefit / risk assessments.
- To define appropriate parameters for database searches.
- To describe the expectations of incidence when differentiating the pharmacologically identified event from the unexplained event.
- To describe the objectives in the study of Health Economics.
- To describe differences between:
 - Discounted life cycle revenue per molecule;
 - Patient rated outcome measures;
 - Examples including the ratings preferred by NICE.

Behaviours

The pharmaceutical physician:

- Recognises the importance of ICH requirements in ensuring that all forms of clinical trials and scientific studies are designed, conducted, analysed and reported in a scientifically valid way.
- Recognises the importance of benefit / risk assessments in regulatory submissions.
- Recognises the importance of signal evaluation, causality assessment and the communication of relevant findings as a key responsibility in helping to safeguard future patients.
- Recognises the benefits of identifying events related to an agent's pharmacology.
- Works collaboratively with colleagues and recognises the importance of Health Economics in the development of submissions to review bodies, such as NICE in the UK.

ITEM: SDM 5 (Competency Level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE: To be able to undertake a constructive review of the statistical methods used and presented in reports and publications.

PMAT, PbD,
CBA, DPM

9.21 – 9.25

1 - 3

Applied Knowledge

Demonstrate knowledge of:

- The key statistical aspects of a clinical study that should be included in a publication or report.

Skills

Demonstrate ability:

- To interpret the results of a statistical analysis based on commonly used statistical procedures presented in a publication or report.

Behaviours

The pharmaceutical physician:

- Recognises the need to be able to review constructively published clinical studies and the importance in the publication of a full description of statistical methodology to ensure proper understanding of the analysis, interpretation and limitations of the scientific work.

ITEM: SDM 6 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to understand the principles of Case Report Form design and clinical data management, including CDISC (Clinical Data Interchange Standards Consortium), Electronic Data Capture and MedDRA, and to be able to provide input to the review of clinical data.	PMAT, PbD, CBA, DPM	9.1 – 9.4	1 - 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The key areas where data management contributes to the clinical trial process. • The impact of poor Case Report Form (CRF) design on the conduct of the clinical trial. • Common issues with CRF completion at the study site and the importance of training site staff and CRAs. • The data management processes involved in data collection from source documents to CRF completion, CRF review and corrections, data entry, query generation and resolution, coding of data, database lock. • 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. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To list the key areas where data management contributes to the clinical trial process. • To identify examples of good CRF design practice and examples of poor CRF design. • To identify common problem areas in CRF completion. • To describe the data cleaning process post data-entry in a paper environment. • To advice on handling of missing data, assessment of violations, withdrawals and errors. • To describe the typical contents of a Data Validation Plan. • To list examples of areas where physicians can provide consultative advice to resolve data issues. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the need to involve data management in all phases of a clinical trial to ensure efficient data collection and robust data for analysis. • Recognises the importance of physicians contributing to reviews of CRF design. • Recognises the need for data management to be involved in training site staff and CRAs during study set-up. • Recognises the importance and impact of medical monitoring, physicians participating in data review/analysis and providing guidance to teams, to ensure a clinically correct database for analysis. 			

ITEM: SDM 6 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
	PbD, CBA, DPM	9.1	1 - 3
Applied Knowledge			
<p>Demonstrate an understanding of the underlying principles for:</p> <ul style="list-style-type: none"> • The internationally recognised databases such as CDISC. • The Electronic Data Capture (EDC) process and the differences in data cleaning activities and role of data management. • MedDRA structure, uses and support and how coding is performed. • Creation, maintenance and security of databases, software validation and archiving. 			

MODULE 4

Clinical Development (CLD)

Aim: To acquire competency to prepare a constructive overview of the disease area and demonstrate the relevance of developing a product 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 constructively 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.

ITEM: CLD 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To be able to describe the data required and how to obtain, analyse and apply them in order to undertake an analysis of a disease area within the industry clinical development environment.	PMAT, PbD, MSF, CBA, DPM	1.1, 2.3, 2.4, 2.5, 5.1, 6.1 – 6.3, 9.23, 9.25, 11.3, 11.11	1, 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • Searching the clinical literature. • How to evaluate and interpret the findings in the clinical development environment. • Target Product Profile. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To conduct a clinical literature search. • To prepare a literature review of a specified disease area. • To write or review constructively a brief report describing: <ul style="list-style-type: none"> ○ The epidemiology and pathophysiology of the disease area; ○ Therapies available and their mechanisms of action; ○ A summary of products under development in this area; • Unmet medical / therapeutic need in this area. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • 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. • Works as part of a team to ensure the fullest understanding of non-clinical, clinical and commercial data and their relevance to the disease area review. 			

ITEM: CLD 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To understand and be able to evaluate non-clinical and Phase I data as they are applied to a Clinical Development Plan for a new drug.	PMAT, PbD, MSF, CBA, DPM	1.1, 1.9, 5.1 – 5.13, 6.1, 6.2, 11.2 – 11.3, 11.8, 11.13	1 - 3
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The justification for the non-clinical safety and toxicology data required for a new product development. • What research, studies and data should be available to make an informed decision to proceed to clinical efficacy studies (Phase II). • The information and data that would preclude the ongoing development of a product. • What types of adverse effects are likely to be encountered in clinical trials for the pharmaceutical agent under development. • The Phase 1 data that would be gathered in clinical pharmacology for a potential new medicine to help determine dose and dosing intervals. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To write a reasoned critique on whether there are appropriate safety data to proceed into clinical efficacy trials for a new drug (real or hypothetical). • To evaluate the clinical pharmacology data for a new drug real or hypothetical. • To review, evaluate and discuss the safety and toxicology data for a new drug candidate (real or hypothetical) planned for a clinical trial programme, from the first-time-in-man (FTIM) studies onwards. • To recommend, with reasons, on the basis of non-clinical and Phase I data, a range of doses to be studied in Phase II. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises that there are many aspects that determine whether a drug can proceed to efficacy trials which are not the remit of the physician e.g. formulation issues, cost of goods etc. In practice it is a team recommendation to which the physician contributes. • Recognises the importance of a medical input to the evaluation of early development data, and shares this with the product development team. • Recognises the value of healthy volunteer studies in product development and participates actively in their evaluation. • Consults with colleagues in the product development team on the impact of early development data on the direction and design of Phase II studies. 			

ITEM: CLD 3 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To demonstrate an understanding of the various end-points used in clinical trials, including clinical outcomes, laboratory values, biological markers used as surrogate end-points and imaging techniques.	PMAT, PbD, MSF, CBA, DPM	1.8, 1.9, 5.1, 5.13, 10.5, 11.2, 11.3, 11.4, 11.13, 11.14	1
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The main imaging techniques used currently in clinical trials. • The main laboratory methods used in clinical trials. • The use and examples of surrogate markers and their difference from clinical endpoints. • The utility of patient-reported and observer-reported outcomes. • Trial design features, including endpoints, needed for Health Technology Appraisal (HTA) procedures. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To recommend, with reasons, appropriate clinical, imaging, laboratory methods and surrogate markers and patient-reported outcomes for a study protocol (real or hypothetical). • To discuss the merits of different study designs (e.g. all-comers v. enriched design strategy). 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the contribution of new technologies and approaches in the field of clinical research on new medicines. • Recognises the time-limitation of publications in a rapidly developing technical field. 			

ITEM: CLD 4 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To understand and be able to construct or assess a Clinical Development Plan for the clinical development of a new product.	PMAT, PbD, MSF, CBA, DPM	2.3, 5.3, 6.2 – 6.5, 9.8, 11.3, 11.8	1, 3
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • The elements of a Clinical Development Plan, including: <ul style="list-style-type: none"> ○ The key studies required for registration; ○ The primary and secondary endpoints; ○ Timelines for study and programme completion; ○ Possible risks that would threaten the plan. • The objectives of marketing support studies. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> • To write or contribute to a Clinical Development Plan for a new drug (real or hypothetical). 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> • Recognises the role, value and benefit of the team approach to clinical development and recognises the contribution of others (such as representatives from PV, statistics, operations, medical affairs, translational medicine and marketing representatives, and external experts) to the successful Clinical Development Plan. 			

ITEM: CLD 5 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To understand the principles underpinning the development of a clinical trial protocol.	PMAT, PbD, MSF, CBA, DPM	2.7, 5.2, 5.4, 7.1, 7.2, 7.3, 7.6, 9.13, 11.2 – 11.4, 11.13, 11.14	1
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • The required critical data, and other information for inclusion in a study. • Choice of design for a clinical trial. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> • To contribute to the design and preparation of a study protocol for a new drug (real or hypothetical). • To review constructively a number of outline protocols considering: <ul style="list-style-type: none"> ○ how they achieve the aims of the Clinical Development Plan; ○ how they comply with ethical requirements. 			
Behaviours			

The pharmaceutical physician:

- Recognises the value of carefully thought out protocols in clinical development and participates actively in their development.
- Is aware of how clinical trials can be conducted in the real world within the target timelines and allocated budget and the need for a risk management plan for the project.

ITEM: CLD 5 (Competency Level 2)**Assessment Methods****PharmaTrain Syllabus****GMP 2013**

PbD, CBA, DPM

9.1, 9.2, 11.2, 11.4

Applied Knowledge**Demonstrate an understanding of the underlying principles for:**

- The design of Case Report Forms (CRFs) and other data capture tools, both electronic and paper-based, and their key features to ensure that data are collected in a practical and unambiguous way.

ITEM: CLD 6 (Competency Level 1)**Assessment Methods****PharmaTrain Syllabus****GMP 2013****OBJECTIVE:**

To have a clear understanding of, and be able to apply, the regulatory and ethical aspects underpinning clinical development.

PMAT, PbD, MSF, CBA, DPM

6.6, 7.4, 10.1 – 10.4, 10.7, 10.9, 10.10, 10.13, 11.3, 11.4, 11.5, 11.16

1 – 4

Applied Knowledge**Demonstrate knowledge of:**

- The principles of the Declaration of Helsinki and the content of the latest version. In addition the pharmaceutical physician needs to know how the regulatory authorities in the EU and USA view and apply the Declaration.
- The ethical issues that might arise from clinical trials.
- The requirements of ICH Good Clinical Practice (see RGN 6).
- The European Clinical Trials Directive (see RGN 6).
- The regulatory requirements for clinical trials in UK, EU and USA, including conducting studies outside the US but under FDA IND regulations Knowledge of UK Statutory Instruments.
- Clinical Trial Application (CTA) procedures (UK) (see RGN 6).
- The EUDRACT database.

Skills**Demonstrate ability:**

- To predict and address the ethical issues arising from clinical studies.
- To draft or review constructively an informed consent form that includes all the ICH-required elements, written in appropriate, patient-friendly language.
- To write or review constructively the clinical section of a CTA and / or an IND.

Behaviours**The pharmaceutical physician:**

- Recognises the ethical environment in which clinical trials are conducted and the contribution made by patients in agreeing to participate in clinical research.
- Recognises that clinical development is a global process regulated by differing regional frameworks.

ITEM: CLD 7 (Competency level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
<p>OBJECTIVE: To have a good working knowledge of the management and conduct of clinical trials, working as part of a team.</p>	PMAT, PbD, MSF, CBA, DPM	2.2, 2.3, 4.1 – 4.6, 7.7 – 7.10, 7.12 – 7.14, 7.16 – 7.18, 9.3, 9.4, 11.2, 11.4	1 – 4
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The time required and project management skills needed to set up a study, identify, assess and recruit investigators and gain their cooperation. • The role of CROs (Contract Research Organisations) in the conduct of clinical trials. • The legal and ethical factors impacting clearance for clinical trial supplies, Case Report Forms (CRFs) and other relevant materials. • 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, within trial decisions, site close-out procedures, CRF correction, source data verification, GCP documentation, trial master file, investigator payments, checks for data quality. • The requirements for: <ul style="list-style-type: none"> ○ financial disclosure; ○ data protection. • Audit and inspection procedures applied to studies before, during and after their conduct. • The reasons for internal QA procedures and the possibilities for mandated external audits and inspections. • The role and responsibilities of the QA department. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To contribute to the development of a project management plan for the clinical development of a new product (real or hypothetical). This should include key milestones. • To describe how to arrange appropriate legal and ethical clearance for clinical trial supplies, Case Report Forms (CRFs) and other relevant materials. 			
Behaviours			
<p>The pharmaceutical physician:</p> <ul style="list-style-type: none"> • Recognises that successful product development requires a multi-disciplinary team approach to which the physician must make timely and effective contributions. • Recognises the need to be extra vigilant when studies are planned for countries where ethical and legal standards are more difficult to enforce. • Consults with colleagues in the product development team on the impact of delays to the project plan and how these may be minimised or compensated. 			

ITEM: CLD 8 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to provide a full and detailed evaluation of all suspected adverse events occurring in clinical trials.	PMAT, PbD, MSF, CBA, DPM	7.15, 9.4, 10.4, 10.21, 10.22, 11.1 – 11.4, 11.6, 11.8, 11.13, 11.16	1, 2
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The ICH E6 guideline definition and classification of adverse events and use of MedDRA terminology. The working requirements for adverse event reporting at each stage of product development in UK, EU, USA. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To evaluate adverse events for severity and causality. To categorise and 'report' some hypothetical examples of adverse events based on patient case histories. To be vigilant for identifying adverse events that are not necessarily drug-related, but have been associated historically with adverse reactions for other drugs, and are therefore worthy of heightened pharmacovigilance e.g. hepatotoxicity, Stevens Johnson Syndrome. 			
Behaviours			
The pharmaceutical physician:			
<ul style="list-style-type: none"> Recognises the importance of a thorough evaluation of all emerging safety data as part of the developing safety profile of a product, in order to identify adverse safety signals early and avoid exposing patients to unnecessary risk. 			

ITEM: CLD 9 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to interpret and explain the results of clinical studies and be able to create and constructively evaluate clinical study reports and manuscripts prepared for publication.	PMAT, PbD, MSF, CBA, DPM	7.11, 7.19, 9.22, 9.23, 11.13, 11.15, 11.16	1 – 4
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> The process involved in the preparation of clinical study reports and 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. The establishment and use of clinical trial registries. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> To interpret and explain the results of clinical studies in close cooperation with statisticians and disease experts. To write clear, coherent and comprehensive reports of clinical research undertaken. To summarise the results of a programme of clinical research. 			

- To assess the design and conduct of studies for a product (real or hypothetical).
- To constructively review the results to determine the clinical significance of the data.
- To assess the risks and benefits of a potential new medicine.
- To explain the principles of meta-analysis.

Behaviours

The pharmaceutical physician:

- Recognises the scientific and ethical imperative to submit the results of scientific research to peer review.
- 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.
- Recognises the impact of clinical trial data on the stock market.

MODULE 5

Healthcare Marketplace (HMP)

Aim: To be able to keep the welfare of patients and clinical trial participants at the forefront of decision-making in the promotion of medicines and design of clinical trials; To acquire knowledge of the healthcare environment in which pharmaceutical marketing takes place; To be able to apply this knowledge & Good Medical Practice to the role of the pharmaceutical physician; To ensure that marketing activities in the healthcare environment are and remain appropriate, ethical and legal.

ITEM: HMP 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To demonstrate an understanding of the commercial 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 the use of medicines.	PMAT, PbD, MSF, CBA, DPM	10.1, 10.2, 10.15, 12.4, 13.5 – 13.7, 13.10	1, 3
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The various components of the legal and regulatory framework in which pharmaceutical medicine needs to operate: • the role of the MHRA and other regulatory bodies; • the Medicines Act; the Human Medicines Regulations 2012 as amended; the Bribery Act 2010; • UK Advertising Regulations (The Blue Guide); • the principles of self-regulation and complaints processes; • the Code of Practice for the Pharmaceutical Industry (UK ABPI Code of Practice), PAGB Codes; • other regulations, codes and guidelines applying to Pharmaceutical Physician'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; the role of the MHRA and other regulatory bodies; • GMC (UK) and Good Medical Practice; • product life-cycle management including impact of clinical studies. • the key stakeholders and the main healthcare organisations (public & private) within the relevant UK healthcare environment, (e.g. NHS, Department of Health, MHRA, NICE, SMC, and other health technology assessment groups), and in other key markets, e.g. IQWiG in Germany, the French National Authority for Health (HAS); • The contribution and decision-making processes, in relation to the marketing of medicines, within the healthcare environment, of: <ul style="list-style-type: none"> ○ The National Institute for Health and Care Excellence (NICE) or equivalent; ○ value assessments of pharmaceuticals; ○ disease management guidelines; ○ Drugs and Therapeutics Committees; ○ computerised prescribing systems • Reference works e.g. BNF, Martindale, MIMS. 			
Skills			

Demonstrate ability:

- To analyse the roles, importance, relative contribution and interactions of these components in supporting the legal and regulatory framework within which pharmaceutical medicine operates.
- To evaluate the major interactions between the key stakeholders in the healthcare marketplace.
- To interpret the interactions between the different groups and processes and how they can affect the use of medicines.

Behaviours**The pharmaceutical physician:**

- Recognises the significance and authority of different levels of the law/regulation in the interpretation and operation of the legal and regulatory framework.
- Recognises how these groups influence the use of medicines within the healthcare environment.
- Recognises how these interactions influence the provision of healthcare.

ITEM: HMP 1 (Competency level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
	PbD, CBA, DPM	13.5, 13.7	1, 3

Applied Knowledge**Demonstrate an understanding of the underlying principles for:**

- The role of the NHS Business Services Authority (Prescription Pricing).
- Distribution channels for medicines, including parallel importing.
- Reimbursement mechanisms and pharmaceutical pricing regulations.

ITEM: HMP 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
----------------------------------	--------------------	----------------------	----------

OBJECTIVE: 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.	PMAT, PbD, MSF, TO, CBA, DPM	10.14, 10.15, 10.23, 12.1 – 12.8, 13.6	1 – 4
--	------------------------------	--	-------

Applied Knowledge**Demonstrate knowledge of:**

- The process involved in the preparation and production of legally compliant communications to support medical-marketing activities.
- The relevance of targeting materials to the appropriate audiences e.g. journals / conferences, and ensuring consistency with commercial messages.
- Product information legislation and guidance with reference to the Human Medicines Regulations as amended, and the Code of Practice for the Pharmaceutical Industry.
- 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.

Skills

Demonstrate ability:

- To construct medical marketing materials/documents appropriate for the audience and consistent with the strategic direction for the promotion of the medicine:
 - Briefing documents;
 - Presentations and publications;
 - Therapeutic training to medical representatives and other non-medically qualified staff;
 - Materials for communications e.g. publications/presentations.
- To evaluate a range of medical marketing materials for medical and scientific accuracy, legal and regulatory compliance and comprehension by the reader.
- To analyse selected materials and activities e.g. media communications, professional and public relations, pre-launch activities, with regard to medical, scientific, educational and promotional content.
- To ensure a balanced perspective (safety and efficacy) is evident in medicine promotion and communication.
- To be able to create alternative texts for advertising and promotion.
- To lead colleagues to a legally compliant and ethical position on “grey area” promotional decisions, particularly in areas of uncertainty.

Behaviours

The pharmaceutical physician:

- Recognises the importance and challenges of operating within a legal framework for medical-marketing communication and the consequences of non-compliance.
- Recognises the importance of ensuring the compliance of all promotional material with the content of the SmPC.
- Recognises the importance and consequences of differentiating medical communications as promotional within a defined therapeutic area and of the need for such communications to be marketing orientated.

ITEM: HMP 2 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
	PbD, CBA, DPM	13.5, 13.6	1- 4

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- Marketing research and profiling in the context of regulations with regard to:
 - competition in the healthcare market;
 - segmentation of customers and markets;
 - customer targeting;
 - methods of promotion;
- activities of public and professional relations companies.
- disease awareness campaigns.

Behaviours

The pharmaceutical physician

- Recognises how marketing research and profiling data can contribute to effective promotional activities and the constraints of regulation in this context.
- Recognises the contribution and constraints of marketing data in the promotion of medicines.

ITEM: HMP 3 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to describe the structure and function of the pharmaceutical industry, and the organisations within it, key stakeholders, the relevance of commercial drivers and how these business elements impact on the broader healthcare marketplace.	PMAT, PbD,	2.1, 13.8, 13.9	1, 3
Applied Knowledge			
Demonstrate an understanding of the underlying principles for: <ul style="list-style-type: none"> • The structure and function of the pharmaceutical industry: <ul style="list-style-type: none"> ○ Global, regional and national trends; ○ The roles of, and relationship between, the relevant trade organisations, including the Association of the British Pharmaceutical Industry (ABPI), British Medical Association (BMA), medical Royal Colleges, Faculty of Pharmaceutical Medicine; ○ The structure and function of pharmaceutical companies; ○ Essential documents / SOPs required of a Company/pharmaceutical organisation; ○ Nature of organisational relations of Medical department/function with other areas in the organisation. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the relevance of the internal pharmaceutical industry environment in determining the nature of the industry's interactions in the healthcare market. • Recognises how internal business operations and drivers impact the interactions with and relationships between the pharmaceutical industry and the wider healthcare environment. • Recognises the role of medical governance in the commercial environment. • Recognises the different and complementary contribution made by trade and professional bodies. 			

ITEM: HMP 4 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to describe the information required and how to analyse and apply it in order to undertake a commercial analysis of potential for a pharmaceutical product within the industry business environment.	PMAT, PbD, MSF, CBA, DPM	1.4, 1.6, 2.6, 5.1, 6.5, 13.8 – 13/10	1
Applied Knowledge			

Demonstrate knowledge of:

- The elements involved in the commercial assessment of a pharmaceutical product:
 - profiling and positioning;
 - clinical data;
 - pricing;
 - products and services;
 - intellectual property (IP);
 - others, for example, health economics, costs of promotion, reimbursement and implications of formulary listing / delisting, licensing and impact of cost of goods / royalties, return on investment (ROI), 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, generic medicines.
- The components required for the evaluation of an in-licensing / collaboration option:
 - identifying candidates;
 - portfolio fit and management;
 - due diligence;
 - product efficacy and safety;
 - intellectual property (IP), data exclusivity, patent s etc;
 - commercial assessment.

Skills**Demonstrate ability:**

- To evaluate the commercial potential for a pharmaceutical product, real or hypothetical.
- To evaluate the commercial potential for an in-licensing opportunity for a pharmaceutical product, real or hypothetical.

Behaviours**The pharmaceutical physician:**

- Recognises the breadth and depth of data requirements and the inherent limitations in the commercial analysis of pharmaceutical product potential.
- Recognises the commercial potential and limitations of in-licensing and collaborative options.

ITEM: HMP 4 (Competency level 2)**Assessment Methods****PharmaTrain Syllabus****GMP 2013**

PbD, CBA, DPM

10.16

1

Applied Knowledge**Demonstrate an understanding of the underlying principles for:**

- The clinical, regulatory and commercial aspects of a pharmaceutical reclassification:
 - Prescription Only Medicine (POM) to Pharmacy (P);
 - Pharmacy (P) to General Sales List (GSL).

Behaviours**The pharmaceutical physician:**

- Recognises the clinical (particularly safety-related) and commercial implications of pharmaceutical reclassifications.

ITEM: HMP 5 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To understand the commercial competitor environment when evaluating the opportunity for a new product during development, or a currently marketed product.	PMAT, PbD, MSF, CBA, DPM	5.1, 13.1 – 13.5, 13.11	1
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The key components of a competitive commercial product analysis for a: <ul style="list-style-type: none"> ○ marketed product; ○ pipeline product; ○ therapy area; ○ competitor product. • Product assessment by health technology assessment bodies, e.g. the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC), and others: <ul style="list-style-type: none"> ○ the Quality Adjusted Life Year (QALY) and its use as a tool for assessment; ○ the differences between a formal Health Technology Appraisal (HTA) and Guidelines / Guidance; ○ other forms of health economic evaluation using cost-effectiveness and / or cost-minimisation. • Assessing products in development using probability of success. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To perform a competitive product analysis for a product, real or hypothetical, at two different stages in its development. • To evaluate the promotional platform of a competitor product. • To construct objection-handling statements. • To contribute to a HTA and/ or to the development of a guideline. • To appraise constructively health economic models produced for assessment of a product. 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the value of a robust competitive commercial product analysis for products at different stages in their development. 			

ITEM: HMP 6 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
<p>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.</p>	PMAT, PbD, MSF, CBA, DPM	8.1, 8.2, 8.4 – 8.9, 8.12, 8.16, 8.17, 10.17	1 - 4
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The identity of the industry's key stakeholders in the external environment and how the industry's activities impacts on them, including the general public. • The ethical issues which arise and approaches considered in reaching a judgement in: <ul style="list-style-type: none"> ○ the investigation and management of fraud and misconduct e.g. in clinical research; ○ unlicensed use of medicines e.g. compassionate use; ○ Phase IV studies; ○ Post-Marketing Surveillance studies; ○ open label clinical trial extensions; ○ investigator-initiated studies; ○ charging for named patient supplies; ○ giving a balanced and objective clinical / scientific view / response in keeping with company strategy and professional ethics; ○ creating a policy on information that may legally be supplied to patients provided by medical information within regulation; ○ developing a Data on File statement; ○ Data transparency; ○ Grants, donations and joint working with NHS. • Corporate communications and reputation. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To perform an industry key stakeholder analysis. • To analyse the important relationships and interactions between the key stakeholders. • To discuss how ethical judgments are made and relevant guidelines applied in the different scenarios outlined in HMP 6. • To perform ethical evaluations in the areas outlined in HMP 6. 			
Behaviours			
<p>The pharmaceutical physician:</p> <ul style="list-style-type: none"> • 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. • 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. 			

MODULE 6

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 principles of international regulatory reporting requirements, on the timely revisions of product information and practical methods for managing risk to patients and clinical trial subjects.

ITEM: DSS 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: To understand the key regulatory requirements for pharmacovigilance, both in the major (ICH) regions and locally, and their historical background.	PMAT, PbD, CBA, DPM	7.4, 10.2, 10.4, 10.6, 10.9, 10.10, 11.1, 11.5	1 – 4
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The responsibilities and liabilities of investigators, clinicians, study monitors, sponsors and manufacturers in the pre- and post-marketing phases to detect, assess and report suspected adverse events associated with medicines (in the country where the Pharmaceutical Physician operates). • The requirements and processes for reporting to the MHRA in the UK and to the EMA. • The requirements for informing prescribers, investigators, ethics committees and regulatory agencies of important safety concerns. • The pharmacovigilance operations of the MHRA and of the EMA. • The pharmacovigilance operations of the FDA in the USA and of its requirements for reporting. • The relevant sections of the Medicines Act 1968 and subsequent Statutory Instruments relating to drug safety and pharmacovigilance. • The relevant ICH provisions for safety surveillance. • The role and responsibilities of the EEA Qualified Person in Pharmacovigilance (QPPV). • Relevant pharmacovigilance sections from: <ul style="list-style-type: none"> • EU Directives and Regulations; • ICH and CHMP Guidelines. • The CIOMS Working Groups and Reports (such as CIOMS I-IX). • Good Pharmacovigilance Practices (GVP). • 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. • The evolution of drug surveillance methods, and pharmacovigilance regulations worldwide, their harmonisation, and inter- and intra-company reporting systems for assembling and reporting suspected adverse reactions. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To locate the relevant sources of information on regulations and identify any new requirements. Evaluate whether these have implications in terms of revising processes to ensure compliance. • To discuss interactions a QPPV is most likely to have with a pharmaceutical physician and the actions required by the Pharmaceutical Physician to support the QPPV. 			

- To apply guidelines and directives and ensure compliance to them in all aspects of pharmacovigilance with particular focus on Good Pharmacovigilance Practices (GVP Modules).

Behaviours

The pharmaceutical physician:

- 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.
- Recognises the importance of adherence to these regulations and the need to stay fully aware of updates / changes to regulations and guidelines.
- Recognises the importance of the QPPV role.
- Recognises the importance of 'landmark' cases in bringing about change including increased regulation and more sophisticated reporting systems worldwide.

ITEM: DSS 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to carry out all medical assessments required to meet the requirements for drug safety reporting both at the level of the individual patient (case report) and aggregate report.	PMAT, PbD, MSF, CBA, DPM	10.14, 10.23, 11.2, 11.4, 11.5, 11.7, 11.9, 11.10, 11.14	1 – 4
Applied Knowledge			
Demonstrate knowledge of:			
<ul style="list-style-type: none"> • The national, regional and international regulations relating to the collection and reporting of suspected Adverse Drug Reactions (ADR). • The contents of aggregate reports required by regulatory authorities, e.g. PSURs/DSURs. • The contents of safety sections of Summary Product Characteristics (SmPC), Patient Information Leaflets (PIL) and package information. • Processes to collect, analyse and report product quality complaints (PQCs) and any associated adverse events. 			
Skills			
Demonstrate ability:			
<ul style="list-style-type: none"> • To review medically the case reports from spontaneous sources from the current literature and from clinical studies. • To note relevant information about benefit-risk including other suspected ADRs and transfer the relevant information to the report formats for submission to relevant regulatory agencies. • To apply ethical judgements and ensure adherence to appropriate guidelines when carrying out post-marketing surveillance studies. • To assess medically the serious adverse events (SAEs) from clinical trials and determine their causal relationship to the study drug and expectedness. • To evaluate medically an existing PSUR/DSUR. • To write the overall safety evaluation section of a PSUR (real or simulated). • To write and to be able to review constructively the safety section of a PIL and package information. • To evaluate the impact on patient safety and the relationship with patients, healthcare professionals and regulators of inadequately assessed and managed Product Quality Complaints (PQCs). • To discuss potential mitigation activities for PQCs e.g. change to process, withdrawal of a batch. • To discuss the impact on patient safety of Risk Communication/Direct Healthcare Professional 			

Communication (DHPC).

Behaviours

The pharmaceutical physician:

- Recognises the importance of meeting the requirements for reporting of ADRs.
- Recognises the overall function of the PSUR in terms of updating any safety matters concerning a medicine.
- Recognises how important it is that the PIL is written with consideration for the target audience to aid compliance.
- Recognises the importance of identifying and managing proactively risks to quality.

ITEM: DSS 3 (Competency Level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

The pharmaceutical physician will have a clear understanding of spontaneous reporting and signal detection methodologies and be able to assess medically AE/ADR reports as part of causality assessment.

PMAT, PbD,
MSF, CBA,
DPM

7.3, 8, 9.25,
10.21, 10.25,
10.26, 11.1 –
11.16, 13.3,
14.2, 14.6 –
14.9

1, 2

Applied Knowledge

Demonstrate knowledge of:

- The major pharmaco-epidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases.
- The major methods of post-marketing surveillance.
- The application of the requirements for Post-Authorisation Safety Studies (PASS), and Post-Authorisation Efficacy Studies (PAES) in the UK and in the EU.
- The common causal mechanisms for ADRs including their classifications.
- The mechanisms of drug interactions.
- The principles of causality assessment and causality algorithms to classify events as to their likely causal attribution to a particular medicine.
- The characteristics that make an ADR reportable according to international guidelines.
- Definition of medication error, off label, overdose, abuse and misuse, and pregnancy cases.
- The application of epidemiological methods to spontaneous reporting.
- Signal detection and identification of potential safety issues.
- Risk minimisation activities.

Skills

Demonstrate ability:

- To apply the definitions of adverse event, serious adverse event, unexpected / unlabelled adverse event, suspected adverse drug reaction and clinically significant abnormal laboratory test value; and discuss the differences between them.
- To 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.
- To formulate appropriate follow-up questions to reporting healthcare professionals and consumers as well as specifying the data that are important in the assessment of adverse event / reaction reports.
- To evaluate constructively some published research data.
- To assess medically the post-marketing suspected ADR reports and determine seriousness, causal relationship to suspect drug and expectedness.
- To assess ADRs and other relevant benefit-risk information reported in the literature.
- To assess potential signals by using appropriate methods to assess adverse event frequencies in an external adverse event database e.g. FDA AERS / WHO Uppsala.

Behaviours**The pharmaceutical physician:**

- Recognises the need for clear definitions and procedures / guidelines for adverse event reporting from both healthcare professionals and consumers.
- Recognises the importance of ongoing signal evaluation, causality assessment and the communication of relevant findings as a key responsibility in helping to safeguard future patients.
- Recognises the importance of medical assessment of adverse events from all potential sources and its potential future use in treating or advising patients.

ITEM: DSS 3 (Competency Level 2)**Assessment Methods****PharmaTrain Syllabus****GMP 2013**

PbD, CBA, DPM

11.2, 11.4, 11.6, 1, 2
11.7, 11.12, 11.13**Applied Knowledge****Demonstrate an understanding of the underlying principles for:**

- Coding systems for drug safety e.g. MedDRA.
- The methods and applications of all signal generation methods in pharmacovigilance and the processes required for prioritisation and evaluation of detected signals.

ITEM: DSS 4 (Competency Level 1)**Assessment Methods****PharmaTrain Syllabus****GMP 2013****OBJECTIVE:**

To understand the principles and methods of evaluation of risk and benefit balance and the principles and methods for managing risk to patients and clinical trial subjects.

PMAT, PbD,
MSF, CBA, DPM7.5, 10.14, 10.21, 1 – 4
10.22, 11.3, 11.5**Applied Knowledge**

Demonstrate knowledge of:

- The principles and methods for risk / benefit evaluation and related decisions during pre-marketing development.
- The principles and process for development of safety specifications documents.
- The CIOMS VI report in respect of safety in clinical trials.
- The structure, roles and responsibilities of data safety monitoring committees.
- The principles of risk and benefit assessment based on CIOMS IV – Report of CIOMS Working Group IV.
- The principles and methods of post-marketing risk management plans (based on ICH E2E).
- The options and mechanisms for optimising safety in relation to benefit.

Skills**Demonstrate ability:**

- To review constructively the relevant documents e.g. protocol, PIL, safety specifications, risk management plan, for appropriate risk and benefit statements.
- To make appropriate medical contributions for effective risk management plans by identifying risks to patients, potential risks and missing information and proposing appropriate risk mitigation activities.

Behaviours**The pharmaceutical physician:**

- Recognises the importance of the physician's role in risk and benefit assessment and risk management and ability to work in a team with colleagues and show medical leadership to ensure an approach focussed on the needs of patients.

ITEM: DSS 5 (Competency Level 2)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will understand the variety of regulatory actions possible to address concerns about patient safety.	PMAT, PbD, MSF, CBA, DPM	10.21, 10.24, 11.7, 11.8, 11.10, 11.13, 11.15, 11.16	1, 2

Applied Knowledge**Demonstrate an understanding of the underlying principles for:**

- The key regulatory actions including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension, withdrawal and recall.
- The European procedures for reassessment of risk: benefit (Articles 31 & 36 of Directive 2001/83/EEC).
- The occurrence of medication error within a clinical setting and the potential consequences of use outside the labelled recommendations. Historical examples of medication error e.g. intrathecal administration of vincristine.
- The risk for a medical error occurring with a specific product and for including the identified risk in risk management documentation, risk mitigation plans and labelling.
- Identifying sources of information on medication errors and the regulatory reporting requirements of identified cases.

Behaviours**The pharmaceutical physician:**

- Recognises the importance of these regulatory actions to help ensure patient safety.
- Recognises the risk that medication error represents to patient safety and the need to minimise the risk.

ITEM: DSS 6 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
<p>OBJECTIVE: The pharmaceutical physician will understand the importance of communication of safety issues, the variety of formats required to meet audience needs and have the ability to contribute to the development of such communications.</p>	PMAT, PbD, MSF, CBA, DPM	10.14, 10.24, 11.15, 11.16, 12.2	1 – 3
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The requirements regarding safety aspects of the Summary of Product Characteristics (SmPC). • Assessment of urgent safety issues, including product recall, and generation of appropriate communications to regulatory bodies, healthcare professionals and patients. • The availability of urgent communication tools; the opportunities and pitfalls of their use. • The key elements of Good Pharmacovigilance Practices Module XV (safety communication). • The techniques/methods of communicating risk and benefit, and risk-benefit balance. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To review SmPCs of company products in the context of PSUR/PBRERs to ensure all safety issues are covered appropriately, particularly in relation to clarity and completeness. • To evaluate and discuss urgent safety issues including patient communications and be able to write a Direct Healthcare Professional Communication (DHCP) letter for a real or hypothetical issue. • To critically evaluate the use of social media as a communication tool for urgent issues. • To prepare press briefings, investor and patient communications. • Shows an understanding of the needs of healthcare professionals and patients in relation to urgent safety communications. 			
Behaviours			
<p>The pharmaceutical physician:</p> <ul style="list-style-type: none"> • Contributes to ensuring that the SmPC reflects appropriately the safety profile of the medicine. • Participates actively in the medical discussions around product recall. • Shows an understanding of the needs of healthcare professionals in relation to urgent safety communications. 			
ITEM: DSS 6 (Competency Level 2)	Assessment Methods	PharmaTrains Syllabus	GMP 2013
	PbD, MSF, CBA, DPM	11.15, 11.16	1 – 3
Applied Knowledge			
<p>Demonstrate an understanding of the underlying principles for:</p> <ul style="list-style-type: none"> • Communications planning and the need for coordination with key stakeholders in handling a drug safety issue. • The drafting of press briefings. 			

Behaviours

The pharmaceutical physician:

- Recognises the importance of communication of safety issues and the need for a variety of formats to meet different customer needs.

ITEM: DSS 7 (Competency Level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

The pharmaceutical physician 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.

PbD, MSF, CBA, DPM

11.15

1 - 3

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- The organisation and conduct of a crisis management team.
- Identifying the key individuals to be included in a crisis management team.
- Identifying the main steps involved in assessing and reacting to a potential crisis situation.
- Describing the appropriate response to various simulated drug safety issues.
- The legal responsibilities and liabilities of pharmaceutical companies and pharmaceutical physicians in respect of drug safety issues.

Behaviours

The pharmaceutical physician:

- Recognises the need for planned procedures to be in place and the urgency required to implement these plans appropriately.
- Consults effectively with all relevant parties.

ITEM: DSS 8 (Competency Level 2)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

To demonstrate an understanding of the areas of progress, likely major advances and future challenges in drug safety and pharmacovigilance.

PbD, TO, MSF, CBA

1.8, 3.2, 3.5, 5.10, 8.15, 10.8, 11.11, 11.14 – 11.16, 14.2, 14.3, 14.5

1 - 3

Applied Knowledge

Demonstrate an understanding of the underlying principles for:

- Defining the key markers of progress – examination of evidence that the output from existing safety surveillance systems has improved health.
- Safety and ethical aspects of advanced therapies, such as gene therapy, and other new technologies.
- Significant developments in clinical pharmacology e.g. pharmacogenomics / pharmacogenetics, understanding of enzyme systems, and their role in safety aspects of medicines' development and surveillance.
- Future challenges for pharmacovigilance, and evaluation of how any advances and developments may impact on medicines' and patient safety surveillance.

Behaviours

The pharmaceutical physician:

- Demonstrate a willingness to remain abreast of advances in research and technology and apply new knowledge and learn new skills.

MODULE 7

Interpersonal, Management and Leadership Skills (IML)

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: IML 1 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
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.	PMAT, PbD, MSF, CBA		1 - 4
Applied Knowledge			
<p>Demonstrate knowledge of:</p> <ul style="list-style-type: none"> • The components of employment legislation that are of relevance to the operation of a Medical Department and other areas of the pharmaceutical managed environment including differences between UK practices and those in other countries in the research-based pharmaceutical industry. • Roles and responsibilities of and relationships with key support functions e.g. Finance, Legal, Human Resources Departments. • The elements of Health & Safety Executive legislation that have importance in the pharmaceutical environment. • The principles of financing within the pharmaceutical sector as it applies to the industry, companies, departments and projects. • The principles of process evaluation, standard operating procedures, and audit in improving quality. 			
Skills			
<p>Demonstrate ability:</p> <ul style="list-style-type: none"> • To manage stakeholder interactions and relationships with key departments, e.g. marketing, sales, R&D, consumer products (over-the-counter medicines), and key support functions, e.g. finance, legal, human resources departments. • Identify trends, future options and strategy within the context of pharmaceutical medicine. • To manage projects by identifying and prioritising tasks and responsibilities including delegation and competent supervision. 			
Behaviours			
<p>The pharmaceutical physician:</p> <ul style="list-style-type: none"> • Recognises the importance of time management and the efficient use of resources to deliver on projects. • Creates a climate of continuous improvement by open-mindedness to new ideas. 			

ITEM: IML 2 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician 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.	PMAT, PbD, MSF, CBA		1 - 4
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • The general principles of people management. • The principles and practices of conducting competitive employment interviews and of selecting new staff. • Methods of performance management and appraisal, their purpose, application and outcomes. • Motivational techniques. • Methods used to retain and develop staff to their full potential including the role of personal development plans (PDP). • The principles and common practices of managing a team in line or as a matrix. • The difference between management and leadership, and the principles common to both. • The difference between appraisal, assessment and performance review, and the need for all of them in education, training and personal development. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To differentiate between educational and performance appraisal. • To describe the principles of effective objective setting. • To give constructive feedback, and actively engage in own appraisal. • To structure and deliver an effective appraisal meeting. • To describe sources of appropriate feedback on performance and their relative importance, how to give feedback, and measure outcomes. • To apply motivational techniques in reaching a project outcome. • To differentiate between specialist training and management training and how they can be complementary. • To outline appropriate specialist training and management training plans and how they can be incorporated within the Pharmaceutical Physician's organisational roles and responsibilities. • To participate in succession planning and talent management. • To apply leadership and motivational skills to multidisciplinary teams in one of the following areas: <ul style="list-style-type: none"> ○ In line ○ In matrix ○ Local ○ Global 			
Behaviours			
The pharmaceutical physician: <ul style="list-style-type: none"> • Recognises the importance of management / leadership style and influence on team dynamics and reaching departmental / project goals. • Recognises the limits of own professional competence and only practises within these. 			

ITEM: IML 3 (Competency Level 1)	Assessment Methods	PharmaTrain Syllabus	GMP 2013
OBJECTIVE: The pharmaceutical physician will be able to demonstrate applied knowledge and competency in a range of interpersonal and communication skills relevant to the practice of pharmaceutical medicine.	PMAT, PbD, MSF, CBA		1 - 4
Applied Knowledge			
Demonstrate knowledge of: <ul style="list-style-type: none"> • Negotiating. • Influencing. • Networking. • Facilitation and conflict resolution methods. • The critical role of IT and communications technology management in contributing to the effective and efficient performance within an organisation. • The principles applied by an effective meeting chair. • The principles of effective presentations. • The principles and practices of interacting with the print and broadcast media on matters relating to medicines and / or pharmaceutical medicine. • The GMC guidance on communicating information consistent with Good Medical Practice. 			
Skills			
Demonstrate ability: <ul style="list-style-type: none"> • To use negotiating skills to reach an outcome. • To use a range of influencing skills to construct a committee / advisory board to meet defined objectives. • To use networking skills to build a database of key influencers, opinion leaders or experts in a product / therapy area. • To differentiate 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. • To outline the principles of knowledge management and its importance in the context of the pharmaceutical organisation. • To chair meetings effectively, including video conferences and teleconferences, to reach timely outcomes in at least one of the following: <ul style="list-style-type: none"> ○ Development projects; ○ Management projects; ○ Committees; ○ Speaker meetings. • To make effective audiovisual presentations in at least one of the following areas: <ul style="list-style-type: none"> ○ Product related ○ Therapeutic field related ○ Project related ○ Case study and feedback • To recognise issues and required skills in responding to or interacting with the print or broadcast media. • To recognise the potential for harm, such as loss of confidentiality, when communicating via 			

different channels.

Behaviours

The pharmaceutical physician:

- Recognises the importance of interpersonal skills for pharmaceutical physicians to influence / drive project / team outcomes.
- Must always be prepared appropriately, and act with honesty and integrity in all communications with internal and external stakeholders.
- Recognise and show respect for diversity and differences (professional roles, culture) in others.

ITEM: IML 4 (Competency Level 1)

Assessment Methods

PharmaTrain Syllabus

GMP 2013

OBJECTIVE:

The pharmaceutical physician will ensure that the knowledge, skills and behaviours associated with the competent practice of pharmaceutical medicine are communicated effectively, and will acquire the best techniques and practices to achieve this.

PMAT, PbD,
MSF, TO, CBA

1, 3, 4

Applied Knowledge

Demonstrate knowledge of:

- Relevant educational theories and principles, notably adult learning principles relevant to medical education.
- Literature relevant to developments and challenges in medical education.
- The roles of bodies involved in medical education and other sectors.
- Identification of learning methods and effective learning objectives and learning outcomes.
- The structure of an effective appraisal interview.
- The differences between formative and summative assessment and their role in medical education.
- The role of workplace-based assessments, the assessment tools in use, their relationship to course learning outcomes, factors influencing their selection and the need for monitoring evaluation.
- The appropriate local course of action to assist a trainee experiencing difficulty in making progress within their training programme.

Skills

Demonstrate ability:

- To provide effective and appropriate feedback after teaching and promote learner reflection.
- To conduct developmental conversations as appropriate, for example, appraisal, supervision, mentoring.
- To vary teaching format and stimulus, appropriate to situation and subject.
- To demonstrate effective lecture, presentation and small group teaching sessions.
- To lead or participate in departmental teaching programmes, including journal clubs.
- To identify and plan learning activities in the workplace.
- To manage personal time and resources effectively for the benefit of the educational programme and the needs of learners.

Behaviours

The pharmaceutical physician:

- Recognises the importance of the role of the pharmaceutical physician as an educator within the multi-disciplinary team (e.g. clinical research, medical services, pharmaceutical development) and uses medical education to enhance understanding of its role in the care and safety of patients.
- Recognises the need to incorporate educational opportunities within the workplace.
- Demonstrates willingness to teach trainees and others in a variety of settings to maximise effective communication and practical skills for the benefit and safety of patients.
- Demonstrates consideration for learners including well-being and development needs.
- Maintains honesty and objectivity during assessment and appraisal.
- Shows willingness to participate in workplace-based assessments and demonstrates a clear understanding of their purpose.
- Shows willingness to take up formal training as a trainer, as appropriate, and responds to feedback after training sessions.
- Recognises the importance of personal development as a role model to guide trainees in aspects of good professional behaviour.
- Shows willingness to advance own educational capability through continuous learning.

4 Learning and Teaching

4.1 The Training Programme

The organisation and delivery of postgraduate training is the statutory responsibility of the GMC, which devolves responsibility for the local organisation and delivery of training to the deaneries. The Pharmaceutical Medicine Virtual Deanery is responsible for the organisation and delivery of specialty training in pharmaceutical medicine. The Pharmaceutical Medicine Virtual Deanery is the national deanery for pharmaceutical medicine, and is composed of the Faculty of Pharmaceutical Medicine, the JRCPTB, and the postgraduate dean in pharmaceutical medicine.

Learning is delivered in three modalities:

- The specialty knowledge base of The Syllabus for Pharmaceutical Medicine (PharmaTrain Syllabus) is acquired through experience, private study and taught course(s) and tested through the examination for the Diploma in Pharmaceutical Medicine. The specialty knowledge base can be acquired and tested before or at the same time as the acquisition of practical competencies in pharmaceutical medicine (applied knowledge, skills and attitudes/behaviours). The relevant syllabus topics (knowledge) are mapped against competencies (module items) expressed as applied knowledge, skills, attitudes/behaviours (see **Appendix 2** for details of the development of the syllabus, curriculum and Diploma in Pharmaceutical Medicine examination).
- Practical modules of pharmaceutical medicine are completed through on-the-job activity leading to the acquisition of applied knowledge, skills and attitudes/behaviours (performance/competencies)

or

- through interactive Module courses or modular item courses.

4.2 Teaching and learning methods

Teaching and learning methods in pharmaceutical medicine have been 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 modalities offering learning experiences include:

- apprenticeship (experiential) learning
- structured postgraduate courses in pharmaceutical medicine; university based
- interactive structured courses
- problem- and case-based scenarios
- national and international symposia and conferences
- self-directed and distance learning (journals, textbooks and internet)
- formal training at local, national, international (themed)

- courses and study days
- in-company training programmes
- self-assessment
- reflective practice and commentary
- small-group seminar learning with peers. Teachers are experts & thought leaders from industry, regulatory bodies, university
- one-to-one teaching and learning

Teaching and learning methods in pharmaceutical medicine have developed over several decades to meet the needs of doctors working in a dynamic, rapidly-developing, research-based, regulated and competitive international 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 physicians 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.

The curriculum will be delivered through a variety of learning experiences. Trainees will learn from practice those skills appropriate to their level of training and to their post within the department.

Trainees will achieve the competencies described in the curriculum through a variety of learning methods. There will be a balance of different modes of learning from formal teaching programmes to experiential learning 'on-the-job'. The proportion of time allocated to different learning methods may vary depending on the nature of the post.

This section identifies the types of situations in which a trainee will learn.

Learning with peers - There are many opportunities for trainees to learn with their peers. Local project and other teaching opportunities allow trainees of varied levels of experience to come together for small group sessions. Examination preparation encourages the formation of self-help groups and learning sets.

Trainees acquire knowledge and application of knowledge through experiential (apprenticeship) learning on-the-job, through attendance at structured courses related to the specialist knowledge base, attendance at formal approved structured interactive module courses, and supplementary courses as appropriate to meet the requirements of a curricular item.

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

Work-based experiential learning: The content of work-based experiential learning, the learning means by which applied knowledge, as well as skills and appropriate professional behaviours are acquired, is decided by the training team through the Training Plan, but includes active participation in:

- Work-based experiential learning – against job description
- Project-based learning – e.g. drug development
- Supervised one-to-one and group instruction and consultation
- National and international multidisciplinary group and team project working
- Case and project presentation
- Simulated scenarios and case studies e.g. in-licensing; crisis management
- Document identification, retrieval and summary e.g. regulatory
- Web-based research e.g. literature survey
- Participation in feasibility studies and due diligence activities e.g. POM to P switch, in-licensing
- Journal clubs
- Research presentations

Independent self-directed learning: Trainees will use this time in a variety of ways depending upon their stage of learning. Suggested activities include:

- Reading, including web-based material
- Independent study
- Distance learning (journals, textbooks and internet)
- Reflective commentary
- Self-assessment questions
- Maintenance of personal portfolio (self-assessment, reflective learning, personal development plan)
- Specialised projects
- Achieving personal learning goals beyond the essential, core curriculum

Formal study courses: Learning in more formalised settings, for example:

- Postgraduate courses in pharmaceutical medicine
- Revision courses and study days / weekends
- PMST external module courses (Faculty approved, interactive, with quality management/quality control) – cover all six operational modules
- In-company and external short courses
- Department, company and industry lectures and seminars
- Time made available for formal courses is encouraged, subject to local conditions. Examples include management courses and communication courses.

4.2.1 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 **section 4.2.2** below).

In PMST it is mandatory that three of the seven modules, including the common module (IML), are completed in work. Thus, for a trainee, any two specialty 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 (external module courses), or by a mix of in-work experience and supplementary courses provided in or outside the LEP.

In practice since 2003 the balance of learning for those completing and those planning PMST is that 75% (variance 43%-100%) of the curriculum is covered in the workplace, including some in-house meetings / seminars, and 26% through external interactive module courses.

4.2.2 Achievement of knowledge and competencies

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

The specialty knowledge base is acquired over a minimum period of time, usually but not necessarily around two years prior to sitting the Diploma in Pharmaceutical Medicine examination ('the Diploma'). 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. Attendance at a structured course is not, however, mandatory. 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 or CESR.

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

Every effort is made to achieve competences through work experience during PMST and apart from changing job to acquire competences, 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.

External module courses are Deanery-approved (through SAC-PM), interactive, quality assured courses provided under contract to the Faculty by independent organisations and course providers. Each of the specialty modules of PMST is catered for by an external module course. These are available for trainees to attend if they have no exposure in the workplace to a whole module e.g. Clinical Pharmacology, Healthcare Marketplace. The courses are approved by the Deanery (curriculum, content, delivery, assessments, assignments) and quality-managed by the Faculty's quality management panels for courses. Trainees are assessed for competency by the course.

Other courses for PMST are either internal (in-company) or external courses, which cover one or more items of a module, and are attended by trainees to supplement in-work experience or to cover items which are not available in-work. Attendance on these courses is determined by the trainee's personal development plan (PDP), when the course is seen to be fit-for-purpose. Assessment of competency on such as course is through workplace-based assessment, rather than course assessment. These courses are not quality managed by the Deanery.

4.2.3 Educational strategies

Pharmaceutical 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. Some will have been associated with new drug development within clinical practice through being involved in the sponsored assessment of new compounds (multi-centre clinical trials) or in one or more clinical conditions or in healthy-volunteer single-dose studies. Most teaching hospital or major medical units are accustomed to evaluating new therapies against existing ones.

Increasingly, pharmaceutical companies have changed in several ways that actually facilitate postgraduate training in pharmaceutical medicine and provides a well-defined career pathway for trainee pharmaceutical physicians. As a result of mergers at national and international levels, there are fewer but larger innovative companies. The majority possess basic scientific research facilities in which new compounds are discovered and understandably the company may prefer to direct the medical development programme itself and often to plan and initiate their clinical evaluation.

In addition to these pre-licence medical activities, the post-licensing medical responsibilities are considerable. A major one is close surveillance of the safety of products and the prompt reporting of individual suspected adverse drug reactions to regulatory authorities in all countries where the product is marketed or is undergoing pre-marketing clinical evaluations.

Ideas for new formulations or new clinical uses of already marketed products will involve the medical function.

The standards expected in pre-clinical human studies, in pre- and post-licence clinical trials, in safety surveillance procedures and notifications, and in marketing programmes now require thorough training of all medical staff and the institution of complete and thorough surveillance of the effectiveness and safety of medicines in clinical practice.

The standards in training of pharmaceutical physicians must fulfil the expectations of doctors and patients and legal requirements of society and, in particular, the expectations of legal and regulatory compliance laid down by the regulatory authorities.

A doctor may join a small pharmaceutical company, which may have only one or two products, but this environment may not be appropriate for trainee pharmaceutical physicians, who require experience across the breadth of pharmaceutical medicine.

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 workplace-based experiential learning include:

Clinical Pharmacology:

- Screen volunteers
- Undertake medical examination of research subjects; discussion with GPs
- Obtain informed consent
- Study preparation
- Dosing research subject, 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 trial 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 other technicians and experts on an ongoing basis
- Approve supply of drugs to outside investigators who wish to conduct human studies
- Review constructively 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 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 on company's medicines regarding adverse reactions, treatment of overdose, 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 Assessment

This curriculum for PMST defines the standards of knowledge, skills and behaviours which must be demonstrated in order to achieve progressive development towards the award of the CCT and CESR.

Competencies (knowledge, skills and attitudes/behaviours) take time and systematic practice to acquire and become embedded in regular performance. Implicit therefore in a competency-based programme of training must be an understanding of both the minimum level of frequency of experience, and the time required to acquire competencies and confirm performance in the practices of pharmaceutical medicine.

Assessment strategies for PMST must not deliver just snapshots of skills and competencies, but must deliver a programme of assessment which looks at the sustainability of competences and the professional performance of trainees in everyday practice of pharmaceutical medicine (Gold Guide May 2014).

The emphasis on workplace-based assessments aims to address this through assessing performance and demonstration of standards and competencies in pharmaceutical medicine. Trainers (Educational Supervisors) and trainees must be realistic about undertaking these assessments and employers must ensure that appropriate opportunities are provided to enable this to happen effectively (Gold Guide May 2014).

Trainees gain competence at different rates, depending on their own abilities, their determination and their exposure to situations which enable them to develop the required competencies. The rate of progress in acquisition of the competencies in PMST is defined for pharmaceutical medicine in the curriculum, so that the postgraduate dean, trainers, trainees and employers are clear as to what is acceptable progress in PMST (this will enable a reasonable limit for remediation to be set and trainees to be aware of the boundaries within which remediation can and will be offered) (see also ARCP Decision Aid - **section 5.5**).

5.1 The Assessment System

Assessment is a formally defined process within the curriculum in which a trainee's progress in PMST is assessed and measured using a range of defined and validated formative assessment tools, along with professional and triangulated judgements about the trainee's rate of progress. It results in an Outcome following evaluation of the written evidence of progress and is essential if the trainee is to progress, and to confirm that the required competences are being achieved.

The purpose of the assessment system is to:

- Enhance learning by providing formative assessment, enabling trainees to receive immediate feedback, measure their own performance and identify areas for development
- Drive learning and enhance the training process by making it clear what is required of trainees and motivating them to ensure they receive suitable training and experience
- Provide robust, summative evidence that trainees are meeting the curriculum standards during the training programme
- Ensure trainees are acquiring competencies
- Assess trainees' actual performance in the workplace
- Ensure that trainees possess the essential underlying knowledge required for their specialty
- Inform the Annual Review of Competence Progression (ARCP), identifying any requirements for targeted or additional training where necessary and facilitating decisions regarding progression through the training programme
- Identify trainees who should be advised to consider changes of career direction

The integrated assessment system comprises workplace-based assessments and knowledge – based assessments.

Workplace-based assessments will take place throughout the training programme to allow trainees continually to gather evidence of learning and to provide trainees with formative feedback. They are not individually summative but overall outcomes from a number of such assessments provide evidence for summative decision making. The number and range of these will ensure a reliable assessment of the training relevant to their stage of training and achieve coverage of the curriculum.

5.2 Assessment blueprint

Assessment methods have been blueprinted against the PMST curricular Module Items. It is not expected that each Item of the curriculum will be assessed using a formal assessment tool. Rather Items will be sampled across the curriculum and throughout the programme and are likely to include the following:

- Core area (items) of module
- Key project(s) for trainee
- Ongoing long-term project / activity
- Project developing core competency in pharmaceutical medicine
- Specific non-routine activity, e.g. teaching
- Module courses and course-based assignment(s)
- Generic competencies and multi-sourced feedback (MSF)

Consideration of how assessments are conducted in the trainee's work:

- A real project encounter
- Direct observation of a skill
- Behaviour over time
- Overall project management
- Knowledge assessment
- Reflective practice
- Simulation

Selected projects / Items of the curriculum will have multiple assessments over time, possibly by different assessors, and if appropriate may be subject to multiple assessment methods.

In the curriculum content, (see section 3.1), the 'Assessment Methods' shown are those that are appropriate as possible tools that could be used to assess each competency. It is not expected that all competences will be assessed and that where they are assessed not every tool will be used.

5.3 Assessment methods

The following assessment methods are used in the integrated assessment system:

- Examinations and certificates:

The Diploma in Pharmaceutical Medicine (the Diploma) is the specialty knowledge base of pharmaceutical medicine; it is a summative assessment and exit examination for the PMST programme. It is a common test for all trainees. The Diploma is composed of three written papers: multiple-choice question (MCQ), short-answer question (SAQ) and critical appraisal papers.

The Diploma must be passed before a CCT can be awarded.

Information about the Diploma, including guidance for candidates, is available on the Faculty of Pharmaceutical Medicine website (www.fpm.org.uk).

Candidates who have not entered the PMST programme, or trainees who are out of programme due to a career break or maternity leave for example, can sit the Diploma examination, but they must enter or re-enter the training programme within seven (7) years of passing the examination if they want the exam to count towards the award of their CCT or CESR.

- Workplace-based assessments:
 - Pharmaceutical Medicine Assessment Tool (PMAT)
 - Project-based Discussion (PbD)
 - Multi-Source Feedback (MSF)
 - Teaching Observation (TO)
- Course-Based Assignment (CBA)

These methods are described briefly below. Workplace-based assessments should be recorded in the trainee's Training Record. The workplace-based assessment methods include feedback opportunities as an integral part of the assessment process; this is explained in the guidance notes provided for the techniques.

1. Pharmaceutical Medicine Assessment Tool (PMAT)

The PMAT is an assessment that focuses on the competencies that trainees in pharmaceutical medicine demonstrate in their everyday encounters with projects and colleagues.

Competences can be defined as those behavioural characteristics which lead to outstanding or superior performance in a job role. They complement traditional skills and knowledge in representing deeper seated qualities, including behaviours and values which can contribute to the difference between average and outstanding performance. They are dynamic and interact with each other and are well suited to measurement of progress over time in personal learning and development. The competencies described in the PMAT are all interlinked and fall into five general categories:

- **Understanding the environment** (analytical thinking) **Working with others** (communication & presentation skills; teamwork; negotiation skills)
- **Personal effectiveness** (building expertise)
- **Delivery** (concern for quality; planning and prioritisation; flexibility and initiative; change management)
- **Managing performance** (people management skills; leadership)

The PMAT is an observation or 'snapshot' of a trainee interaction with project or colleagues. It involves direct observation by an assessor of trainees' performance in real work situations and is designed to assess a wide range of competences appropriate for the practising pharmaceutical physician. Not all competences can be assessed on a single occasion.

2. Project-based Discussion (PbD)

A PbD assesses the performance of a trainee in the management of a project to provide an indication of competence in areas such as reasoning, decision-making and application of medical knowledge in relation to project goals and outcomes. It also serves as a method to document conversations about and presentations of projects by trainees. The PbD should include discussion about a written record (such as written plans, progress reports, final reports). A typical encounter might be around the presentation of an interim project update to the project team.

The PbD is a structured narrative-based instrument for assessment of areas of application, learning, competency and performance related to non-standard project(s) being undertaken by the trainee at a point in time. It can be linked closely with associated PMAT assessment(s).

It enables the trainee to include reflective commentary and self-assessment in relation to such structured questions as:

- What did you do?
- What supporting documents are available (evidence)?
- What have you learned from this project (so far)?
- How does this project fulfil the requirements (all or partial) of the curricular Modules/Items listed?

It enables the assessor to comment critically on areas of trainee performance on this occasion:

- Summary of what was described and the evidence available to support this.
- Was the evidence presented satisfactory?

- Does the project fulfil the requirements (all or partial) of the curricular modules/items listed?
- Key points covered by the discussion.
- Is there a PMAT linked to this assessment?
- If so, which competencies were assessed?

3. Multi-Source Feedback (MSF)

MSF is an assessment involving systematic collection and feedback of performance data on an individual derived from multiple observers of his / her performance and behaviour. MSF is a method of assessing generic skills such as verbal communication, leadership, team-working, teaching, punctuality, reliability and diligence. This provides objective systematic collection and feedback of performance data on a trainee, derived from a number of colleagues.

'Raters' are individuals with whom the trainee works, and includes doctors, administration staff, and other allied professionals. The trainee will not see the individual responses by raters; feedback is given to the trainee by the Educational Supervisor. MSF also serves as a form of assessment of attitudes & behaviour. Whilst MSF is said to be an objective assessment of these generic difficult-to-measure attributes, they are a collection of retrospective and subjective opinions of professionals based on observations over a period of time.

4. Teaching Observation (TO)

The Teaching Observation is designed to provide a framework for assessors to provide structured formative feedback to a trainee on their competency at teaching. The Teaching Observation can be based on any instance of formalised teaching by the trainee that has been observed by the assessor. The process should be trainee-led (identifying appropriate teaching sessions and assessors).

5. Course-Based Assignments (CBA)

Course-Based Assignments (CBA) are those assessments applied by PMST external module course providers to assess the competencies of trainees completing external module courses. They normally take the form of post-course written assignments which are marked against criteria and standards laid down by the course (and approved by the FPM & SAC-PM). They are designed to assess the competency of trainees in skills and behaviours acquired during the course at the level of applied knowledge (knows how) and/or simulated activity (shows how).

Although CBAs are course-specific, it is expected that trainees will reach a 'satisfactory' level ($\geq 50\%$) in each assignment set. Whilst mainly a summative assessment, there are formative elements in that extensive feedback to the trainee is available if required and remedial activity may be put in place by the course provider for those who do not reach a satisfactory level.

5.4 Decisions on progress – ARCP

Structured postgraduate medical training, including PMST, is dependent on having a curriculum which sets out clearly the standards and competencies of practice, an assessment strategy to know whether those standards have been achieved and an infrastructure which supports a training environment within the context of the requirements of work delivery and job description(s).

The three key elements which support trainees in this process are appraisal, assessment and annual planning. Together they contribute to the Annual Review of Competence Progression (ARCP).

The ARCP is the formal method by which a trainee's progression through their training programme is monitored and recorded. ARCP is not an assessment – it is the review of evidence of training and assessment. The ARCP process is described in A Reference Guide for Postgraduate Specialty Training in the UK (the “Gold Guide” – available from <http://specialtytraining.hee.nhs.uk/>). Deaneries are responsible for organising and conducting ARCPs. The evidence to be reviewed by ARCP panels should be collected in the trainee e-portfolio.

The ARCP Decision Aid is included in **section 5.5**, giving details of the evidence required of trainees for submission to the ARCP panels.

5.5 ARCP Decision Aid

PMST Curriculum areas *, **	PMST Year 1	PMST Year 2	PMST Year 3	PMST Year 4
	% = Module Completed	% = Module Completed	% = Module Completed	% = Module Completed
Core Module (A) (In-work)	15% (evidence + WPBA: PMAT, PbD, TO)	30% (evidence + WPBA: PMAT, PbD, TO)	75% (evidence + WPBA: PMAT, PbD, TO)	100% (evidence + WPBA: PMAT, PbD, TO)
Core Module (B) (In-work)	15% (evidence + WPBA: PMAT, PbD, TO)	30% (evidence + WPBA: PMAT, PbD, TO)	75% (evidence + WPBA: PMAT, PbD, TO)	100% (evidence + WPBA: PMAT, PbD, TO)
Module (C) (In-work or Course)	0-15% (evidence + WPBA: PMAT, PbD, TO)	15-30% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	50-75% (evidence + WPBA: PMAT, PbD, TO); 100% if EMC (assessment CBA)	100% (evidence + WPBA PMAT, PbD, TO) 100% if EMC (assessment CBA)
Module (D) (In-work or Course)	0-15% (evidence + WPBA: PMAT, PbD, TO)	15-30% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	50-75% (evidence + WPBA: PMAT, PbD, TO); 100% if EMC (assessment CBA)	100% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)
Module (E) (In-work or Course)	0-15% (evidence + WPBA PMAT, PbD, TO)	15-30% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	50-75% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	100% (evidence + WPBA PMAT, PbD, TO) 100% if EMC (assessment CBA)
Module (F) (In-work or Course)	0-15% (evidence + WPBA: PMAT, PbD, TO)	15-30% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	50-75% (evidence + WPBA: PMAT, PbD, TO) 100% if EMC (assessment CBA)	100% (evidence + WPBA PMAT, PbD, TO) 100% if EMC (assessment CBA)
Module (G) Generic IML (Core; in-work)	0-15% (evidence + WPBA: PMAT, PbD, TO)	15-30% (evidence + WPBA: PMAT, PbD, TO, MSF)	50-75% (evidence + WPBA: PMAT, PbD, TO, MSF)	100% (evidence + WPBA: PMAT, PbD, TO)
DPM	-	(DPM)	(DPM)	(DPM) (could sit Year 2, 3 & 4)

* Modules A,B,C,D,E,F are from Medicines Regulation (RGN), Clinical Pharmacology (CLP), Statistics & Data Management (SDM), Clinical Development (CLD), Healthcare Marketplace (HMP) and Drug Safety Surveillance (DSS): two modules must be selected as core and must be completed in-work; the remainder to be completed in- work, by module course or by a mix of in-work and courses. Module G is the common module of Interpersonal, Management and Leadership Skills (IML): this is core and must be completed in-work. Other key: PMAT (Pharmaceutical Medicine Assessment Tool); MSF (Multi-Source Feedback); CBA (Course-Based Assignment), PbD (Project-based Discussion); TO (Teaching Observation); EMC (External Module Course); WPBA (Workplace-Based Assessment). ** For In-work activities it is aimed to complete 15% after PMST Year 1, 30% after PMST Year 2, 75% after PMST Year 3 and 100% after PMST Year 4.

5.6 Penultimate Year Assessment (PYA)

The penultimate ARCP prior to the anticipated CCT date, is known as the Penultimate Year Assessment (PYA). The PYA will include an external assessor from outside the training programme. JRCPTB and the Deanery will coordinate the appointment of this assessor.

5.7 Complaints and appeals

All workplace-based assessment methods incorporate direct feedback from the assessor to the trainee and the opportunity to discuss the outcome. If a trainee has a complaint about the outcome from a specific assessment this is their first opportunity to raise it.

The appeals process for the Diploma in Pharmaceutical Medicine is detailed on the Faculty's website: <http://www.fpm.org.uk/trainingexams/exams/dippharmed>

Appeals against decisions concerning in-year assessments (ARCPs) are managed by the Deanery. If a formal complaint about assessment is to be pursued this should be referred in the first instance to the chair of the SAC-PM who is accountable to the Deanery.

6 Supervision and feedback

6.1 Supervision

All elements of work in PMST must be supervised with the level of supervision varying depending on the experience of the trainee and the degree of exposure / responsibility in projects and activities undertaken. Trainees in PMST will at all times have a named Educational Supervisor (ES), responsible for overseeing their education and training.

The responsibilities of ESs have been defined by the GMC in the document 'The Trainee Doctor: Foundation and specialty, including GP training'.

6.1.1. Educational Supervisor (ES)

A trainer who is selected and appropriately trained to be responsible for the overall supervision and management of a specified trainee's educational progress. The ES supervises on a regular basis and through personal contact a trainee undertaking a PMST programme in a site / environment approved for training. 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. In particular the ES is responsible for ensuring availability of components of the common module – Interpersonal, Management and Leadership Skills. The ES is responsible for ensuring that the PMST programme fulfils the principles and standards laid down in Good Medical Practice.

To provide educational supervision during the PMST programme, the ES should be in regular contact with the trainee 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 trainee.

In some circumstances, with approval of the Senior Specialty Adviser (SSA), an ES may delegate overall educational supervision or supervision of certain training modules to an Associate ES (AES), not necessarily medically qualified, whilst retaining overall responsibility for supervision of training.

The ES and AES must be willing to undergo induction and training in the responsibilities, skills and processes of supervision of PMST; for example, the conduct of educational and performance appraisals and assessments of performance and competency. The Deanery will offer or facilitate any appropriate training that it considers necessary or is requested.

It is expected that ES and AES will undergo refresher training in the role and responsibility of educational supervision in PMST. Additionally it is appropriate that ES (and AES) should have the opportunity for additional training in areas of the role appropriate for educational supervision e.g. appraisal, workplace-based assessment, reflective practice, helping trainees in difficulty. Such programmes are available from the Deanery.

6.1.2 Mechanisms for supervision

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

Trainees should work with a level of educational supervision appropriate to their experience and competence. In keeping with the principles of Good Medical Practice, trainees will know that they must limit their experience to within their level of competency and seek help and support without hesitation.

The ES and trainee should undertake formal educational appraisals on a 4-monthly basis and a formal annual performance appraisal for PMST prior to the annual ARCP review. **(See section 6.2 Appraisal)**

The ES should keep the SSA, who acts on behalf of the Faculty and the postgraduate dean (PGD), informed about: significant problems that arise in the provision of educational components, such as a trainee experiencing difficulties in achieving educational objectives, their performance not reaching the required standard, and problems relating to the professional and personal development of the trainee, as they relate to the PMST programme. Such issues should be discussed with the trainee in the first place and remedial measures adopted as soon as possible. It may be necessary, with the trainee's permission, to raise these matters with the SSA and / or PGD prior to the ARCP review.

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

- a) PMST meetings / advisory / educational (ongoing)
- b) Educational appraisals (usually four-monthly)
- c) Annual performance appraisal
- d) Performance and competency assessments (as necessary for PMST curricular Items)

Points c. and d. above will form part of the ARCP. Confidential aspects of appraisals, notably of b. above by mutual agreement between trainee and ES may be lodged in

the trainee e-portfolio, and not presented at the ARCP or other external scrutiny, except under exceptional circumstances e.g. appeals.

The ES should maintain adequate records of interactions with trainees, including competency assessments and appraisals. These records will be needed for the ARCP process, notably the ARCP meeting with the PGD (or as delegated by the PGD).

6.1.3 Role of SSA and the ARCP process

The SSA, through an advisory and monitoring role of a training environment (local education provider [LEP]), contributes to the supervision of trainees through regular visits to the LEP and discussions with trainees, ESs and others, such as peers and managers of the trainees.

The ARCP process ensures effective supervision of the trainees. ESs are intended to accompany trainees to ARCP reviews and can be questioned themselves by the ARCP panel regarding aspects of supervision. At the ARCP review, the ES comments on trainee progress and achievement including assessments and appraisals.

6.1.4 Mechanisms for feedback

Opportunities for feedback to trainees about their performance will arise through the use of the workplace-based assessments, regular appraisal meetings with supervisors, other meetings and discussions with supervisors and colleagues, and feedback from ARCP.

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 Medical Practice and revalidation.

Thus feedback to the trainee on progress and achievements in PMST, including acquisition of competencies, assessments made and standards reached, strengths and deficiencies can be made in a number of ways in a variety of circumstances throughout PMST, some of which are:

- An initial meeting between trainee and ES shortly after enrolment into PMST to establish learning goals and the Training Plan
- Regular (e.g. monthly) meetings between ES and trainee to discuss projects and learning
- Formative, developmental educational appraisals (e.g. at 4-monthly intervals) between trainee and ES to discuss and to feedback on learning, learning objectives, projects, proposals, plans, problems and personal matters
- Annual performance appraisal to discuss assessments, achievements and progress against the Training Plan(s) and preparation for the new Training Plan
- Feedback from the ARCP

- Appropriately structured written feedback (anonymised) from departmental staff, colleagues and others on competencies, attitudes / behaviour through Multi-source feedback (MSF)
- Structured written feedback from ES (ES Report Form) on any topic.

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

6.2 Appraisal

A formal process of appraisals and reviews underpins training. This process ensures adequate supervision during training, provides continuity between posts and different supervisors and is one of the main ways of providing feedback to trainees. All appraisals should be recorded in the trainee e-portfolio.

6.2.1 Educational appraisal

Educational appraisal is a formative, developmental process which allows the trainee and the ES to meet at regular intervals (4-monthly) to review how the requirements of the curriculum are being met and to discuss successes and deficiencies of trainee and training in a confidential setting. Educational appraisals present an opportunity for deviations and deficiencies to be addressed, and are a major opportunity for feedback on learning, learning objectives, projects, proposals, plans, problems and personal matters both to the trainee on performance, and to the trainer on how supervision and facilitation of training is progressing.

6.2.2 Annual Performance Appraisal

Annual performance appraisal is the opportunity to consider what and how much has been achieved in PMST against the set objectives for the year; and for new objectives to be set. Unlike educational appraisal, annual performance appraisal is a summative evaluation, and its outcome and report feeds into the ARCP process. Annual performance appraisal enables trainee and trainer to discuss projects, assessments, achievements and progress against the training plan(s) and preparation for the new training plan. Reviewing progress through the curriculum will help trainees to compile an effective personal development plan (PDP) of objectives for the coming period.

6.2.3 Induction appraisal

The trainee and ES should have an appraisal meeting at the beginning of each post to review the trainee's progress so far, identify the learning opportunities presented by the post and agree learning objectives for the period ahead. This PDP should also be discussed and agreed during the induction appraisal.

6.2.4 Exit appraisal

Prior to changing job or post, trainees should review their PMST curriculum progress and PDP with their ES using evidence from the Training Record. Specific concerns may be highlighted from this appraisal. The end of post appraisal form should also record the areas where further work is required to overcome any shortcomings that have been identified. Further evidence of competence in certain areas may be needed, such as planned workplace-based assessments, and this should be

recorded. If there are significant concerns following the exit appraisal then the SSA and the Programme Director should be informed.

7 Managing curriculum implementation

The introduction of a structured competency-based training programme for PMST and the adoption of competency assessment procedures represent 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 trainees and those responsible for training, so that trainees receive adequate support and guidance throughout the training period.

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

7.1 Intended use of curriculum by Educational Supervisors (ESs) and trainees

This curriculum is a web-based document which is available from the Joint Royal Colleges of Physicians Training Board (JRCPTB) website www.jrcptb.org.uk, or from the Faculty of Pharmaceutical Medicine's website www.fpm.org.uk. It can also be made available on CD on request. Hard copies of the curriculum can be prepared at any time from the electronic sources.

The ESs and other trainers will be expected to use the curriculum as the basis of their discussion with trainees. Both ESs and trainees are expected to have a good knowledge of the curriculum and should use it as a guide for their training programme.

Each trainee will engage with the curriculum by maintaining a trainee e-portfolio, which is administered by the JRCPTB. The trainee will use the curriculum to develop learning objectives and reflect on learning experiences.

The Faculty website www.fpm.org.uk also allows access to all supporting material for PMST which currently includes:

- Background and organisation of PMST
- Enrolment procedures
- Guidance on the trainee e-portfolio
- PMST and revalidation forms
- Available module courses; timetable, providers, registration details
- Preparation for ARCP
- ARCP decision aid
- PMST guidance
- PowerPoint presentations on pharmaceutical medicine, Faculty, background to PMST, PMST overview and procedures, competency assessments, educational and performance appraisals
- CPD and revalidation; guidance and procedures
- Access to literature and reference material
- Accumulating library of projects and portfolios
- Links to related websites; NHS, industry, regulatory, academic bodies; curriculum content learning material; educational bodies and courses

- PMST complaints and appeal procedures

In addition past examination papers (short questions and critical appraisal papers only) for the Diploma in Pharmaceutical Medicine can be downloaded from the Faculty's website at <http://www.fpm.org.uk/trainingexams/exams/dippharmed>.

It is intended that the curriculum as approved by GMC and published by JRCPTB and the Faculty is a reference document for trainees and their ESs when preparing the PDP.

The trainee's programme of in-work modular training (JRCPTB Form B) and job description, together with current and upcoming projects in which the trainee will be involved will be used to plan which topics and Items of the curriculum modules can be undertaken. These will be entered in the Training Plan for the next period of 6-12 months.

The curriculum document also details what competency level is expected for a particular 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 trainee confirms the requirements of the PMST PDP 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.

7.1.1 Means of ensuring curriculum coverage

Each trainee has an individualised PMST programme derived from the curriculum and mapped initially in JRCPTB 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 Training Programme Director. The need to show how pharmaceutical physicians 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.

Pharmaceutical physicians will provide feedback on their training (see **section 7.2.4**) 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 (see **section 7.2.7**).

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 the pharmaceutical physician's role and responsibility in pharmaceutical medicine practice.

7.1.2 PMST practical (specialty) 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 can be undertaken either in work or through courses.

Each trainee must depict a minimum of two specialty 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 operational modules will be different for trainees these form the core requirement for the in-work experiential training of PMST.

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 module items will form part of the training.

7.1.3 PMST common module in pharmaceutical medicine

All items in the common module of Interpersonal, Management and Leadership Skills must be addressed during PMST. The common module is a core module in PMST and the majority of items will be undertaken on-the-job.

7.1.4 Role of local Faculty in curriculum implementation

The core 'Training Team' for PMST comprises the trainee, the ES and the SSA. These work together to define the programme content, facilitate availability of learning opportunities and resources, assess and appraise the outcomes and quality control the programme delivery in order to meet GMC standards for the CCT and CESR.

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

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

7.1.4.1 Senior Specialty Adviser (SSA) and curriculum implementation

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

The role of SSA is a joint appointment of the Faculty and 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 into the role and training, organised by the Faculty, into PMST and the background to responsibilities of the SSA with the expected duties and activities in undertaking the role. The SSA is responsible to the Training Programme Director, acting on behalf of the Faculty and the PGD. The SSA has a duty of responsibility, diligence and care to the JRCPTB and the Specialty Advisory Committee on Pharmaceutical Medicine (SAC-PM).

The SSA is assigned to a LEP (company; contract research organisation; medicines regulatory authority) to provide advice to the LEP on PMST and to trainees on their PMST programmes, and to oversee (quality manage) the delivery of the PMST programme against the GMC's standards.

7.1.4.2 Educational Supervisor (ES) and curriculum implementation

The role of the ES in curriculum implementation is outlined in **section 6.1.1** and **6.1.2**.

7.1.4.3 Trainees' responsibilities for curriculum implementation

One of the basic principles of a workplace-centred competency-based education and training programme is that the trainee 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 trainee with the motivation, drive and enthusiasm to undertake specialty 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 trainee for curriculum implementation and learning through utilisation of opportunities include:

- Ensuring enrolment eligibility;
- Selection of ES for approval;
- Arranging and planning enrolment meeting with SSA and ES;
- Completion and submission of enrolment application;
- Preparation of PDP;
- Enrolment and attendance on postgraduate training courses;
- Planning and preparation for assessments of competency;
- Planning and preparation for educational and performance appraisals;
- Planning and preparation for ARCP;
- Maintaining the trainee e-portfolio and keeping it up to date, notably the linking of evidence, completed assessments, and reflective practice forms to the module items of the curriculum; the rating of the achievement of competencies, and completion of the Pharmaceutical Medicine Annual Appraisal, Supervisor's Report and PDP within the trainee e-portfolio;
- Collection, collation, cataloguing and uploading of evidence of competencies, and ensuring its authentication / validation by ES, and others as required;
- Writing reports from self-directed learning and reflection;
- Implementing remedial activity following appraisals and ARCP reviews;

- Maintaining communication with trainers and administrators (Faculty, JRCPTB/SAC-PM);
- 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.

Pharmaceutical physicians require instruction, guidance and support to achieve the goals and make progress in PMST. There is a means of logging, with authentication by the trainee and 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 (ARCP Review) are intended to provide trainees 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, trainees 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 trainee development and progress to meet educational needs.

7.1.5 Curriculum management in programmes

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

- Possibility for exemption from one module as a result of prior training;
- JRCPTB Form A, which states overall which parts of the curriculum are available as training opportunities at the particular site / training environment;
- the trainee's job description which determines the scope of his/her work and the training projects and activities which might present themselves in the course of work over a period of time;
- which operational modules of practical training will be the two core modules for in-work training (the majority of Items to be completed in real-life as part of the job);
- which other modules or part modules will be completed in-work and thus which external Module course or other Item courses will be required;
- how the specialty knowledge base will be acquired – through attendance on a postgraduate course, or through work experience and personal study.

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

The aim in PMST is for all 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 ARCP.

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 JRCPTB Form B.

Some of these are:

- Non-availability of training project or activity as planned
- New training project or activity not planned for
- More items of modules covered in work than expected
- Overlap of topics and items between modules
- 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 common module must also be managed actively throughout PMST. This requires accruing experience in Interpersonal, Management and Leadership Skills and demonstrably fulfilling the tenets of the four domains of Good Medical Practice; these are not mainly discrete competencies of knowledge and application of knowledge but represent an approach to professional work and behaviour that develops over time and is subject to continuous assessment and appraisal to ensure that the professional standards expected of a specialist pharmaceutical physician are met.

7.1.6 Curriculum management across programmes

Management of the curriculum across programmes as a whole is the responsibility of the Deanery, the Training Programme Director and the Specialty Advisory Committee on Pharmaceutical Medicine (SAC-PM).

Each trainee has an individualised programme (*ad personam*) for PMST that is derived directly from the curriculum.

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

The common module applies to all trainees and accrued competencies and behaviours must be demonstrated before a CCT or a CESR can be awarded.

It is in the specialty modules where individual programmes differ most including the nature and complexity of projects and activities covering identical items of the curriculum. These depend on the project, the training environment / site, the involvement and engagement of the trainee, the nature of the evidence of competency and the expectations of the ES 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 from a curricular Item which 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:

- Common interpretation of curricular requirements by trainees, ESs and SSAs
- Regular communication across programmes by trainees, ESs and SSAs
- Outcomes (assessments) to meet external standards set by regulation and law, international industry and company standards
- Application of valid, reliable, practical assessment tools
- Feedback from informal meetings and educational appraisals
- Formal feedback from performance appraisals
- Feedback from ARCP reviews

7.1.7 Movement of trainees

Trainees move jobs, locations, sites and companies during their training.

Approximately 55% of pharmaceutical physicians will make such movements during the four years of PMST. In pharmaceutical medicine movement between competitive companies may also encounter issues of confidentiality and conflicts of interest.

In order to ensure continuity of training, appropriate transition between training programmes, and contact and administrative record of trainees and training programmes, the workplace movement process of trainees must be managed actively.

Trainees should inform their ES and SSA of their intention or decision to move jobs, and subsequently the Faculty and JRCPTB will be informed. JRCPTB Form C records the transition process between jobs, the debriefing of the trainee from the past job and briefing into the new job, the appointment of new ES and, ultimately, allocation of new SSA.

7.2 Recording progress

On enrolling with JRCPTB trainees will be given access to their personal trainee e-portfolio for PMST. The e-portfolio allows the trainee to upload his or her evidence, which will be built up to inform decisions on their progress and provides tools to support the education and development of pharmaceutical physicians.

The trainee's main responsibilities are to ensure the e-portfolio is kept up to date, assessments have been completed and recorded, maintain their PDP, record their reflections on learning and record their progress through the curriculum by rating their achievement in completing the module items.

The ES's main responsibilities are to use evidence uploaded by the trainee to e-portfolio - such as outcomes of assessments, reflections and PDP – to inform appraisal meetings. They are also expected to complete the Supervisor's Report, Pharmaceutical Medicine Annual Appraisal, update the trainee's record of progress through the curriculum by rating the trainee's achievement, and write end-of-post (exit) appraisals.

Attainment of competencies by trainees, which includes project / task completion, assessment of competency and filing of authenticated and validated evidence in the

trainee e-portfolio, will be recorded through completion of the trainee e-portfolio. This involves the trainee and ES rating the trainee's achievement against the relevant competency (curricular item), and recording how the competency was achieved.

The trainee e-portfolio will be used at the ARCP to gauge the progression of competency attainment and programme completion against the ARCP decision aid criteria.

8 Curriculum Review and Updating

Trainees will follow the curriculum currently approved at their enrolment into PMST unless it is considered desirable / essential for them to modify their programme to take account of revised / updated / new material. Note that all trainees who will CCT/CESR after December 2015 must transfer to the latest version of the curriculum, and older versions will be decommissioned.

The responsibility for curriculum review and updating lies with the Pharmaceutical Medicine Virtual Deanery (the Deanery), and specifically with the Curriculum and Assessment Working Group (CAWG) of the SAC-PM, working on behalf of the Faculty of Pharmaceutical Medicine and postgraduate dean.

8.1 Curriculum evaluation and monitoring

Evaluation of the PMST curriculum has taken place during the initial stages of curriculum implementation (since 2007) and during the first two years of full implementation of curriculum 2010 (2010-2012). This has resulted in the 2013 review and revision of the curriculum by the CAWG, to produce the 2014 version of PMST curriculum 2010. Evaluation will continue on an ongoing basis, with the intention for a formal review and revision on a 3-yearly basis, contingent on GMC guidance and scheduling.

In the process of curriculum monitoring and evaluation, the CAWG will receive feedback from the SAC-PM, the Faculty's Education Committee, Trainees' Subcommittee, the PMST Courses QM Group of the Professional Standards Committee, the Board of Examiners (Diploma in Pharmaceutical Medicine), trainees, SSAs, ESs, the Training Programme Director, postgraduate course Directors (specialty knowledge base), external module course providers, the postgraduate dean and lay representatives.

Evaluation will consist of:

- GMC national trainee and trainer surveys
- Deanery Reports and Annual Specialty Reports to the GMC
- Feedback from ARCP (including postgraduate dean)
- Outcome of Diploma examinations
- Feedback from Board of Examiners on Diploma examination
- Feedback from PMST Courses QM Group
- Feedback from module course providers
- Review and feedback / commentary by lay representatives

Details of the evaluation will include:

- Relevance of learning outcomes to pharmaceutical medicine practice

- Balance of in-work experiential learning for individual PMST programmes across curricular content
- Balance of real-life, simulated, individual and team-based experience
- Balance and emphasis of material between operational modules
- Uptake and relevance of learning and behaviours in the common module (IML)
- Integration of Medical Leadership, Common Competency and Health Inequalities frameworks and 'curricula' into the PMST curriculum
- Underpinning of curriculum by Good Medical Practice (GMP)
- Opportunities for in-house and off-site course-based learning
- Quality, content, relevance, programmes and delivery of time-limited external module courses (Faculty approved, quality managed), and their assessment systems e.g. Course-Based Assignments (CBA)
- Quality, content, relevance, programmes and delivery of internal and external short courses (not Faculty-approved or quality managed)
- Quality of training in LEPs
- Value of case studies / scenarios in learning (in-work and course-based)
- Assessment methods and tools (validity, reliability, feasibility within training programmes; in-work and course-based)
- Balance of competency levels reached vs. expected; extent of module items addressed / completed
- 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:

- Trainee e-portfolios (evidence of competency) and the ARCP;
- Developments in pharmaceutical medicine (law, regulation, drug development, medicines monitoring, technological advance);
- Developments in pharmaceutical medicine practice (role and work of pharmaceutical physicians, clinical development, pharmacovigilance, medical marketing, codes of practice);
- 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);
- Developments in pre-specialist clinical training (by specialty and College including general practice);
- Eligibility and uptake of overseas (non-EEA) graduates into UK PMST;
- Uptake and nature of international pharmaceutical medicine education and training (European CCT programmes, USA, rest of world);
- Development of electronic portfolio and PMST programme management;
- Movement of trainees and continuing training (by job, company and country);
- Presentation and comprehension of curriculum (by language, syntax, clarity, module overlap, repetition and redundancy, subject emphasis, competency levels, balance of material between modules);
- Volume and extent of PMST programmes (comparison with other specialties).

Monitoring, as opposed to evaluation, will be the responsibility of the Faculty's Education Committee interacting with the trainees, ESs and SSAs. From a practical point of view, the trainee e-portfolio, and the ARCP will be the main monitoring tools. These monitoring outcomes will feed into the CAWG of the SAC-PM.

8.1.1 Trainee involvement

Trainee involvement in curriculum evaluation and monitoring will be facilitated by:

- Feedback following appraisals, assessments, ARCP, Faculty meetings, quality management surveys and LEP visits with trainee interviews, meetings of the Faculty's Trainees' Subcommittee and CAWG
- Representation of trainees on CAWG of SAC-PM
- Ad hoc confidential feedback via ES / SSA to CAWG of SAC-PM

8.2 Curriculum Review

The GMC's standards for curricula and assessment systems (http://www.gmc-uk.org/education/approval_curricula_and_assessment_system.asp) sets out standards by which all specialty including GP training curricula and assessment systems will be evaluated.

These are the standards and requirements that the GMC will hold medical Royal Colleges, Faculties and specialty associations accountable for, in accordance with the Medical Act. The Colleges, Faculties and specialty associations have responsibility and ownership of the curriculum and assessment system for each specialty and sub-specialty. Deaneries and LEPs have responsibility for the delivery of the programmes including workplace-based experience based on the approved curriculum and assessment system.

The SAC-PM will oversee the evaluation of this curriculum and e-portfolio. The curriculum is regarded as a living document, and the committee will ensure that it is able to respond swiftly to new developments. The outcome of regular evaluation will inform the future development of the curriculum.

The SAC-PM will consult widely within the pharmaceutical medicine community, and will involve trainees, and lay representatives in the review process.

The new curriculum will be reviewed after one year to ensure deliverability and new developments. A formal review is planned after three years.

9 Equality and Diversity

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

- Race Relations (Amendment) Act 2000
- Human Rights Act 1998
- Special Educational Needs and Disabilities Act 2001
- Data Protection Acts 1984 and 1998
- Equality Act 2010

The Federation of the Royal Colleges of Physicians 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.

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

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;
- Deaneries must ensure that educational supervisors have had equality and diversity training (at least as an e learning module) every 3 years
- Deaneries must ensure that any specialist participating in trainee interview/appointments committees or processes has had equality and diversity training (at least as an e module) every 3 years.
- ensuring trainees have an appropriate, confidential and supportive route to report examples of inappropriate behaviour of a discriminatory nature. Deaneries and Programme Directors must ensure that on appointment trainees are made aware of the route in which inappropriate or discriminatory behaviour can be reported and supplied with contact names and numbers. Deaneries must also ensure contingency mechanisms are in place if trainees feel unhappy with the response or uncomfortable with the contact individual.
- 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.

10 Appendices

1. Curriculum 2010: Membership of Curriculum and Assessment Working Group of SAC-PM.
2. Development of Pharmaceutical Medicine and PMST Curriculum (extended).

Appendix 1

Membership of Curriculum and Assessment Working Group (CAWG) Review of Revision of PMST Curriculum for Curriculum 2010

Prof Peter Stonier – Convenor
Mrs Laura Cooper – Education Administrator FPM
Mrs Winnie Wade – RCP Education Dept
Ms Hannah Watts – JRCPTB
Mr Jonathan Whale – RCP Education Dept
Mr Joe Booth – RCP Education Dept
Mr David Parry – RCP Education Dept

Dr Malcolm Barratt-Johnson
Dr Kevin Bridgman
Dr Karen Cheng
Dr Joseph Chiesa
Dr Barny Edohasim (Trainee)
Dr Brian Edwards
Dr Diana England (Trainee)
Dr Anne Fairey
Dr Brian Gennery
Dr Mike Hardman
Dr Ruth Hargreaves
Ms Barbara Hepworth-Jones
Dr David Ingram
Dr Allison Jeynes-Ellis
Dr Richard Kay
Dr Cheryl Key (Trainee)
Dr Harpal Lamba (Trainee)
Dr Alan Lenox-Smith
Prof Tim Mant
Dr Sharon McCullough
Dr Tom Morris
Dr Ossie Morton (Late)
Dr Chris Mugglestone
Dr Joanna Nakielny
Dr Latha Parvataneni
Dr Gillian Pover
Dr Rob Sands
Dr Anissa Tse
Dr Mike Robertson (Lay member)

Membership of 2013 CAWG

Prof Peter Stonier – Convenor, Director of Education and Training, FPM
Mr Konrad Obiora – Professional Standards Administrator, FPM
Ms Hannah Watts – Curriculum and Assessment Manager, JRCPTB

Ms Zoë Fleet – Curriculum and Assessment Project Officer, JRCPTB
Ms Felicity Stuart – Committee Manager, JRCPTB

Dr Nitin Bagul (Trainee)
Dr Malcolm Barratt-Johnson
Dr Kevin Bridgman
Dr Karen Cheng
Dr Joseph Chiesa
Dr Daria Dejewska
Dr Brian Edwards
Dr Diana England (Trainee)
Dr Anthony Fox
Dr Juleen Gayed (Trainee)
Prof Brian Gennery
Dr Mike Hardman
Dr Emma Harvey
Dr David Ingram
Dr Vaidyam Kanagadurga (Trainee)
Prof Richard Kay
Dr Jasmine Lichfield (Trainee)
Dr Ulrike Lorch
Prof Tim Mant
Dr Grace Macaulay (Trainee)
Dr Sharon McCullough
Dr David Montgomery
Dr Lisa Moore-Ramdin (Trainee)
Dr Thomas Morris
Dr Chris Mugglestone
Dr Joanna Nakielny
Dr Virginia Norris
Dr Seleen Ong
Dr Zoya Panahloo
Dr Richard Philipson
Dr Gillian Pover
Dr Sankarasubramanian Rajaram (Trainee)
Dr Robert Sands
Dr Jit Solanki
Dr Subash Srinivasan
Dr Jonathan Stewart
Dr Sally Taylor
Dr Shankar Thiagarajah
Dr Neil Thomason (Trainee)
Dr Anissa Tse
Dr Mitra Vahdati-Bolouri (Trainee)
Dr Robert van Maanen
Dr Dele Wallace
Dr Muhammad Zafar (Trainee)

Appendix 2

Pharmaceutical Medicine and Development of the Curriculum for PMST

Evolution of Pharmaceutical Medicine

Pharmaceutical medicine became a listed medical specialty in the UK in April 2002. The discipline had developed earlier and postgraduate education programmes had been designed. The three UK Royal Colleges of Physicians introduced a knowledge-based Diploma in 1976 and a part-time postgraduate training course was started.

Until about 50 years ago, very few pharmaceutical companies employed doctors full-time. Most companies sought advice on a part-time basis from those consultants working in certain clinical specialties, which coincided with the company's current range of marketed medicines. This advice focussed largely on the use of products in routine clinical practice. However, from such contacts, some unmet needs were often identified, such as different formulations and other unit doses. The company's marketing representatives often learned of these needs on visits to doctors.

Pharmaceutical companies already employed pharmacy graduates to advise on and respond to product enquiries received either directly from doctors or dispensing pharmacists or indirectly from the marketing representatives. In addition, other pharmacy graduates were involved internally in the development of new medicines. Their roles included the choice of appropriate formulations, such as tablets, capsules, suppositories, injections, inhalation devices, creams and ointments, etc., for the medical conditions to be treated. They also supervised good manufacturing practices in both production of raw materials and of formulated products, together with chemists, bacteriologists and biologists.

The clinical evaluation of the efficacy and safety of new medicines or new formulations of existing medicines was undertaken by external clinical specialists. The pharmaceutical company's contact with these clinicians and their supporting staff (e.g. hospital pharmacists, nurses, and laboratory scientists and technicians) was usually undertaken by pharmacists. However, many pharmaceutical companies began to invite external clinical experts to assist on a part-time basis in the design of the studies being planned and in the choice of the clinical investigators, and in the interpretation and publication of findings. Company staff, often pharmacists and increasingly nurses, undertook the routine monitoring of progress and findings in these studies.

This advisory function by external medical specialists was not ideal, as their availability was limited and not always timely, and their personal opinion might be at variance with that of others. Therefore, pharmaceutical companies began to employ medical graduates as full- or part-time advisers exclusively for the company and they were based within the company. The title of medical director was commonly adopted and a medical department evolved with existing or new staff, such as pharmacists and nurses, thus concentrating the professional interface with clinicians into this department. This applied particularly to the handling of enquiries on marketed products. However, clinical studies of products after marketing were initiated or assisted by the medical department, which encouraged publication of the outcomes.

In the pre-licensing period of a new medicine, a similar change took place and medical graduates with appropriate post-graduate training and experience were

recruited to the research and development arm of the company. The specialty of clinical pharmacology was becoming important in medical schools, based on the customary academic roles of teaching and research. The specialty had an impact in the wider medical community because the licensing of new medicines now required detailed evidence of human drug metabolism, of pharmacokinetics and of the mechanism and incidence of drug-induced side-effects.

Most medical graduates now being recruited to the pharmaceutical industry had several years of post-graduate clinical training, often to senior trainee grade, and practical experience in clinical pharmacological studies and/or large-scale pre- or post-marketing clinical trials. Thus, clinical research became a feature of the research arm of the pharmaceutical company, where an interface with research scientists was facilitated.

The specialty of Pharmaceutical Medicine evolved from these needs inside the pharmaceutical industry and from the regulatory framework for the licensing of products and their safety surveillance.

Governance and regulation in pharmaceutical medicine

The development, including clinical development, manufacturing, supply and distribution, labelling and advertising of medicines have been conducted under international regulation and legislation, which has become increasingly comprehensive year on year for almost 50 years. European Union Council Directives on all aspects of pharmaceutical activity are transposed into national legislation. Additionally, guidelines, codes of practice, professional codes and codes of ethics all impact the work of pharmaceutical and regulatory physicians in the practice of Pharmaceutical Medicine in relation to the development and maintenance of medicinal products.

The legal and regulatory framework which governs pharmaceutical medicine does so, however, with the intent both of safeguarding the public and promoting a competitive and successful research-based pharmaceutical industry. Once an industry which was essentially 'self-regulating within a legal framework', the pharmaceutical industry, and with it the specialty of Pharmaceutical Medicine, is today arguably the most regulated of industries.

In terms of governance, pharmaceutical physicians are accountable for the nature, legality and standards, including ethical standards, of their work to their employers, to the General Medical Council, to their professional bodies and under the law as administered by the national Drug Regulatory Authority.

Curriculum 2010: Development and consensus

The development of the PMST curriculum 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) was implemented in 2003 (known as *Higher Medical Training [HMT]*), and comprises a syllabus and a practical, workplace-centred, competency-based, curriculum. The PMST curriculum was approved by GMC in 2007, and adopted from 1 August 2007. This is the first review and revision of the PMST curriculum, and will be referred to as 'Curriculum 2010'.

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 prevailing practices and attitudes in 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 (now JRCPTB) 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 were 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 (now BrAPP) together with the University of Wales Institute of Science and Technology, UWIST (now Cardiff University) 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 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 syllabus 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 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 curriculum 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 sections, 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 for 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 was separated into nine sections, the scope and content of which were largely unchanged from those prior to 2003 but the presentation was updated to bring them in line with recent developments in specialty training and to take account of advances and changes in the practice of pharmaceutical medicine. The Syllabus had nine sections; the first six sections correspond to the specialty knowledge for the operational modules of the specialty training programme in pharmaceutical medicine. 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 covers *'The Role of the Medical Department'*, which emphasised the roles and organisation of what is the main workplace and centre of operations for pharmaceutical physicians.

The Board of the Faculty has approved a further revision of the Diploma syllabus in March 2006, with removal of this section, leaving an 8-Section syllabus, with other changes in the main relating to regulations and procedures for the examination.

In 2009 the syllabus was offered by the Faculty to Innovation Medicines Initiative (IMI), PharmaTrain, along with, we understand, the current International Federation of Associations of Pharmaceutical Physicians (IFAPP) syllabus, as the basis for PharmaTrain's international syllabus for pharmaceutical medicine, recognising the requirement for update, review and revision for widespread harmonised, international use under the PharmaTrain banner (presented as PharmaTrain Syllabus 2010).

Given the provenance of the syllabus summarised above, the Faculty was pleased to receive the PharmaTrain Syllabus 2010 as the updated and revised syllabus for pharmaceutical medicine. As a public partner of IMI PharmaTrain, the Faculty recognises that the PharmaTrain Syllabus 2010 carries the brand of 'PharmaTrain'. The Faculty also recognises, and welcomes, the opportunity afforded by PharmaTrain for, in future, systematic, collective and harmonised review and revision of this international syllabus, and agrees to abide by the requirements and conditions established for this, and to which the Faculty will assuredly contribute.

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 eight 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 two years from taking up a post in pharmaceutical medicine.

Agreement on specialty knowledge base curriculum

The Syllabus for Pharmaceutical Medicine has always been lodged with the Board of Examiners for the Diploma in Pharmaceutical Medicine, initially reporting to the JCHMT (now JRCPTB) 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 for 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 1994.

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)

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

The Faculty of Pharmaceutical Medicine and the JCHMT (now JRCPTB) 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.

On 30 September 2005, the Postgraduate Medical Education and Training Board (PMETB) took over the work of the STA (and the JCPTGP), under the new legislation of *The General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003*. The Certificate of Completion of Training (CCT) replaced the Certificate of Completion of Specialist Training (CCST). In April 2010 the PMETB merged with the GMC, and under the *General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010*, the GMC took over responsibility for approval of undergraduate and specialty training programmes, and the award of the CCT and Certificate of Eligibility for Specialist Registration (CESR).

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 procedure, 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) 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 published between December 1999 and April 2000 [refs. 9-13].

Agreement on Higher Medical Training curriculum

The curriculum for HMT 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].

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 Trainees 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 agency; 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, human pharmacology, medicines' regulation, pharmacovigilance, or special interests in the field of pharmaceutical medicine, such as medical-marketing, legal and ethical issues, 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 company medical department or pharmaceutical organisation 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 pharmaceutical physicians 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 pharmaceutical physicians to develop special interests whilst gaining experience and competencies through continuing professional development to further their expertise over time.

Curriculum and specialty

The PMST curriculum covering knowledge, applied knowledge, practical competencies and generic aspects of pharmaceutical medicine is designed for training of pharmaceutical physicians who enter the specialty of pharmaceutical medicine after at least four 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 PMST curriculum 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 through gaining a CCT.

Link of curriculum to stages of education and training

The curriculum for PMST covers a minimum period of four years of specialty 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 two years of post-foundation clinical training in a specialty training programme or appointment before embarking on PMST. For PMST there is no restriction on the specialty from which doctors may come to join pharmaceutical medicine.

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 field of medical practice.

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

- proceed with their continuing professional development (CPD) in pharmaceutical medicine to remain up to date and maintain their place on the specialist register;
- review their practice in the light of Good Medical Practice;
- 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 PMST programmes

Each pharmaceutical physician enrolled in PMST undertakes a personalised (*ad personam*) training programme, which must be completed satisfactorily before the award of the CCT or CESR can be made.

This involves acquisition of the specialty knowledge base assessed by the Diploma in Pharmaceutical Medicine examination. A pass in the Diploma examination is the standard for acquisition of the specialty knowledge base and is mandatory before the award of a CCT.

It also involves demonstrating competency in all of the items of the modules set down in the PMST curriculum through a combination of learning methods; in-work experience and course-based or other learning modalities.

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

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.

The common module, comprising Interpersonal and Management Skills appropriate for pharmaceutical physicians and covering the four domains of Good Medical Practice (GMP) (as laid down by the GMC), must also be completed through in-work

experience, particularly since the principles of GMP set standards of practice in terms of competency, care and conduct which underpin the whole PMST programme.

The remaining operational modules may be completed in work, or through approved interactive External Module Courses, or through a combination of in-work experience and taught courses internal or external to the training organisation.

Each *ad personam* PMST programme of training must be approved by the GMC prior to enrolment. On enrolment trainees are issued with National Training Number.

References

- 1 Smith RN. A short history of the Board of Examiners. *Int J Pharm Med* 2000; **14**: 283-289.
- 2 Luscombe D, Salek MS. An International Postgraduate Course in Pharmaceutical Medicine: a review of 25 years. *Int J Pharm Med* 2001; **15**:
- 3 Binns TB. A diploma in pharmaceutical medicine. *Scot. Med. J.* 1976; **21**: 163.
- 4 Goldberg A, Smith RN. Pharmaceutical Medicine. *Lancet* 1985; i: 447-448.
- 5 Pharmaceutical Medicine. Ed. DM Burley and TB Binns. London: Edward Arnold, 1985.
- 6 The Textbook of Pharmaceutical Medicine. Ed. JP Griffin, FO Wells and PF D'Arcy. Belfast: The Queen's University, 1993.
- 7 Shelley JH. Changes to the Regulations for the Diploma in Pharmaceutical Medicine. *Pharm. Med.* 1991; **5**: 81-86.
- 8 Faculty. Specialist Training in Pharmaceutical Medicine. *Int. J. Pharm. Med.* 1997; **11**: 223-231.
- 9 Commentary. Delphi Exercise. *Int. J. Pharm. Med.* 1999; **13**: 240.
- 10 Millson, DS, Phelan, MJ, Boardman, HF, Blackshaw, CA. Higher medical training in pharmaceutical medicine: Delphi exercise on healthcare marketplace advanced module. *Int. J. Pharm. Med.* 1999; **13**: 285-288.
- 11 Phelan MJ, Boardman, HF, Millson. Higher medical training in pharmaceutical medicine: Delphi exercise on clinical pharmacology and medicines regulation advanced modules. *Int. J. Pharm. Med.* 1999; **13**: 341-345.
- 12 Boardman, HF, Millson, DS, Phelan MJ. Higher medical training in pharmaceutical medicine: Delphi exercise on drug safety surveillance and statistics and data management advanced modules. *Int. J. Pharm. Med.* 2000; **14**: 47-51.
- 13 Millson, MJ, Phelan MJ, Boardman, HF. Higher medical training in pharmaceutical medicine: Delphi exercise on clinical development advanced module and course delivery and assessment. *Int. J. Pharm. Med.* 2000; **14**: 105-108.
- 14 Editorial. Outcomes from the Delphi exercise on training modules. *Int. J. Pharm. Med.* 2000; **14**: 65.