# Curriculum for Pharmaceutical Medicine Specialty Training

## Implementation August 2021

# Contents

# 1. Introduction

Pharmaceutical medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration and monitoring of medicines and medical devices, and the medical study of marketed medicines for the benefit of patients and the public. The development and provision of medicines is of direct importance to the NHS. Patients and doctors expect medicines to be of the highest quality, supported by reliable evidence for their efficacy, safety and effectiveness.

Doctors who practise pharmaceutical medicine have a major responsibility for ensuring the ongoing accuracy of the Product Information on medicines: the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) and how this information is interpreted and communicated in the health service and for the public.

# 2. Purpose

## 2.1 Purpose of the curriculum

The purpose of the pharmaceutical medicine curriculum is to equip doctors with the generic professional and specialty capabilities in practice (CiPs) to be entrusted to fulfil their roles within the specialty. The curriculum informs the assessments and sets the standards for professional certification in pharmaceutical medicine. During the training programme the doctor will acquire additional knowledge as defined in the syllabus for the Diploma in Pharmaceutical Medicine (DPM) and will undertake the generic professional CiPs, which have been mapped to the General Medical Council's (GMC's) 'Generic professional capabilities framework' (GPC framework)[1], and the specialty CiPs, which will be demonstrated by high quality reflective practice and assessed through workplace-based assessments to demonstrate the acquisition of capabilities and the competence of professional practice.

To acquire a Certificate of Completion of Training (CCT) or its equivalent, the doctor will be required to demonstrate knowledge of the syllabus by passing the DPM examination and to demonstrate the acquisition of the required capabilities by the time of the final Annual Review of Competence Progression (ARCP) within the programme.

Pharmaceutical medicine is a diverse specialty with numerous roles each with specific knowledge, skills and capabilities. The curriculum is

designed to cover all these diverse requirements; teaching and learning methods to achieve training across the curriculum are discussed in section 4.2.

The work of all doctors practising pharmaceutical medicine impacts upon the lives and well-being of patients, whilst some too have direct contact with patients. Pharmaceutical physicians work with multi-disciplinary teams throughout the lifecycle of a medicine to generate, analyse, evaluate and report on scientific and clinical data. The resulting information is shared openly with all stakeholders in the development and regulation of medicines towards the timely provision of medicines for maximum benefit and minimal risk to patients.

Doctors practising pharmaceutical medicine engage in the development of medicines, including the design, ethical conduct and reporting of clinical trials of new and established medicines. All pharmaceutical physicians work within this specialist area to monitor the safety of medical products through vigilance systems and practices to provide evidence-based evaluations of the benefits and risks of products to support their appropriate clinical use.

The capabilities in practice that a doctor in training must acquire to complete pharmaceutical medicine specialty training and the levels are set out in section 2.2 below.

Doctors enter pharmaceutical medicine from a wide variety of clinical specialties with clinical capabilities to prescribe medicines safely and observe and report the effects of medicines for the benefit of patients. There are limited interdependencies between the pharmaceutical medicine curriculum and other training programmes because doctors who practise pharmaceutical medicine normally work and train outside the NHS.

One physicianly specialty with which pharmaceutical medicine shares some capabilities is clinical pharmacology and therapeutics (CPT). Examples of such interdependency is the management of adverse drug reactions and medication errors, contributing to ensuring safe and effective use of medicines (through Product Information), including personalised medicines, the conduct of health technology assessments, and broadly around experimental medicines through the design and conduct of clinical trials, and notably exploratory phase clinical trials.

Further, the generic capabilities and mapping of the pharmaceutical medicine curriculum to the GMC's GPC framework will facilitate transferability of learning outcomes and performance where doctors move across other medical specialties and disciplines.

This purpose statement has been endorsed by the GMC's Curriculum Oversight Group and confirmed as meeting the needs of the health services of the four countries of the UK.

## 2.2 High level learning outcomes – capabilities in practice (CiPs)
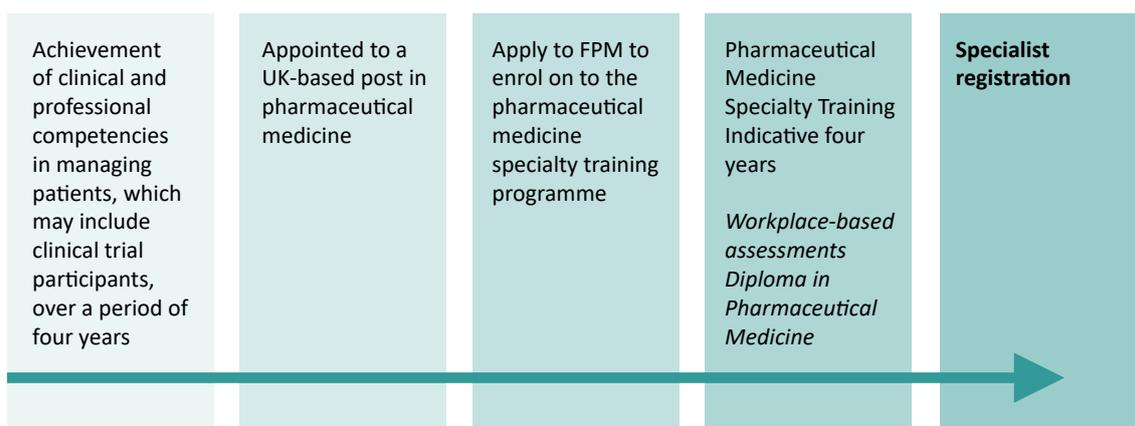
### Specialty CiPs

**CiP 1**  Enables and supports patients' timely access to medicines appropriate for their clinical needs

**CiP 2**  Operates within ethical, regulatory and good practice frameworks

**CiP 3**  Participates in data generation, analysis and communication

**CiP 4**  Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices

**CiP 5**  Conducts clinical research for the development of medical products

**CiP 6**  Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation

**CiP 7**  Provides up to date evaluations of the benefits and risks of medical products

**CiP 8**  Supports business decision-making and progression in medical product innovation and development

### Generic CiPs

**CiP 9**  Upholds professional standards and the duties of the GMC's 'Good Medical Practice' and the Faculty of Pharmaceutical Medicine's 'Good Pharmaceutical Medicine Practice'

**CiP 10**  Works competently within pharmaceutical organisational and management systems

**CiP 11**  Remains up to date with research and best practices in pharmaceutical medicine, employs reflective practice and undertakes continuing professional development

**CiP 12**  Applies the principles and practices of leadership and multi-disciplinary teamworking, teaching and developing others

**CiP 13**  Engages in quality improvement activities, ensuring that ethical, regulatory, and professional business standards are maintained

**CiP 14**  Keeps the safety of patients and the reliability of evidence at the forefront of decision-making in the design of development programmes for new and marketed medicines

## 2.3 Training pathway

Doctors can enrol on to the pharmaceutical medicine specialty training programme at ST3 if they have achieved clinical and professional competencies in managing patients, which may include clinical trial participants, over a period of four years and satisfied other eligibility criteria, which are available on the Faculty of Pharmaceutical Medicine's (FPM's) website at **www.fpm.org.uk**.

| Achievement of clinical and professional competencies in managing patients, which may include clinical trial participants, over a period of four years | Appointed to a UK-based post in pharmaceutical medicine | Apply to FPM to enrol on to the pharmaceutical medicine specialty training programme | Pharmaceutical Medicine Specialty Training Indicative four years *Workplace-based assessments Diploma in Pharmaceutical Medicine* | **Specialist registration** |
|---|---|---|---|---|

## 2.4 Duration of training

The duration of specialty training in pharmaceutical medicine is an indicative four years.

Trainees will have the option to complete the specialty training programme in pharmaceutical medicine in less than the indicative time of four years if they demonstrate full acquisition of all the capabilities. A decision about early completion of the programme will normally be made at the trainee's second ARCP. There may also be a small number of trainees who develop more slowly and will require an extension of training in line with the 'Reference Guide for Postgraduate Specialty Training in the UK' (the Gold Guide).

## 2.5 Less than full time training

Trainees are entitled to opt for less than full time training programmes.

Less than full time trainees should assume that their training will be of a duration pro-rata with the time indicated/recommended, but this should be reviewed in accordance with the Gold Guide.

## 2.6 Generic Professional Capabilities & Good Medical Practice

The GMC developed the GPC framework with the Academy of Medical Royal Colleges (AoMRC) to describe the fundamental, career-long, generic capabilities required of every doctor. The framework describes the requirement to develop and maintain key professional values and behaviours, knowledge, and skills, using a common language. The framework will be relevant at all stages of medical education, training and practice.

**The nine domains of the GMC's Generic Professional Capabilities**

Professional knowledge

Professional skills

Health promotion & illness prevention

Research & scholarship

**Professional values & behaviours**

Leadership & team

Education & training

Patient safety & quality improvement

Safeguarding vulnerable groups

Good Medical Practice (GMP)[2] is incorporated in the GPC framework. In describing the principles, duties and responsibilities of doctors the GPC framework articulates GMP as a series of achievable educational outcomes to enable curriculum design and assessment.

The GPC framework describes nine domains with associated descriptors outlining the performance and professional behaviour for those completing a CCT or its equivalent. These attributes are the common, minimum and generic standards expected of all medical practitioners achieving a CCT or its equivalent.

The nine domains and subsections of the GPC framework are directly identifiable in the curriculum. They are mapped to each of the generic and specialty CiPs, which are in turn mapped to the assessment blueprint. This is to emphasise those core professional capabilities that are essential to medical practice and which are demonstrated at every stage of training.

# 3. Content of Learning

The curriculum is spiral, and the topics and themes will be revisited to expand understanding and expertise. The level of entrustment for capabilities in practice (CiPs) will increase as a trainee progresses from needing direct supervision to ability to be entrusted to act unsupervised.



## 3.1   Capabilities in practice

CiPs describe the professional tasks or work within the scope of the specialty. CiPs are based on the concept of entrustable professional activities[3] which use the professional judgement of appropriately trained, expert assessors as a defensible way of forming global judgements of professional performance.

Each CiP has a set of descriptors associated with that activity or task. Descriptors are intended to help trainees and trainers recognise the knowledge, skills and attitudes which should be demonstrated. Doctors in training may use these descriptors to provide evidence of how their performance meets or exceeds the minimum expected level of performance for their year of training. The descriptors are not a comprehensive list and there are many more examples that would provide equally valid evidence of performance.

Many of the CiP descriptors refer to patient engagement and shared decision making. This is to emphasise the importance of patients being engaged in decisions about their own treatment and care, by exploring care or treatment options and their risks and benefits and discussing choices available. Additionally, the CiPs repeatedly refer to the need to demonstrate professional behaviour regarding patients, clinical trial participants, colleagues and others. Good doctors

work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive the highest quality medicines and medical products that will support them to live as well as possible, whatever their illness or disability. Appropriate professional behaviour should reflect the principles of GMP and the GPC framework.

To complete training and be recommended to the GMC for the award of CCT or its equivalent and entry on to the specialist register, the doctor must demonstrate that they are capable of unsupervised practice in all generic and specialty CiPs. Once a trainee has achieved level 4 sign off for a CiP it will not be necessary to repeat assessment of that CiP if capability is maintained.

This section of the curriculum details the eight specialty CiPs and the six generic CiPs for pharmaceutical medicine. The expected levels of performance, mapping to relevant GPCs and the evidence that may be used to make an entrustment decision are given for each CiP. The list of evidence for each CiP is not prescriptive and other types of evidence may be equally valid for that CiP.

## 3.2   Specialty capabilities in practice

The specialty CiPs describe the tasks or activities which are essential to the practice of pharmaceutical medicine. The CiPs have been mapped to the nine GPC domains to reflect the professional generic capabilities required to undertake the tasks or activities.

Satisfactory sign off will require educational supervisors to make entrustment decisions on the level of supervision required for each CiP. More detail is provided in the programme of assessment section of the curriculum.

# Specialty capabilities in practice (CiPs)

| CiP 1 | Enables and supports patients' timely access to medicines appropriate for their clinical needs |
|---|---|
| **Descriptors** | • Identifies areas of unmet medical need and related evidence gaps. <br><br> • Provides clinical input into product profiling and positioning. <br><br> • Contributes to the development of Health Technology Assessments (HTAs). <br><br> • Engages in pharmacoeconomic procedures associated with health technology commercialisation. <br><br> • Keeps the welfare and interests of patients and clinical trial participants at the forefront of decision-making. <br><br> • Provides effective procedures giving patients access to unlicensed medicines. <br><br> • Participates in liaising with regulators regarding patient engagement in medicines development. <br><br> • Participates in activities that influence the development lifecycle of medicines. <br><br> • Identifies and engages with stakeholders in the provision of medicines; facilitates the collection of qualitative data and feedback on the safe and effective use of medicines. <br><br> • Participates in generating strategic insights affecting the use of medicines. |
| **GPCs** | **Domain 1: Professional values and behaviours** <br><br> **Domain 2: Professional skills** <br><br> • Practical skills <br> • Communication and interpersonal skills <br> • Dealing with complexity and uncertainty <br><br> **Domain 3: Professional knowledge** <br><br> • Professional requirements <br> • National legislative requirements <br> • The health service and healthcare systems in the four countries <br><br> **Domain 4: Capabilities in health promotion and illness prevention** |

| | |
|---|---|
| | **Domain 5: Capabilities in leadership and team working** |
| | **Domain 6: Capabilities in patient safety and quality improvement** |
| | • Patient safety<br>• Quality improvement |
| | **Domain 7: Capabilities in safeguarding vulnerable groups** |
| | **Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Regulatory submissions/HTA submissions<br>• Clinical research documentation<br>• Documentation of area of unmet medical need<br>• Patient engagement activities<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| CiP 2 | Operates within ethical, regulatory and good practice frameworks |
|---|---|
| **Descriptors** | • Aptitude to work within local, regional and international regulatory and ethical frameworks, recognising guidelines and applying patient-centred good practices.<br><br>• Able to author, review, revise medical components for regulatory submissions both locally and regionally.<br><br>• Able to formulate responses to regulatory and health authorities, and research ethics committees.<br><br>• Complies with all codes of practice applicable to the biopharmaceutical industry.<br><br>• Undertakes internal mandatory training, follows applicable Standard Operating Procedures (SOPs), and has an aptitude for continuous quality improvement in the workplace.<br><br>• Keeps up to date with regulations and assesses the impact of regulatory change on medicines development and lifecycle management. |

| | |
|---|---|
| **GPCs** | **Domain 1: Professional values and behaviours** |
| | **Domain 2: Professional skills** |
| | • Practical skills |
| | **Domain 3: Professional knowledge** |
| | • Professional requirements<br>• National legislative requirements |
| | **Domain 5: Capabilities in leadership and team working** |
| | **Domain 6: Capabilities in patient safety and quality improvement** |
| | • Patient safety<br>• Quality improvement |
| | **Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Ethics submission documents and approvals (Protocol, Informed Consent Form, Patient Information Sheet)<br>• Attendance at a Research Ethics Committee (REC) meeting<br>• Clinical Trial Application (CTA)/ Investigational New Drug (IND) Application<br>• Common Technical Document (CTD) compilation and/or other regulatory submissions<br>• Label change activities, documentation/consultation<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| CiP 3 | Participates in data generation, analysis and communication |
|---|---|
| **Descriptors** | • Generates information and conducts data analysis.<br><br>• Undertakes scientific and medical writing and review.<br><br>• Prepares reviews/reports; presentations/publications.<br><br>• Identifies relevant data sources.<br><br>• Reviews the medical and scientific literature. |

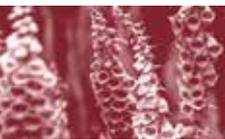| | |
|---|---|
| | • Reviews critically scientific and medical research publications.<br><br>• Discusses and interprets statistical principles and applications in the development of medicines.<br><br>• Contributes to the analysis and review of regulatory documents.<br><br>• Contributes to the creation and review of strategic and policy documents.<br><br>• Utilises systems to maintain data quality, integrity and confidentiality. |
| **GPCs** | **Domain 1: Professional values and behaviours**<br><br>**Domain 2: Professional skills**<br><br>• Practical skills<br>• Communication and interpersonal skills<br><br>**Domain 3: Professional knowledge**<br><br>• Professional requirements<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Publications/reports/product information<br>• Symposia//workshops/meetings<br>• Regulatory submissions/HTA submissions/product labelling<br>• Promotional material/corporate communication<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| | |
|---|---|
| **CiP 4** | **Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices** |
| **Descriptors** | • Applies the principles of pharmacokinetic and pharmacodynamic assessments, modelling and simulation, and exposure-effect relationships in clinical trial design and oversight. |

| | |
|---|---|
| | • Assesses and contributes to the design of early phase (exploratory) clinical development programmes and clinical trials.<br><br>• Communicates the design of a clinical trial and the potential risks and benefits.<br><br>• Interprets data from clinical trials and reviews how they impact the continued conduct of a trial and the design of   other clinical trials in the development plan.<br><br>• Involved in multi-disciplinary team decision-making.<br><br>• Contributes to interactions with regulatory authorities and research ethics committees.<br><br>• Able to manage projects including their planning, budgets, timelines, efficiency assessments and quality improvement activities. |
| **GPCs** | **Domain 2: Professional skills**<br><br>• Practical skills<br>• Communication and interpersonal skills<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Regulatory documents<br><br>• Submissions to research ethics committee and submissions to competent authority for Clinical Trial Authorisation<br><br>• Product documentation<br>  - Investigator Brochure<br>  - Investigational Medicinal Product Dossier<br>  - Clinical Risk Management Plan<br>  - Briefing documents, e.g. for scientific advice<br><br>• Clinical programme documentation<br>  - Clinical Development Plan<br>  - Outcomes of safety review meetings (could also fall under product documentation) |

- Clinical trial/study documentation
  - Clinical study synopsis or protocol
  - Informed Consent Form
  - Interim safety summaries

- Reports, presentations and publications
  - Posters and manuscripts
  - Clinical Study Reports

- WPBAs
- Core competencies
- ES report
- Course assessment
- DPM

| **CiP 5** | **Conducts clinical research for the development of medical products** |
|---|---|
| **Descriptors** | • Contributes to the authorship/review of a Clinical Development Plan (CDP).<br><br>• Applies the principles of Good Clinical Practice (GCP), other relevant GxPs and regulatory requirements.<br><br>• Identifies, manages and mitigates risk in special populations.<br><br>• Contributes to the review and adaptation of study specific documents.<br><br>• Contributes to project management strategies.<br><br>• Utilises quality management systems for the conduct of clinical studies.<br><br>• Able to oversee the conduct of clinical studies.<br><br>• Able to interpret the results of clinical studies and contribute to authorship/review of Clinical Study Reports (CSR). |
| **GPCs** | **Domain 1: Professional values and behaviours**<br><br>**Domain 2: Professional skills**<br><br>• Practical skills<br>• Communication and interpersonal skills<br>• Dealing with complexity and uncertainty |

| | **Domain 3: Professional knowledge** |
|---|---|
| | • Professional requirements<br>• National legislative requirements<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 7: Capabilities in safeguarding vulnerable groups** |
| **Evidence to inform decision** | • Case Report Forms (CRFs)/data capture tools<br>• Ethical/regulatory/project/study-specific documentation<br>• Content of Common Technical Document (CTD); eCTD<br>• Drug safety, risk management and mitigation materials<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| **CiP 6** | **Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation** |
|---|---|
| **Descriptors** | • Knows the requirements for reporting adverse events and demonstrates an ability to report adverse events and perform a causality assessment.<br><br>• Designs and executes methods to monitor and assess safety data and to carry out continuous safety monitoring.<br><br>• Analyses and summarises safety data from all sources; presents conclusions.<br><br>• Performs a benefit-risk evaluation; able to identify if new information will alter the benefit-risk balance and effect the safety of patients.<br><br>• Identifies and manages risks to guide appropriate use of a medical product. |

| | |
|---|---|
| | • Communicates new safety findings effectively and recommends appropriate risk management strategies and risk minimisation activities. |
| | • Locates safety information associated with a medical product and provides advice on its safe and effective use. |
| **GPCs** | **Domain 2: Professional skills**<br><br>• Practical skills<br>• Communication and interpersonal skills<br><br>**Domain 3: Professional knowledge**<br><br>• Professional requirements<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 7: Capabilities in safeguarding vulnerable groups**<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Authorship and/or review of text in core safety documents<br>• Written advice on the safe use of a medical product<br>• Individual Case Safety Report (ICSR)<br>• Safety monitoring<br>• Risk management and mitigation activities<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| | **CiP 7** | **Provides up to date evaluations of the benefits and risks of medical products** |
|---|---|---|
| **Descriptors** | | • Uses the benefit-risk evaluation of a medical product to perform a patient, product or product development impact assessment. |

| | |
|---|---|
| | • Applies statistical principles including quantitative and relevant qualitative methods to reach conclusions in benefit-risk evaluation.<br><br>• Applies assessments of benefit-risk balance to reach milestone decisions in product development.<br><br>• Provides clear explanation of the benefits and risks of a medical product to enable appropriate patient engagement.<br><br>• Proposes product management strategies and risk mitigation. |
| **GPCs** | **Domain 1: Professional values and behaviour**<br><br>**Domain 2: Professional skills**<br><br>• Practical skills<br>• Communication and interpersonal skills<br>• Dealing with complexity and uncertainty<br><br>**Domain 3: Professional knowledge**<br><br>• Professional requirements<br><br>**Domain 4: Capabilities in health promotion and illness prevention**<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • First in Human (FiH) and early (exploratory) development study documentation<br>• Clinical Overviews and Summaries<br>• Drug safety and pharmacovigilance signal management documentation<br>• Managing off-licence access to medicines<br>• Patient engagement activities in product development<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment<br>• DPM |

| CiP 8 | Supports business decision-making and progression in medical product innovation and development |
|---|---|
| **Descriptors** | • Works as part of a team in creating the Target Product Profile and designing the Clinical Development Plan by providing medical and clinical input within the context of the business development plan and commercial feasibility.<br><br>• Provides a medical contribution to due diligence with respect to product profiling, positioning within the market and addressing unmet medical needs.<br><br>• Identifies the possible position in the portfolio for products in development or during in-licensing.<br><br>• Involved in medical product lifecycle planning and management.<br><br>• Demonstrates an ability to facilitate business decision-making during the development and lifecycle of the medical product. |
| **GPCs** | **Domain 1: Professional values and behaviours**<br><br>**Domain 2: Professional skills**<br><br>• Communication and interpersonal skills<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 7: Capabilities in safeguarding vulnerable groups**<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Summary of Product Characteristics (SmPC)<br>• Target Product Profile document<br>• Clinical Development Plan<br>• Decision to progress to next clinical development phase<br>• Health Economics/Outcomes Research data in clinical development to support HTA and other post authorisation activities<br>• Reports and presentations<br>• Regulatory reclassification documents<br>• WPBAs<br>• Core competencies |

| | |
|---|---|
| • ES report | |
| • Course assessment | |
| • DPM | |

## 3.3 Generic capabilities in practice

The six generic CiPs cover the universal requirements of all specialties as described in GMP and the GPC framework. Assessment of the generic CiPs will be underpinned by the nine GPC domains and evidenced against the expected performance and behaviour for the trainee's stage of training.

For each generic CiP there is a set of descriptors of the observable skills and behaviours which would demonstrate that a trainee has met the level expected for the stage of training. The descriptors are not a comprehensive list and there may be more examples that would provide equally valid evidence of performance.

# Generic capabilities in practice (CiPs)

| CiP 9 | Upholds professional standards and the duties of the GMC's 'Good Medical Practice' and the Faculty of Pharmaceutical Medicine's 'Good Pharmaceutical Medicine Practice' |
|---|---|
| **Descriptors** | • Trusted to act honestly, openly and with integrity when interacting with patients, clinical trial participants, colleagues and other stakeholders.<br><br>• Able to recognise and practise within the limits of own professional competence and knows when to seek advice.<br><br>• Works within legal and regulatory standards and requirements.<br><br>• Applies the principles of equality and diversity in all professional interactions.<br><br>• Ensure that ethical considerations are paramount in medical practice and gain advice when dealing with conflicting ethical challenges.<br><br>• In all communications apply medical, regulatory, and professional standards, as recognised in the biopharmaceutical industry codes of practice.<br><br>• Recognises the privacy of any patient information they receive and ensures that patient confidentiality is maintained.<br><br>• Able to handle, store and transmit records containing personal information in line with data protection requirements. |

| | |
|---|---|
| **GPCs** | **Domain 1: Professional values and behaviours** |
| | **Domain 2: Professional skills** |
| | • Practical skills<br>• Communication and interpersonal skills<br>• Dealing with complexity and uncertainty |
| | **Domain 3: Professional knowledge** |
| | • Professional requirements<br>• National legislative requirements |
| | **Domain 5: Capabilities in leadership and team working** |
| | **Domain 6: Capabilities in patient safety and quality improvement** |
| | • Patient safety<br>• Quality improvement |
| **Evidence to inform decision** | • Informed consent documentation and actions.<br>• Communications and presentations<br>• Equality and diversity training<br>• Ethical and professional activities or conduct in clinical research<br>• Clinical trial registries<br>• Good publication practice guidelines (GPP3 – International Society of Medical Publication Professionals (ISMPP)); publishing work of the company<br>• Management of miscellaneous product matters and issues<br>• Review and sign off all materials and activities to ensure appropriate corporate compliance with industry codes of practice<br>• General Data Protection Regulation (GDPR) and data protection training<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

| CiP 10 | Works competently within pharmaceutical organisational and management systems |
|---|---|

| Descriptors | <ul><li>Maintains accountability to the organisation for the scope of their role and for working within the appropriate medical/governance framework.</li><li>Understands the structure and organisation of the pharmaceutical industry in the context of the production and provision of medicines and medical products for the benefit of patients.</li><li>Demonstrates appropriate professional values and behaviours in performing the role of a pharmaceutical physician.</li><li>Understands the organisation, accountabilities and responsibilities of national and regional regulatory agencies and related bodies.</li><li>Understands the legislative framework that the pharmaceutical industry operates in; keeps up to date with legal and regulatory developments and applies these in practice.</li><li>Understands the structure and organisation of relevant healthcare systems, e.g. the National Health Service (NHS) and related health organisations, e.g. National Institute for Health and Care Excellence (NICE).</li><li>Always performs within regulatory and professional guidelines and codes of practice.</li></ul> |
|---|---|

| GPCs | **Domain 1: Professional values and behaviours**<br><br>**Domain 2: Professional skills**<ul><li>Communication and interpersonal skills</li><li>Dealing with complexity and uncertainty</li></ul>**Domain 3: Professional knowledge**<ul><li>Professional requirements</li><li>National legislative requirements</li><li>The health service and healthcare systems in the four countries</li></ul>**Domain 4: Capabilities in health promotion and illness prevention**<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<ul><li>Patient safety</li><li>Quality improvement</li></ul> |
|---|---|

| | Domain 7: Capabilities in safeguarding vulnerable groups<br><br>Domain 8: Capabilities in education and training<br><br>Domain 9: Capabilities in research and scholarship |
|---|---|
| **Evidence to inform decision** | • Documentary/oral presentations<br>• Meetings participation/leadership<br>• Personal/Professional Development Plan<br>• Equality and diversity training<br>• Code of practice training<br>• Health and safety training<br>• Documentation from a completed project led by trainee<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

| **CiP 11** | **Remains up to date with research and best practices in pharmaceutical medicine, employs reflective practice and undertakes continuing professional development** |
|---|---|
| **Descriptors** | • Adapts to the dynamic environment of pharmaceutical medicine and the need to anticipate changes and remain up to date.<br><br>• Critically appraises emerging trends and technologies in pharmaceutical medicine.<br><br>• Demonstrates an aptitude for life-long learning, taking ownership of their personal development plan, identifying gaps, and seeking continuing professional development activities to address these.<br><br>• Able to receive and respond to constructive feedback.<br><br>• Reflects on and learns from their professional practice and that of others. |
| **GPCs** | **Domain 1: Professional values and behaviours**<br><br>**Domain 2: Professional skill**s<br><br>• Communication and interpersonal skills<br>• Dealing with complexity and uncertainty |

| | |
|---|---|
| | **Domain 3: Professional knowledge**<br><br>• Professional requirements<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 8: Capabilities in education and training**<br><br>**Domain 9: Capabilities in research and scholarship** |
| **Evidence to inform decision** | • Annual appraisals<br>• Notes and reflection from courses attended<br>• Presentations at congresses/conferences<br>• Personal/Professional Development Plan<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

| CiP 12 | Applies the principles and practices of leadership and multi-disciplinary teamworking, teaching and developing others |
|---|---|
| **Descriptors** | • Demonstrates applied knowledge and competence in leadership, teaching and mentoring relevant to the practice of pharmaceutical medicine.<br><br>• Ensures that the knowledge, skills, and behaviours associated with the competent practice of pharmaceutical medicine are communicated effectively and acquires the best techniques and practices to achieve this.<br><br>• Demonstrates leadership in applying knowledge to decision-making in teams.<br><br>• Demonstrates leadership in applying knowledge to educate and develop the capabilities of others.<br><br>• Contributes to teaching and training colleagues, including other healthcare professionals and other professionals e.g. scientists.<br><br>• Takes on a mentoring role for doctors in training and other colleagues. |

| | |
|---|---|
| | • Where possible, supports colleagues who have problems with their performance or health and take appropriate action, including action plan development.<br><br>• Appraises and assesses learning outcomes honestly and objectively.<br><br>• Supports, mentors and/or supervises colleagues, trainees and/or direct reports appropriately, including using relevant feedback tools, so that they can learn in a risk-managed environment. |
| **GPCs** | **Domain 1: Professional values and behaviour**<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 8: Capabilities in education and training** |
| **Evidence to inform decision** | • Project management/team leadership/multi-disciplinary team participation<br>• Delivery of teaching/training to in-house staff<br>• Reviewing a business case<br>• Drafting departmental objectives<br>• Appraisal output from local line management<br>• Assessing others<br>• Leadership/managerial skills training<br>• Providing guidance on Personal/Professional Development Plans<br>• External stakeholder interactions<br>• Multi-Source Feedback (MSF)<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

| | |
|---|---|
| **CiP 13** | **Engages in quality improvement activities, ensuring that ethical, regulatory, and professional business standards are maintained** |
| **Descriptors** | • Contributes to the quality assurance of standards in clinical research.<br><br>• Facilitates regular reviews and audit of work activities and responding constructively to the outcomes.<br><br>• Identifies need for root cause analysis of problems and delivers amended processes where necessary. |

| | |
|---|---|
| | • Able to provide further training if appropriate.<br><br>• Demonstrates engagement in feedback from patients, patient organisations, colleagues, healthcare professionals, regulatory.<br><br>• Participates in quality improvement activities. |
| **GPCs** | **Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 8: Capabilities in education and training** |
| **Evidence to inform decision** | • Training in ICH GCP (E6) and ICH quality guidelines (ICH Q8, Q9, Q10)<br>• Quality Management System (QMS) of a company<br>• Quality assurance assessments, audits and/or data quality checks in relation to clinical trials and clinical research<br>• Authorship and / or detailed review of SOPs<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

| | |
|---|---|
| **CiP 14** | **Keeps the safety of patients and the reliability of evidence at the forefront of decision-making in the design of development programmes for new and marketed medicines** |
| **Descriptors** | • Shows respect for patients and treats them fairly and without discrimination; recognises and respects diversity in others; considers the needs of special populations and, where appropriate, ensures that they are not excluded from clinical research.<br><br>• Communicate information clearly, considering the audience that will be receiving it.<br><br>• Recognises the contribution of patients and clinical trial participants; works in partnership with patients/patient advocates in the interests of public health. |

| | |
|---|---|
| | • Contributes to and complies with systems to protect patients, taking prompt action when patient safety may be compromised.<br><br>• Protects patients and colleagues from any risk posed by own health. |
| **GPCs** | **Domain 4: Capabilities in health promotion and illness prevention**<br><br>**Domain 5: Capabilities in leadership and team working**<br><br>**Domain 6: Capabilities in patient safety and quality improvement**<br><br>• Patient safety<br>• Quality improvement<br><br>**Domain 7: Capabilities in safeguarding vulnerable groups**<br><br>**Domain 8: Capabilities in education and training** |
| **Evidence to inform decision** | • Managing internal and/or external stakeholder interactions and relationships<br>• Participating in Ethics Committee meetings as an applicant and/or as a member<br>• Authorship and/or review of documents relating to the development and lifecycle management of medical product<br>• Clinical trial registration/reporting<br>• Review/sign off promotional and non-promotional material<br>• Risk minimisation measures<br>• Working within an appropriate governance framework when assessing proposals for novel and/or unlicensed use of medicines<br>• Incident management or safety review processes<br>• WPBAs<br>• Core competencies<br>• ES report<br>• Course assessment |

# 4. Learning & Teaching
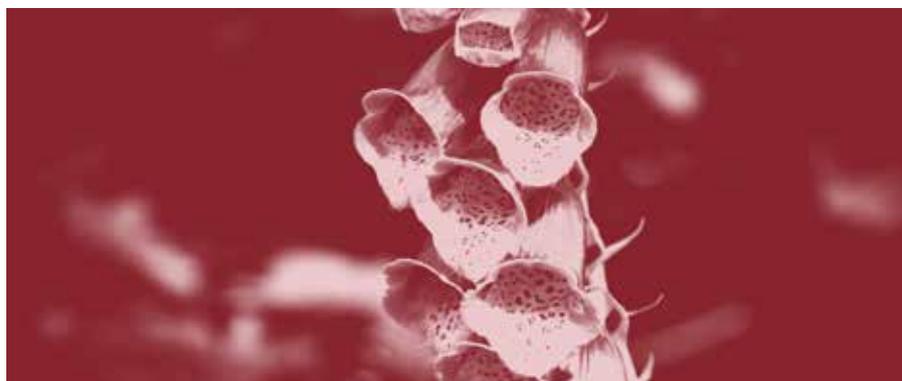


## 4.1    The training programme

The organisation and delivery of postgraduate training is the responsibility of the four statutory education bodies (SEBs) - Health Education England (HEE), NHS Education for Scotland (NES), Health Education and Improvement Wales (HEIW) and the Northern Ireland Medical and Dental Training Agency (NIMDTA).

The Pharmaceutical Medicine Deanery is responsible for the organisation and delivery of specialty training in pharmaceutical medicine and is composed of the postgraduate dean for pharmaceutical medicine, FPM and the Joint Royal Colleges of Physicians' Training Board (JRCPTB).

FPM's director of specialty training (DST) is responsible for coordinating the specialty training programme, implementing the curriculum and responding to the GMC on curriculum and programme quality management issues.

FPM's specialty training manager (STM) is responsible for overseeing the management of the specialty training programme such as preparing data for the GMC's annual national training survey and ARCP progression data reviews; managing the ARCP process and responding to GMC quality assurance queries and requests.

In the United Kingdom, the local organisation and delivery of training is overseen by GMC-approved local education providers (LEPs).

Trainees will have an appropriate a named educational supervisor.

Progression through the programme will be determined by the ARCP process. The training requirements for each indicative year of training are summarised in the ARCP decision aid, which is available on FPM's website at **www.fpm.org.uk**.

The sequence of training should ensure appropriate progression in experience and responsibility. The training to be provided at each LEP is defined to ensure that the curriculum requirements are met.

### 4.1.1 Pharmaceutical Medicine Specialty Training

The Pharmaceutical Medicine Specialty Training (PMST) programme over an indicative time of four years comprises:

**The specialty knowledge base for pharmaceutical medicine**

This is acquired from the syllabus for pharmaceutical medicine (PharmaTrain syllabus) through experience, private study and taught course(s) and tested through the DPM examination. The specialty knowledge base can be acquired and tested before or at the same time as the acquisition of specialty and generic capabilities in pharmaceutical medicine.

**Capabilities in practice for pharmaceutical medicine**

The 14 capabilities in practice (CiPs), eight specialty and six generic CiPs, of the PMST curriculum are completed through on-the-job activity leading to the acquisition of applied knowledge, skills and attitudes/behaviours, and an assessment of entrustability without supervision (level 4) across all the CiPs. The outcome of completing PMST is the CCT or its equivalent.

### 4.1.2 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 experiences in areas of the PMST curriculum.

Acquisition of the specialty knowledge base comes from the workplace experience and private study that could be supplemented with attendance at a structured course and through other means.

### 4.1.3 Achievement of knowledge base and capabilities in practice

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

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

The main means for many to achieve the specialty knowledge is through attendance at a postgraduate course in pharmaceutical medicine; attendance at a structured course is not mandatory. The outcome of acquisition of the specialty knowledge base is passing the DPM examination, which is mandatory before completion of PMST to gain a CCT or its equivalent.

Achievement of the CiPs also takes place in the workplace as far as possible directly as part of the trainee's job. Every effort is made to achieve CiPs through work experience during PMST and apart from changing job to acquire broad experience, other strategies can sometimes be employed, such as a job exchange or secondment to another site, overseas or to a service provider company.

Where there are no opportunities for a core topic of the PMST curriculum to be acquired in work, attendance on a course may be necessary. Courses might provide the main exposure to an area of applied knowledge or skill or might be supplementary to knowledge and skills acquired in the workplace. Courses for PMST are either internal (in-company) or external courses, which cover one or more topics of the curriculum. 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 learning outcomes on such courses is through workplace-based assessment (WPBA) for internal courses and through course assessments for external courses.

External courses appropriate for learning for PMST are increasingly subject to quality management to meet FPM and professional standards for postgraduate education and training, often through processes meeting the requirements of accreditation.

### 4.1.4   Taking time out of programme

There are several circumstances when a trainee may seek to spend some time out of specialty training, such as taking a career break or undertaking a professional qualification. All such requests must be agreed by the postgraduate dean in advance and trainees are advised to discuss their proposals as early as possible. Full guidance on taking time out of programme can be found in the Gold Guide.

## 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 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:

- experiential learning (workplace-based)
- structured postgraduate courses in pharmaceutical medicine (e.g. 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)
- in-company training programmes
- self-assessment
- reflective practice and commentary
- small-group seminar learning with peers. Leadership from industry, regulatory bodies, academia
- one-to-one teaching and learning

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

Teaching has moved to outcome- and competency-based learning from the familiar didactic lectures in the classroom. Scientists from industry and academia, clinicians from hospital medicine and general practice and senior pharmaceutical physicians present, share and discuss the latest research and its impact in the clinical setting and on medicines development.

Basic education and training should take place in short 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 by pre-course reading and research and post-course assignments and assessments, also increasingly by distance learning through correspondence or the internet.

## 4.2.1   Work-based experiential learning

The content of work-based experiential learning is decided by the trainee and their educational supervisor and recorded in the trainee's PDP. The learning experiences by which applied knowledge, skills and behaviours are acquired include 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
- online research e.g. literature survey
- participation in feasibility studies and due diligence activities e.g. reclassification, in-licensing
- journal clubs
- research presentations

## 4.2.2   Formal postgraduate teaching

The content of these sessions is determined by the local education provider (LEP) and the deanery and will be based on the curriculum. There are many opportunities throughout the year for formal teaching in the local postgraduate teaching sessions and at regional, national and international meetings.

Suggested activities include:

- a programme of formal regular teaching sessions to cohorts of trainees
- research, audit and quality improvement projects
- lectures and small group teaching
- critical appraisal and evidence-based medicine and journal clubs
- joint specialty meetings
- attendance at training programmes organised on a deanery or regional basis, which are designed to cover aspects of the training programme outlined in this curriculum.

### 4.2.3　Learning with peers

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

The trainee will acquire and apply knowledge through experiential learning on-the-job, through attendance at structured courses related to the specialist knowledge base, and supplementary courses as appropriate to meet the requirements of the curriculum.

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.

### 4.2.4　Independent self-directed learning

Trainees will use this time in a variety of ways depending upon their stage of training. Suggested activities include:

- reading, including online material such as e-Learning for Healthcare (e-LfH)
- maintenance of personal portfolio (independent study, self-assessment, reflective learning and practice, quality improvement activity, personal development plan)
- audit, quality improvement and research projects
- reading journals and web-based material
- achieving personal learning goals beyond the essential, core curriculum

### 4.2.5　Formal study courses

Time to be made available for formal courses is encouraged.  Examples include management and leadership courses and communication courses. Other examples are:

- postgraduate courses in pharmaceutical medicine
- revision courses, study days and weekends
- curricular topic-based short courses and masterclasses
- local, regional, national lectures and seminars

# 5. Programme of Assessment

## 5.1 Purpose of assessment

The purpose of the programme of assessment is to:

- assess trainees' actual performance in the workplace
- enhance learning by providing formative assessment, enabling trainees to receive immediate feedback, understand 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
- demonstrate that trainees have acquired the CiPs
- ensure that trainees meet GMP requirements
- ensure that trainees possess the essential underlying knowledge required for their specialty
- provide robust, summative evidence that trainees are meeting the curriculum standards during the training programme
- inform the 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.

## 5.2 The programme of assessment

The programme of assessment refers to the integrated framework of examination, assessments in the workplace and judgements made about a trainee during their approved programme of training. The purpose of the programme of assessment is to provide evidence for, to ensure acquisition of and to communicate the expected levels of performance at critical progression points in training, and to demonstrate satisfactory completion of training as required by the curriculum.

The programme of assessment is comprised of several different individual types of assessment. A range of assessments is needed to generate the necessary evidence required for global judgements to be made about satisfactory performance, progression in, and completion of, training. All assessments, including those conducted in the workplace, are linked to the relevant curricular learning outcomes, e.g. through the blueprinting of the assessment system to the stated curricular outcomes.

The programme of assessment emphasises the importance and centrality of professional judgement in making sure learners have met the learning outcomes and expected levels of performance set out in the approved curricula. Assessors will make accountable, professional judgements. The programme of assessment includes how professional judgements are used and collated to support decisions on progression and satisfactory completion of training.

The assessments will be supported by structured feedback for trainees. Assessment tools will be both formative and summative. Assessment will take place throughout the training programme to allow trainees to gather evidence of learning continually and to provide formative feedback. Those assessment tools which are not identified individually as summative will contribute to summative judgements about a trainee's progress as part of the programme of assessment. The number and range of these will ensure a reliable assessment of the training relevant to the trainee's stage of training and achieve coverage of the curriculum.

Reflection and feedback should be an integral component to all workplace-based assessments (WPBAs). For trainees to maximise benefit, reflection and feedback should take place as soon as possible after an event. Every work- and training-related encounter can provide a unique opportunity for reflection and feedback and this process should occur frequently. Feedback should be of high quality and should include an action plan for future development for the trainee. Both trainees and trainers should recognise and respect cultural differences when giving and receiving feedback.

## 5.3   Assessment of CiPs

Assessment of CiPs involves looking across a range of different skills and behaviours to make global decisions about a trainee's suitability to undertake tasks or take on responsibilities.

Supervisors and others contributing to assessment will provide formative feedback to the trainee on their performance throughout the training year. This feedback will include a global rating ('global assessment anchor statement') to indicate to the trainee how they are progressing at that stage of training for each CiP. To support this, WPBAs and educational supervisor reports will include the global assessment anchor statements.

### Global assessment anchor statements

| **Below expectations** for this year of training | **Meeting expectations** for this year of training | **Above expectations** for this year of training |

Towards the end of the training year, trainees will make a self-assessment of their progression for each CiP and record this in the e-portfolio with signposting to the evidence to support their rating ('global assessment anchor statement').

The educational supervisor (ES) will review the evidence in the e-portfolio including WPBAs and the trainee's self-assessment. They will then record their judgement on the trainee's performance in each CiP utilising the global assessment anchor statements in the ES report with commentary.

The ES will also record the indicative level of supervision (i.e. levels 1 – 4) required for each CiP with detailed comments to justify their entrustment decision.

The ES will also indicate in the ES report the most appropriate global assessment anchor statement for overall performance of all the CiPs.

**Level descriptors for specialty and generic CiPs**

**Level 1**   Entrusted to observe only.

**Level 2**   Entrusted to act with direct supervision: Has applied knowledge and understanding of skills required for capabilities and is able to act with them in practice under continuing supervision.

**Level 3**   Entrusted to act with indirect supervision: Applies knowledge and skills capably to undertake tasks and activities whilst remaining under continual supervision.

**Level 4**   Entrusted to act unsupervised.

The ARCP will be informed by the ES report and the evidence presented in the e-portfolio. The ARCP panel will make the final summative judgement on whether the trainee has achieved the appropriate level of supervision for each specialty and generic CiP. The ARCP panel will determine whether the trainee can progress to the next year of training in accordance with the Gold Guide. ARCPs will be held for each training year. The final ARCP will ensure trainees have achieved level 4 in all CiPs for the critical progression point at completion of training.

## 5.4   Critical progression points

The progression point for pharmaceutical medicine is completion of specialty training. Trainees will be required to be entrusted at level 4 in all CiPs by the end of training to achieve an ARCP outcome 6 and be recommended for a CCT or its equivalent.

The ES report will make a recommendation to the ARCP panel as to whether the trainee has met the defined levels for the CiPs required for each year of training. The ARCP panel will make the final decision on whether the trainee can be signed off and progress to the next year of training (see section 5.6).

The outline grid (Table 1) below sets out the expected level of supervision and entrustment for the specialty CiPs and includes the critical progression points across the whole training programme.

**Table 1**

**Outline grid of levels expected for pharmaceutical medicine specialty and generic CiPs**

Levels to be achieved by the end of each training year for specialty and generic CiPs

**Level descriptors**

**Level 1:** Entrusted to observe only
**Level 2:** Entrusted to act with direct supervision
**Level 3:** Entrusted to act with indirect supervision
**Level 4:** Entrusted to act unsupervised

| Specialty CiPs | ST3 | ST4 | ST5 | ST6 |
|---|---|---|---|---|
| Enables and supports patients' timely access to medicines appropriate for their clinical needs | 1-2 | 2-3 | 3-4 | 4 |
| Operates within ethical, regulatory and good practice frameworks | 2 | 2-3 | 3-4 | 4 |
| Participates in data generation, analysis and communication | 2 | 2-3 | 3-4 | 4 |
| Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices | 1-2 | 2-3 | 3-4 | 4 |
| Conducts clinical research for the development of medical products | 1-2 | 2-3 | 3-4 | 4 |
| Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation | 1-2 | 2-3 | 3-4 | 4 |
| Provides up to date evaluations of the benefits and risks of medical products | 2 | 2-3 | 3-4 | 4 |
| Supports business decision-making and progression in medical product innovation and development | 2 | 2-3 | 3-4 | 4 |

Critical progression point

| Generic CiPs | ST3 | ST4 | ST5 | ST6 |
|---|---|---|---|---|
| Upholds professional standards and the duties of the GMC's 'Good Medical Practice' and the Faculty of Pharmaceutical Medicine's 'Good Pharmaceutical Medicine Practice' | 4 | - | - | - |
| Works competently within pharmaceutical organisational and management systems | 3 | 4 | - | - |
| Remains up to date with research and best practices in pharmaceutical medicine, employs reflective practice and undertakes continuing professional development | 2-3 | 2-3 | 3 | 4 |
| Applies the principles and practices of leadership and multi-disciplinary teamworking, teaching and developing others | 2 | 2-3 | 3 | 4 |
| Engages in quality improvement activities, ensuring that ethical, regulatory, and professional business standards are maintained | 2 | 2-3 | 2-3 | 4 |
| Keeps the safety of patients and the reliability of evidence at the forefront of decision-making in the design of development programmes for new and marketed medicines | 2 | 2-3 | 2-3 | 4 |

Critical progression point

## 5.5 Evidence of progress

The following methods of assessment will provide evidence of progress in the integrated programme of assessment. The requirements for each training year are specified in the ARCP decision aid (**www.fpm.org.uk**).

### 5.5.1 Summative assessment

The summative assessment is the DPM examination, which is composed of two parts – part 1 is the multiple-choice question (MCQ) paper and part 2 consists of the short answer question (SAQ) paper and the critical appraisal paper (CAP).

### 5.5.2 Formative assessment

The formative assessments for the PMST programme are the WPBAs listed below:

- Pharmaceutical Medicine Assessment Tool (PMAT)
- Observation Assessment Tool (OAT)
- Quality Improvement Project Assessment Tool (QIPAT)
- Multi-Source Feedback (MSF)
- Patient Feedback (PF) (as applicable)

### 5.5.3 Supervisor reports

The ES must use the Pharmaceutical Medicine Educational Supervisor Report (PMESR).

These methods are described briefly below. More information and guidance for trainees, ESs and assessors are available in the e-portfolio and on FPM's website at **www.fpm.org.uk**.

Assessment should be recorded in the trainee's e-portfolio. These methods include feedback opportunities as an integral part of the programme of assessment.

### 5.5.4 Pharmaceutical Medicine Assessment Tool

The Pharmaceutical Medicine Assessment Tool (PMAT) 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 a pharmaceutical setting in relation to project goals and outcomes.

PMAT serves as a method to document conversations about and presentations of projects by trainees.

PMAT should include discussion about a written record (such as written plans, progress reports, and final reports). A typical encounter might be around the presentation of an interim project update to the project team. It is a structured narrative-based instrument for assessment of areas of application, learning, competency and performance related to standard/ non-standard project(s) being undertaken by the trainee.

### 5.5.5   Observation Assessment Tool

The Observation Assessment Tool (OAT) is designed to provide a framework for assessors to provide structured formative feedback to a trainee on their competency in undertaking teaching, delivering a presentation or chairing or participating in a meeting.

The OAT can be based on any instance of a formalised gathering in which the trainee is expected to make a substantial contribution and can be assessed by an observer.

The OAT is designed to assess a trainee's competency to interact effectively in a variety of group and one-to-one tasks and activities.

### 5.5.6   Quality Improvement Project Assessment Tool

The Quality Improvement Project Assessment Tool (QIPAT) is designed to assess a trainee's competence in completing a quality improvement project. The QIPAT can be based on a review of quality improvement project documentation or on a presentation of the quality improvement project at a meeting. If possible, the trainee should be assessed on the same quality improvement project by more than one assessor.

### 5.5.7   Multi-Source Feedback

Multi-Source Feedback (MSF) is a method of assessing generic skills including professional relationships, communication, team-working, leadership, and maintaining trust across the domains of Good Medical Practice.

MSF also serves as a form of assessment of attitudes and behaviours, such as problem solving, planning and prioritisation, maintaining high standards, flexibility and open mindedness and receptiveness to feedback.

This provides systematic collection and feedback of performance data on a trainee, derived from at least 12 respondents who may include colleagues (e.g. doctors, administrative staff and other allied professionals). The trainee will not see the individual responses. Feedback is given to the trainee by the ES.

### 5.5.8 Patient Feedback – as applicable

The Patient Feedback (PF) addresses issues including the behaviour of the doctor. It is intended to assess the trainee's performance in areas such as interpersonal and communication skills and professionalism.

PF is undertaken by doctors who are patient- or research participant-facing in the course of their work and is also part of the requirements for demonstrating the attributes of GMP.

### 5.5.9 Pharmaceutical Medicine Educational Supervisor Report

The ES will periodically (at least annually) record a longitudinal, global report of a trainee's progress based on a range of assessments, potentially including observations in practice or reflection on behaviour by those who have appropriate expertise and experience. The Pharmaceutical Medicine Educational Supervisor Report (PMESR) can incorporate commentary or reports from longitudinal observations, such as from supervisors or formative assessments demonstrating progress over time.

## 5.6   Annual Review of Competence Progression

The Annual Review of Competence Progression (ARCP) process is described in the Gold Guide. Local HEE offices and deaneries are responsible for organising and conducting ARCPs. The evidence to be reviewed by ARCP panels should be collected in the trainee's e-portfolio.

The ARCP process supports the collation and integration of evidence to make decisions about the achievement of expected outcomes.

In preparation for their ARCPs, FPM strongly recommend that trainees have an informal e-portfolio review with their educational supervisor. These provide opportunities for early detection of trainees who are failing to gather the required evidence for ARCP.

The ARCP panel's decisions must be fair, robust and defensible. The panel must make use of evidence from a range of assessments, potentially including exams and observations in practice or reflection on behaviour by those who have appropriate expertise or experience. They can also incorporate commentary or reports from longitudinal observations, such as from supervisors or formative assessments demonstrating progress over time.

There should be a review of the trainee's progress to identify any outstanding targets that the trainee will need to complete to meet all the learning outcomes for completion of training about 12 - 18 months before CCT. This should include an external assessor from outside the training programme.

FPM has provided an ARCP decision aid to guide trainees, supervisors and the ARCP panel. The guide sets out the requirements for a satisfactory ARCP outcome at the end of each training year and the critical progression point. The ARCP decision aid is available on FPM's website: **www.fpm.org.uk.**

## 5.7   Assessment blueprint

The table below show the possible methods of assessment for each CiP. This is a guide and it is not expected that every method will be used for each competency and additional evidence may be used to help make a judgement on capability.

**Blueprint for WPBAs mapped to CiPs**

Learning outcomes

**KEY**

**PMAT**
Pharmaceutical Medicine Assessment Tool

**MSF**
Multi-Source Feedback

**OAT**
Observation Assessment Tool

**QIPAT**
Quality Improvement Project Assessment Tool

**PF**
Patient Feedback (as appropriate)

| Specialty CiPs | PMAT | OAT | QIPAT | MSF | PF |
|---|---|---|---|---|---|
| Enables and supports patients' timely access to medicines appropriate for their clinical needs | X | | X | X | |
| Operates within ethical, regulatory and good practice frameworks | | X | | X | |
| Participates in data generation, analysis and communication | X | X | | X | |
| Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices | X | X | X | X | X |
| Conducts clinical research for the development of medical products | X | | X | X | |
| Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation | X | X | X | X | |
| Provides up to date evaluations of the benefits and risks of medical products | X | X | | X | |
| Supports business decision-making and progression in medical product innovation and development | X | | X | X | |

Learning outcomes

| Generic CiPs | PMAT | OAT | QIPAT | MSF | PF |
|---|---|---|---|---|---|
| Upholds professional standards and the duties of the GMC's 'Good Medical Practice' and the Faculty of Pharmaceutical Medicine's 'Good Pharmaceutical Medicine Practice' | | X | | X | |
| Works competently within pharmaceutical organisational and management systems | | X | | | |
| Remains up to date with research and best practices in pharmaceutical medicine, employs reflective practice and undertakes continuing professional development | X | | X | | |
| Applies the principles and practices of leadership and multi-disciplinary teamworking, teaching and developing others | | X | | X | |
| Engages in quality improvement activities, ensuring that ethical, regulatory, and professional business standards are maintained | | X | | | |
| Keeps the safety of patients and the reliability of evidence at the forefront of decision-making in the design of development programmes for new and marketed medicines | | X | | X | X |

**KEY**

**PMAT**
Pharmaceutical Medicine Assessment Tool

**MSF**
Multi-Source Feedback

**OAT**
Observation Assessment Tool

**QIPAT**
Quality Improvement Project Assessment Tool

**PF**
Patient Feedback (as appropriate)

# 6. Supervision & Feedback



This section of the curriculum describes how trainees will be supervised, and how they will receive feedback on performance. For further information please refer to the AoMRC guidance on 'Improving feedback and reflection to improve learning. A practical guide for trainees and trainers'[4].

Access to high quality, supportive and constructive feedback is essential for the professional development of the trainee. Trainee reflection is an important part of the feedback process and exploration of that reflection with the trainer should ideally be a two-way dialogue. Effective feedback is known to enhance learning and combining self-reflection to feedback promotes deeper learning.

Trainers should be supported to deliver valuable and high-quality feedback. This can be by providing face to face training to trainers. Trainees would also benefit from such training and all involved could also be shown how best to carry out and record reflection.

## 6.1    Educational supervision

All elements of work in training posts must be supervised with the level of supervision varying depending on the experience of the trainee and the project and activity mix undertaken. As training progresses the trainee should be given more autonomy as their capabilities increase.

**Educational supervisor**

Pharmaceutical medicine LEPs must make sure that each trainee has access to a named ES.

The GMC has defined the role and responsibilities of the ES in 'Promoting excellence: standards for medical education and training'[5].

The ES is responsible for the overall supervision and management of a trainee's educational progress towards completing the specialty training programme. The ES meets regularly with the trainee to help plan their training, review progress and achieve agreed learning outcomes. The ES is responsible for the educational agreement, and for bringing together all relevant evidence to form a summative judgement about progression.

The ES needs to be formally recognised by the GMC to carry out their role[6]. It is essential that training in assessment is provided for trainers and trainees to ensure that there is complete understanding of the assessment system, assessment methods, their purposes and use. Training will ensure a shared understanding and a consistency in the use of the workplace-based assessments and the application of standards.

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

**Trainees**

There are many opportunities for feedback for trainees, which can be summarised as follows:

a) There is feedback from FPM's Board of Examiners for DPM candidates who have failed either part 1 or part 2 of this summative examination. The DPM is the mandatory knowledge-based examination which is a critical progression point within the PMST programme.

b) Educational meetings between the trainee and ES are a major opportunity for feedback on performance and its component variables, on meeting standards, on progress and on critique of planning. Educational meetings, held in reserved time, are confidential, non-judgmental events which can be summarised in the e-portfolio.

c) WPBAs offer multiple opportunities for feedback albeit that they have a formal element (assessment) to them. Feedback from WPBAs has immediate relevance for the trainee in terms of next steps and actions. WPBAs include PMAT, OAT and QIPAT.

d) Annual MSF is a major opportunity for feedback to trainees, mainly on attitudes and behavioural aspects of competencies and capability, rather than skills and knowledge.  Feedback, either from scales or anonymised free text is a key purpose of the MSF.

e) The PF tool in pharmaceutical medicine is reserved for those patient-facing doctors, usually conducting clinical trials and having responsibilities for medical care and supervision of study participants; patient and/or healthy volunteers.

f) The ARCP is the formal annual review of trainee achievement and progress in the programme, with the aim of determining progress to the next stage of training, but also providing a feedback opportunity (from the ARCP panel) to the trainee and ES.

g) There are many opportunities during the year for ad hoc meetings between trainees and representatives/stakeholders in the PMST programme, e.g. Specialty Adviser (SA) with trainee, ES and LEP; FPM/deanery with trainee, LEP, SA and ES. These can be for many different reasons, but the opportunity for relevant feedback for the trainee will not be lost, if this is seen as a key aim, e.g. addressing supportive measures for trainees.

h) Training and update meetings from FPM/deanery to groups, e.g. ES networks also offer feedback opportunities, for example for the ES to feedback general matters from FPM/deanery to trainees.

i) In transition from one LEP to another during training offers many opportunities for feedback, and notably for re-setting of training goals and commitments: PDP and prioritisation.

Trainees should actively devise individual learning goals in discussion with their ESs and should subsequently identify the appropriate opportunities to achieve them. Trainees would need to plan their WPBAs accordingly to enable them to provide a picture of their development during a training period according to their individual learning needs.

It is the responsibility of trainees to seek feedback following learning opportunities and WPBAs.

Trainees should conduct self-assessment and reflect on their achievement of capabilities including consideration of constructive feedback.

Furthermore, trainees should formulate personal development plans (PDPs) with further learning goals in discussion with their ESs.

## 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 e-portfolio.

**Annual Appraisal**

On an annual basis, trainees should review the PDP and curriculum progress with their ES using evidence from the e-portfolio. Specific concerns may be highlighted from this appraisal. The annual appraisal form should record the areas where further work is required to overcome any shortcomings. Further evidence of competence in certain areas may be needed, such as planned workplace-based assessments (WPBAs), and this should be recorded. If there are significant concerns following the annual appraisal, then the training programme director should be informed.

**Workplace Transition Appraisal**

Before the trainee leaves employment for another post, an appraisal should be held between trainee and their ES particularly if the trainee or ES has training concerns or the trainee has been set specific targeted training objectives at their ARCP. At this meeting trainees should review their PDP with their ES using evidence from the e-portfolio. Specific concerns may be highlighted from this appraisal. The appraisal form should record the areas where further work is required to overcome any shortcomings. Further evidence of competence in certain areas may be needed, such as planned workplace-based assessments, and this should be recorded.

# 7. Quality Management
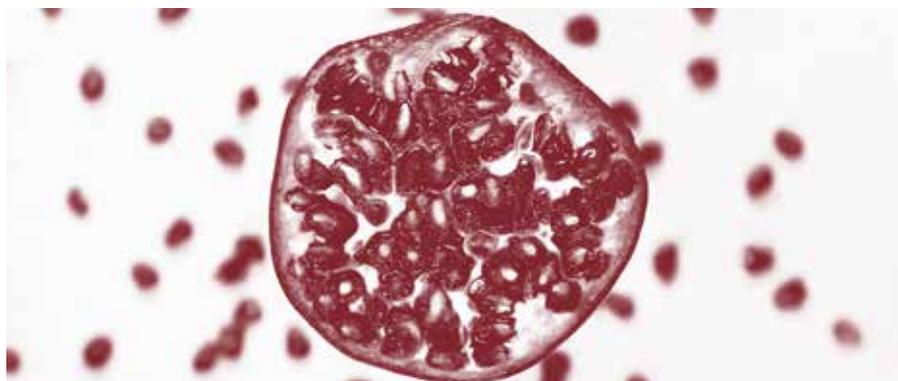


The organisation of specialty training in pharmaceutical medicine is the responsibility of the Pharmaceutical Medicine Deanery. The deanery will oversee the following:

• oversee enrolment and induction of trainees into the specialty
• oversee the quality of local education providers and their delivery of training
• ensure adequate provision of appropriate educational events
• ensure curricula implementation across training programmes
• oversee the workplace-based assessment process within programmes
• coordinate the ARCP process for trainees
• provide systems to identify and assist doctors with training difficulties
• provide flexible training.

Educational programmes to train ESs and assessors in workplace-based assessment are delivered by FPM in collaboration with the deanery.

Development, implementation, monitoring and review of the curriculum are the responsibility of FPM, the JRCPTB and the Specialist Advisory Committee (SAC) jointly.

**The Specialist Advisory Committee**

The Specialist Advisory Committee (SAC) will be formally constituted with the:

- chairperson
- vice chairperson
- postgraduate dean or their deputy
- appointed members
- ex-officio members

It will be the responsibility of FPM, in collaboration with the JRCPTB, to ensure that curriculum developments are communicated to the GMC, trainees and ESs.

The SAC is actively involved in assisting and supporting FPM and the deanery to manage and improve the quality of education within each approved pharmaceutical medicine LEP. They are tasked with activities central to assuring the quality of medical education such as writing the curriculum and assessment systems and recommending trainees eligible for CCT or its equivalent.

FPM and the deanery use data from three quality datasets to provide meaningful quality management. The datasets include the GMC annual national training survey (NTS) data, ARCP outcomes and examination outcomes.

**The Faculty of Pharmaceutical Medicine**

FPM's quality management of the curriculum and its WPBAs will be two-fold; it will involve:

i) ongoing review and monitoring; and

ii) a full review of the content of the curriculum and the WPBAs, normally conducted biennially.

**Ongoing review and monitoring**

FPM will use the following sources of information and data as part of its ongoing review and monitoring of the curriculum and the WPBAs:

- GMC's annual NTS
- GMC's ARCP progression data reports
- GMC's examinations data reports
- JRCPTB reports to the Specialist Advisory Committee on ARCP outcomes
- Information on trainee e-portfolios, e.g. completed PMSERs
- LEP's annual self-assessment
- Specialty Advisers' (SAs') LEP assessment forms
- COVID-19 trainee self-assessment and declaration forms

This is not an exhaustive list and there may be other sources of information that FPM will use as part of its ongoing review of the curriculum.

In addition, FPM will survey trainees and trainers annually on the content of the curriculum and the performance of the WPBAs. FPM will triangulate the results of the surveys with the other sources of information and data listed above to assess whether:

- the CiPs, descriptors and examples of evidence in the curriculum need to be updated or removed;
- the WPBAs are assessing trainees' competencies and capabilities adequately;
- further trainees, ESs and assessors need further training and guidance; or
- there are indications of differential attainment between different groups of trainees and explore methods to address this such as providing additional training for ESs or tutorials for those groups.

FPM's DST will analyse the information and data that have been collected, with the assistance of FPM's STM, and submit a report to the Specialist Advisory Committee (SAC). The report might include recommendations to the SAC to amend parts of the curriculum or the WPBAs or both, which the SAC will be asked to provisionally approve. If the SAC provisionally approves the changes to the curriculum or the WPBAs, the DST will reconvene FPM's Curriculum and Assessment Working Group (CAWG) to update the relevant parts of the curriculum or WPBAs.

The membership of the CAWG will normally include:

i) Trainees
ii) ESs
iii) SAs
iv) Pharmaceutical medicine specialist registrants
v) Lay representative
vi) Patient advocates (if necessary)

On completion of the CAWG's work, FPM will normally consult trainees, ESs and LEPs (patient advocates might also be consulted) on the proposed changes before applying to the GMC for approval. FPM might organise focus groups, particularly on changes that might impact trainees who share protected characteristics, to collect additional feedback and suggestions. The outcome of these focus groups will contribute to FPM's equality and diversity impact assessment of the proposed changes on trainees who share protected characteristics.


**Biennial review**

FPM will normally conduct a full review of the curriculum and the WPBAs biennially. The purpose of the review is to make sure:

i) the curriculum remains relevant to the practice of pharmaceutical medicine;
ii) the WPBAs assess trainees' achievement of the CiPs adequately;
iii) trainees who share protected characteristics continued to be supported to complete the specialty training programme; and
iv) ESs are supported to make fair professional judgements about their trainees' achievement of the CiPs.

The review will normally start six months before the anniversary of the implementation of the curriculum. FPM will invite key groups such as trainees, ESs, LEPs and patient advocates (if necessary) to submit their suggestions to amend or replace the specialty and generic CiPs, descriptors and the WPBAs. FPM will also invite feedback on its guidance documents. The DST will reconvene the CAWG to consider the suggestions and set its terms of reference including the date for completing its work.

The output from the CAWG will be open to consultation and to focus groups if any of the proposed changes will impact on trainees who share protected characteristics. The CAWG will consider the consultation and focus group responses before finalising the draft changes for ratification by the SAC and FPM applying to the GMC to approve the curriculum or assessment changes.

FPM will refer to the GMC's standards and guidance on equality and diversity[7] and supporting trainees from black and minority ethnic backgrounds[8] at all times when undertaking its ongoing and biennial reviews.

# 8. Intended use of the curriculum by trainees and ESs



This curriculum and ARCP decision aid are available from both FPM and JRCPTB websites – **www.fpm.org.uk** and **www.jrcptb.org.uk** respectively.

ESs should use the curriculum and decision aid as the basis of their discussion with trainees, particularly during the appraisal process. Both trainees and ESs 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 an e-portfolio. The trainee will use the curriculum to develop learning objectives and reflect on learning experiences.

**Recording progress in the e-portfolio**

On enrolling with FPM and the JRCPTB, trainees will be given access to the e-portfolio. The e-portfolio allows evidence to be built up to inform decisions on a trainee's progress and provides tools to support trainees' education and development.

The trainee's main responsibilities are to ensure the e-portfolio is kept up to date, arrange assessments and ensure they are recorded, prepare drafts of appraisal forms, maintain their personal development plan, record their reflections on learning and record their progress through the curriculum.

The ES's main responsibilities are to use e-portfolio evidence such as outcomes of assessments, reflections and personal development plans to inform appraisal meetings. They are also expected to update the trainee's record of progress through the curriculum, write educational meeting reports, appraisals and supervisor's reports.

Deaneries, training programme directors and ARCP panels may use the e-portfolio to monitor the progress of trainees for whom they are responsible.

FPM and the JRCPTB may use summarised, anonymous e-portfolio data to support their quality management work.

All appraisal meetings, personal development plans and workplace-based assessments (including MSF) should be recorded in the e-portfolio. Trainees are encouraged to reflect on their learning experiences and to record these in the e-portfolio. Reflections can be kept private or shared with ESs.

Reflections, assessments and other e-portfolio content should be used to provide evidence towards acquisition of curriculum capabilities. Trainees should add their own self-assessment ratings to record their view of their progress. The aims of the self-assessment are:

- to provide the means for reflection and evaluation of current practice
- to inform discussions with supervisors to help both gain insight and assists in developing personal development plans.
- to identify shortcomings between experience, competency and areas defined in the curriculum to guide future clinical exposure and learning.

ESs can sign-off and comment on curriculum capabilities to build up a picture of progression and to inform ARCP panels.

# 9. Equality and diversity



FPM and the Royal Colleges of Physicians (RCP) will comply with and ensure compliance with equality and diversity requirements set out in the Equality Act 2010.

FPM and 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 FPM and the RCP, either as members of staff and officers; as examiners and appraisers; doctors in training or examination candidates.

The deanery's management of quality will ensure that the PMST programme complies with the equality and diversity standards in postgraduate medical training as set by GMC. They should provide access to a professional support unit or equivalent for trainees requiring additional support.

Compliance with anti-discriminatory practice will be assured through:

• monitoring of enrolments processes

• ensuring all FPM representatives including the DST have attended appropriate training sessions prior to appointment or within 12 months of taking up post

• the deanery ensuring that its agents and ESs have had equality and diversity training (for example, an e-learning module) every three years

• the deanery ensuring that any specialist participating in trainee interview/appointments committees or processes has had equality and diversity training (at least as an e-module) every three years

- ensuring trainees have an appropriate, confidential and supportive route to report examples of inappropriate behaviour of a discriminatory nature. The deanery and DST must ensure that on enrolment, trainees are made aware of the route in which inappropriate or discriminatory behaviour can be reported and supplied with contact names and numbers. The deanery must also ensure contingency mechanisms are in place if trainees feel unhappy with the response or uncomfortable with the contact individual

- providing resources to trainees needing support (for example, through the provision of a professional support unit or equivalent)

- monitoring of the DPM examination, and

- ensuring all assessments discriminate on objective and appropriate criteria and do not unfairly advantage or disadvantage a trainee with any of the Equality Act 2010 protected characteristics. All efforts shall be made to ensure the participation of people with a disability in training through reasonable adjustments.

# Endnotes



[1]GMC, '**Generic professional capabilities framework**', May 2017

[2]GMC, '**Good Medical Practice**', 22 April 2013

[3]Ten Cate, Olle., '**Nuts and bolts of entrustable professional activities**', Journal of graduate medical education vol. 5,1 (2013): 157-8. doi:10.4300/JGME-D-12-00380.1

[4]Academy of Medical Royal Colleges, '**Improving feedback and reflection to improve learning:. A practical guide for trainees and trainers**', May 2017

[5]GMC, '**Promoting excellence: standards for medical education and training**', 15 July 2015

[6]GMC, **Recognition and approval of trainers**

[7]GMC, '**Approving changes to curricula, examinations and assessments: equality and diversity requirements**'

[8]GMC, '**How to support successful training for black and minority ethnic doctors: Actions and case studies for medical royal colleges and faculties**'