Essential guidance

for trainees, educational supervisors and assessors

Pharmaceutical Medicine Specialty Training
2021 Curriculum
Version 1

Faculty of
Pharmaceutical Medicine

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1. Introduction

This document contains guidance for trainees and educational supervisors (ESs) on how to use the 2021 specialty training curriculum for pharmaceutical medicine (2021 curriculum) and how a trainee, with support from their ES, can identify activities in their work that could be used as evidence of:

1. engagement with patients, clinical trial participants and their needs; and

2. fulfilment of the relevant capabilities in practice (CiPs).

We explain what each of the CiPs are about and what we expect the trainee to do for each CiP so that their ES can make an informed professional judgement about the trainee's capability. We also give examples of the types of evidence that a trainee could collect to demonstrate their capabilities. This list of examples is not exhaustive.

Reflection is an important element of learning. To inform the annual Pharmaceutical Medicine Educational Supervisors Report (PMESR) and to prepare for the trainee's ARCP, a trainee will need at least annually to reflect for each CiP explaining how the totality of the evidence for that CiP demonstrates that the requirements of the CiP have been progressed during the year and the levels of attainment achieved. Reflection is also included in some workplace-based assessments (WPBAs) and may be added for any learning experiences or items of evidence that the trainee or ES believe are appropriate.

We have included a glossary that explains some of the terms we use in this document and in the curriculum. We recommend you consult the glossary when you read this guidance and the curriculum.

We will review the guidance periodically to make sure it is up to date. We welcome feedback and suggestions on improving the content of the guidance so that it remains relevant to the user. Please send your feedback and suggestions to **pmst@fpm.org.uk**.

Background

All UK medical royal colleges and faculties were required to write new or update current curricula to:

1. include specialty capabilities in practice; and

2. incorporate the General Medical Council's (GMC's) 'Generic professional capabilities framework' in the curricula.

This work followed an independent review called the Shape of Training Review that was led by Professor David Greenaway. Professor Greenaway's

report, ‘Securing the future of excellent patient care’, made several recommendations to change postgraduate medical education and training in the UK to make training programmes more flexible for doctors in training and to ensure that doctors have the required capabilities to meet patient and health service needs. The UK Shape of Training Steering Group published advice on how royal colleges and faculties can implement the recommendations in Professor Greenaway’s report.

Specialty capabilities in practice

The specialty and generic professional capabilities are the key elements of the 2021 curriculum. A capability is the possession of personal qualities, competencies, abilities and capacity to get a job done and have the potential to develop to meet future needs. There are 14 CiPs which cover all aspects of being a pharmaceutical physician:

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.

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.

Generic professional capabilities

The GMC identified generic professional capabilities that a doctor is required to attain during undergraduate and postgraduate UK medical training to ensure that on completion of training the doctor can provide safe, effective and high-quality medical care in the UK. The GMC's generic professional capabilities are categorised under nine domains:

Domain 1 - professional values and behaviours.

Domain 2 - professional skills.

Domain 3 - professional knowledge.

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.

Domain 7 - capabilities in safeguarding vulnerable groups.

Domain 8 - capabilities in education and training.

Domain 9 - capabilities in research and scholarship.

We mapped the nine domains of the GMC's framework to both the specialty and generic CiPs and for some CiPs incorporated them in the wording. Please see the appendix for a table summarising our mapping of the framework to our CiPs.

Descriptors

The descriptors describe the knowledge, skills and behaviours that a trainee might be expected to attain to demonstrate their acquisition of the capabilities and to be judged as achieving the CiP (also known as high-level outcome). The lists of descriptors for each CiP are neither prescriptive nor exhaustive; they are examples to guide the trainee and their ES to recognise the knowledge, skills and attitudes which could be demonstrated. The core competencies and their mapping describe in more detail how the capabilities relate to the international expectations of a pharmaceutical physician. The practical activities and examples of evidence are provided to give suggestions of how capabilities in each CiP might be demonstrated.

The descriptors are written as activity based. It is recognised that where a trainee is not working in a particular area of the specialty these descriptors may be covered in simulated exercises or taught courses.

Expectations of the trainee and educational supervisor

Our expectation is that a trainee will acquire the capabilities in their job without the need to change roles although this may be beneficial, either by a change of role or by secondment, when it is possible/appropriate. The curriculum is designed to develop general pharmaceutical physicians who can transfer their capabilities to other areas of pharmaceutical medicine and potentially to other specialties.

To assist trainees and their ESs in assessing whether competencies have been acquired, we have mapped our CiPs to the core competencies for pharmaceutical medicine. We recommend trainees and ESs refer to the core competencies when they have their educational meetings.

The ES has an important role in supporting their trainee to complete the PMST programme. The ES:

- collaborates with his or her trainee in designing a professional development plan (PDP);
- discusses with the trainee their completion of the PDP at regular educational meetings;
- helps the trainee identify opportunities in the workplace and on courses to complete the CiPs;
- is the first point of contact if a trainee requires support;
- assesses the trainee's competencies; and
- makes a professional judgement on whether the trainee has attained the required level of entrustment.

When can a CiP be signed off?

Questions that the trainee should ask themselves when considering whether they have reached the required level are:

- Does the evidence reflect my acquisition of the capabilities?
- Have I written a reflective commentary at the CiP level that explains how the totality of my evidence demonstrates that I am fully capable?
- Do I have evidence of my generic professional capabilities for this CiP?

Questions that the ES should ask themselves when judging whether their trainee has reached the required level are:

- Is this sufficient evidence to sign off the CiP?
- Do the trainee's reflective commentaries state how the totality of their evidence demonstrate their capability?
- Am I content there is evidence to support the acquisition of the core competencies?
- Is this the best evidence? Would some of this evidence be more appropriate in other CiPs as evidence?
- Is there other evidence that has been missed?

Here is a diagram that illustrates the levels of information that should inform an ES's professional judgement that their trainee has reached the capability and can be signed off.

It is the quality of the evidence and not the quantity that is key to an ES's judgement about the trainee's required level of capability and whether the CiP should be signed off as complete.

Applying the CiPs to a trainee's job

When we designed the specialty and generic CiPs we were aware that pharmaceutical physicians perform a wide range of roles and that many pharmaceutical physicians work in niche areas of the specialty.

We made sure that the CiPs and their descriptors were designed so that a trainee can gain the capabilities regardless of where they work in the specialty.

Core competencies for pharmaceutical physicians

The 'Core competencies in Pharmaceutical Medicine and Medicines Development' sets out the key knowledge, skills and attitudes that a pharmaceutical physician should acquire. We recommend ESs and other assessors use this document to help assess the trainee's performance of the descriptors and make a judgement on their capability.

The 57 core competencies, each described using applied knowledge, skills and behaviours, are listed in appendix 2 and serve to inform the statement of competence of a practitioner in pharmaceutical medicine engaged in the development of medicines. The competent developer of medicines:

1. Is able to identify unmet therapeutic needs, evaluate the evidence for a new candidate for clinical development and design a Clinical Development Plan for a Target Product Profile.

2. Is able to design, execute and evaluate exploratory and confirmatory clinical trials and prepare manuscripts or reports for publication and regulatory submissions.

3. Is able to interpret effectively the regulatory requirements for the clinical development of a new drug through the product life-cycle to ensure its appropriate therapeutic use and proper risk management.

4. Is able to evaluate the choice, application and analysis of post-authorization surveillance methods to meet the requirements of national/international agencies for proper information and risk minimisation to patients and clinical trial participants.

5. Is able to combine the principles of clinical research and business ethics for the conduct of clinical trials and commercial operations within the organisation.

6. Is able to appraise the pharmaceutical business activities in the healthcare environment to ensure that they remain appropriate, ethical and legal to keep the welfare of patients and research participants at the forefront of decision making in the promotion of medicines and design of clinical trials.

7. Is able to interpret the principles and practices of people management and leadership, using effective communication techniques and interpersonal skills to influence key stakeholders and achieve the scientific and business objectives.

The Patient's voice

Patients are becoming increasingly active stakeholders in both their own treatment and in shaping medicines development and adoption, with patient representatives featuring in organisations such as the European Medicines Agency (EMA) and the National Institute for Health and Care Excellence (NICE).

Patients and clinical trial participants are at the heart of pharmaceutical medicine and the work of the pharmaceutical physician. They are at the forefront of the 2021 curriculum and it is important that trainees and ESs can identify areas of the trainee's work where they can demonstrate interactions with patients and clinical trial participants.

We recognise that many pharmaceutical physicians do not have direct contact with patients and clinical trial participants, but their work has a direct impact on them. We have included in this guidance examples of the type of evidence that trainees could collect to demonstrate they have taken account of the patient perspective when they work towards achieving their CiPs.

CiP 1

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

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to engage in the development of medicinal products, mindful of unmet patient needs and the provision of effective medicines for patient use and benefit.

During training, the trainee should, where possible, be given opportunities to relate unmet medical needs and product evidence gaps in the context of product profiling and positioning; engaging in and contributing to pharmacoeconomic processes relating to produce commercialisation and to the development of HTAs; involved in the medical procedures giving patients access to unlicensed medicines; participation in activities determining the lifecycle development of medicines; involved in the medico-marketing activities concerned with the provision of medicines (e.g. at launch of a new medicines and the immediate post-launch period in the development of strategies affecting the safe and effective use of medicines).

Descriptors

- Identifies areas of unmet medical need and related evidence gaps.
- Provides clinical input into product profiling and positioning.
- Contributes to the development of Health Technology Assessments (HTAs).
- Engages in pharmacoeconomic procedures associated with health technology commercialisation.
- Keeps the welfare and interests of patients and clinical trial participants at the forefront of decision-making.
- Provides effective procedures giving patients access to unlicensed medicines.
- Participates in liaising with regulators regarding patient engagement in medicines development.

	• Participates in activities that influence the development lifecycle of medicines. • 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. • Participates in generating strategic insights affecting the use of medicines.
Core competencies	C1, 5, 8, 12, 21, 25, 43 and 48.
Practical activities/ examples of evidence	• Evidence of incorporating the needs of patients in clinical trial designs. • Review or writing protocols for real-world data generation and promotion of medicines. • Organises/contributes to advisory boards, meetings with patients/ patient support groups as a key focus. • Organise or help to organise meetings with patient groups, patient experts. • Organise or help to organise consultations, including focus groups. • Use key guidance or resources on engaging and involving patients. • Involve or facilitate the involvement of patients or patient experts in the development of HTAs. • Development and implementation of contractual arrangements with patients and carers. • Explore patient engagement guidance, training and experience, available on Patient Focused Medicines Development (PFMD suite): **https://pemsuite.org/** The European Patients' Academy on Therapeutic Innovation (EUPATI)Toolbox: **https://eupati.eu/training/patient-engagement/** EUPATI Toolbox: **https://toolbox.eupati.eu** • Undertake training in patient engagement. • Meeting agendas (e.g. discussing approach to early access, named patient supplies). • Reports on feedback or responses to consultations. • Communications with patients, patient experts or clinical trial participants including examples where access could not be granted (e.g. too early in development, only available within a clinical trial, supply constraints).

- contracts developed with patients and carers, including reflections on how to improve these.
- Procedures / Procedure update for processes which describe this work.
- Materials generated following patient consultation, e.g. HTA submission.
- Application of materials from - Completion of training courses on patient engagement, including on **https://pemsuite.org/**
- Reflection on case studies on patient preference studies/application to practice (**https://www.imi-prefer.eu/case-studies/**)

CiP 2

Operates within ethical, regulatory and good practice frameworks

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours needed to work within the legal, ethical and regulatory frameworks established to provide good governance of the biopharmaceutical industry and its activities.

During training, the trainee should, where possible be involved across the lifecycle of medical product development and commercialisation in medical activities resulting in regulatory submissions, research ethics committee interactions, industry codes of practice application and compliance, and continuous quality improvement projects.

Descriptors

- Aptitude to work within local, regional and international regulatory and ethical frameworks, recognising guidelines and applying patient-centred good practices.
- Able to author, review, revise medical components for regulatory submissions both locally and regionally.
- Able to formulate responses to regulatory and health authorities, and research ethics committees.
- Complies with all codes of practice applicable to the biopharmaceutical industry.
- Undertakes internal mandatory training, follows applicable Standard Operating Procedures (SOPs), and has an aptitude for continuous quality improvement in the workplace.

	• Keeps up to date with regulations and assesses the impact of regulatory change on medicines development and lifecycle management.
Core competencies	C2, 3, 5, 7, 8, 12, 13, 18 – 26, 28, 32, 43 and 44.
Practical activities/ examples of evidence	• Authorship/review/responsibility for, including evidence of change or impact of trainee on the document or process: • Ethics submission documents and approvals (Protocol, Informed Consent Form, Patient Information Sheet, Research Ethics Committee (REC) meeting. • Clinical Trial Application (CTA)/Investigational New Drug (IND) Application. • Common Technical Document (CTD) compilation and/or other regulatory submissions. • Managing label changes. • Minutes of discussions regarding compliance considerations, preparation for intercompany dialogue and PMCPA discussions. • Internal or external updating on regulatory & compliance issues including review of PMCPA cases. • Completed medical components for regulatory submissions. • Reflection on regulations / impact of regulatory change on medicines development and lifecycle management. • Application of and reflection on good practice in patient engagement e.g **https://www.efpia.eu/media/413114/workingtogetherwithpatients_patient-remuneration-principles.pdf** **https://www.abpi.org.uk/publications/working-with-patients-and-patient-organisations-a-sourcebook-for-industry/** EUPATI & PFMD are also good sources.

CiP 3

Participates in data generation, analysis and communication

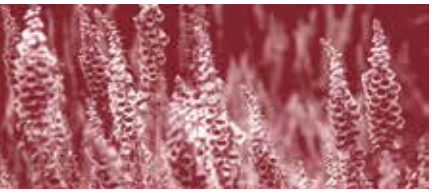
What is this CiP about?

This CiP is designed to ensure that trainees can produce, analyse and communicate data and resulting information to a wide range of stakeholders to inform on the development of knowledge about a medicine and its uses for the benefit of patients.

During training, the trainee should, where possible, be engaged in the generation, analysis, reporting and communication of data and information across the lifecycle of medicines' development and commercialisation. Involved in the preparation of reports and publications relevant to the products/activities in their scope of work. Grows competence in scientific/medical writing and critical review. Statistical principles and applications. Engaged in / appreciates data systems and their maintenance (integrity, quality, confidentiality) key to this work.

Descriptors	• Generates information and conducts data analysis. • Undertakes scientific and medical writing and review. • Prepares reviews/reports; presentations/publications. • Identifies relevant data sources. • Reviews the medical and scientific literature. • Reviews critically scientific and medical research publications. • Discusses and interprets statistical principles and applications in the development of medicines. • Contributes to the analysis and review of regulatory documents. • Contributes to the creation and review of strategic and policy documents. • Utilises systems to maintain data quality, integrity and confidentiality.
Core competencies	C7, 13, 15, 16, 20, 23, 29, 30, 33, 37, 44, 45, 46 and 50.
Practical activities/ examples of evidence	• Leads data extraction from known databases. • Authorship/review of clinical study reports.

Practical activities/ examples of evidence	
	• Authorship/review manuscript for publication. • Authorship/review relevant section of data submission for regulators (scientific advice/CTD). • Participation in the analysis of data result. • Inputs into statistical analysis plan. • Consult with patients in the preparation of lay summaries of clinical studies. • Evidence of patient consultation in the preparation of lay summaries. • Lay summaries of clinical studies. • Policy documentation for patient engagement.



CiP 4

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

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to engage actively in the design and conduct of the exploratory phase (phase I and II studies) of product development. To understand the purpose of these studies and how they link the preclinical development of the drug to widespread clinical development phase of a product in the community for use by patients with target clinical conditions. The subsequent licensing of the product and availability for clinical use.

During training, the trainee should, where possible, be exposed to the work of a phase I unit and learn about study design and how it is enacted in early phase studies (e.g. specialised units; early phase I or phase II studies). Communicates clinical trials and their potential risks and benefits. Impact of a trial on subsequent trials. Collaborative working; MDT meetings and decision making (internal); regulatory authorities and research ethics committees. Project management and quality improvement projects.

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. • Communicates the design of a clinical trial and the potential risks and benefits. • 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. • Involved in multi-disciplinary team decision-making. • Contributes to interactions with regulatory authorities and research ethics committees. • Able to manage projects including their planning, budgets, timelines, efficiency assessments and quality improvement activities.
Core competencies	C1 – 6, 8, 10, 12, 16 and 17.
Practical activities/ examples of evidence	• Discuss early phase clinical trials, to receive scientific advice, and to obtain Clinical Trial Authorisation (CTA). • Review of clinical trial documents (e.g. protocol, IB, consent forms) which show understanding and application of Good Clinical Practice (GCP) and other regulatory requirements, and how they ensure safety of participants and data validity. • Attendance at GCP training. • Attend a plain English course. • Write or review forms and communications with patients, clinical trial participants and their families. • Consulting with patients and clinical trial participants on proposed forms (e.g. consent/re-consent forms) and communications (e.g. lay summaries). • Collection and collation of patient input into clinical trial design.

CiP 5

Conducts clinical research for the development of medical products

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to organise and project manage studies including quality management aspects. This CiP starts at the end of exploratory development of medicines to focus on confirmatory development studies (Phase III) and wider clinical research activities, studies and projects in the community.

During training, the trainee should, where possible, grow capability in project management activities; exposure to all aspects of the planning, organisation and conduct of large (e.g. multi-centre, multi-national) clinical trials; maintains a focus on the welfare and interests of clinical trial participants as a priority in all decision-making. Involvement in the study monitoring activities, notably safety aspects; Involvement in analysis, evaluation, interpretation of results of clinical studies, preparation of clinical study reports and subsequent regulatory submissions and literature publications.

Descriptors	• Contributes to the authorship/ review of a Clinical Development Plan (CDP). • Applies the principles of Good Clinical Practice (GCP), other relevant GxPs and regulatory requirements. • Identifies, manages and mitigates risk in special populations. • Contributes to the review and adaptation of study specific documents. • Contributes to project management strategies. • Utilises quality management systems for the conduct of clinical studies. • Able to oversee the conduct of clinical studies. • Able to interpret the results of clinical studies and contribute to authorship/review of Clinical Study Reports (CSR).
Core competencies	C1 – 18, 24, 27, 31, 34, 36 – 42, 51, 52 and 56.
Practical activities/ examples of evidence	• Authorship or review of a Clinical Development Plan which shows they can identify the necessary elements including feasibility for the development of a new product or device.

Practical activities/ examples of evidence

- Review of clinical trial documents (e.g. protocol, Investigator's Brochure (IB), consent forms) which show understanding and application of Good Clinical Practice (GCP) and other regulatory requirements and how they ensure safety of participants and data validity.
- Attendance at GCP training.
- Review or authorship of clinical trial or benefit risk documents which show the ability to integrate multiple sources of information for unmet medical needs and application of this knowledge (for example the ability to select the most appropriate study design and end points).
- Review or authorship of clinical trial or benefit risk documents, which show the ability to identify, manage and mitigate risk in special populations such as women of child-bearing potential (WOCBP), children and older people.
- Involve patients in the development in patient reported outcomes.
- Attend patient-themed conferences or meetings.
- Conference/course attendance.
- Notes of meetings with patient advisors & patient organisations.
- Examples of communication of complex scientific issues in health literate ways.

CiP 6

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

What is this CiP about?

This CiP is designed to ensure that trainees can engage in pharmacovigilance systems to acquire and demonstrate capability in the surveillance of the safety of medicines during development and clinical use. Involvement in the collection, analysis and reporting of safety information, in the timely revision of product information and in the practical methods for managing risk to patients and clinical trial participants.

During training, the trainee should, where possible, be engaged as appropriate in different aspects of drug safety and surveillance activities in the lifecycle of the medicine depending on their own job role: AE/ADR collection, collation, individual case safety report preparation and regulatory reporting; the preparation of aggregate reports for use in signal detection, risk management mitigation and minimisation, and the contribution of safety systems to the overall risk benefit balance of medicines, and their maintenance.

Descriptors	• Knows the requirements for reporting adverse events and demonstrates an ability to report adverse events and perform a causality assessment. • Designs and executes methods to monitor and assess safety data and to carry out continuous safety monitoring. • Analyses and summarises safety data from all sources; presents conclusions. • Performs a benefit-risk evaluation; able to identify if new information will alter the benefit-risk balance and effect the safety of patients. • 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.
Core competencies	C2, 3, 16 – 21, 28 – 35 and 44.
Practical activities/ examples of evidence	• Published documents with evidence of writing or review and approval of safety text, e.g. IB, Protocol, CSR, CDS, PSUR/PBRER, DSUR, RMP. • Identification or management of a safety finding or risk, including stakeholder identification, inclusion in decision making, communication. • Providing appropriate advice on the safe use of the product, e.g., response to a clinician query for -compassionate or off label use, contribution to safety text addressing a safety concern in a protocol or SmPC. • contribution to materials for investigators or clinicians to communicate the management of a patient who develops a known Adverse Drug Reaction (ADR). • Awareness of importance of capturing AEs, e.g., evidence of reporting of an identified AE to the Yellow Card scheme, other national scheme or to the company process, from literature or interactions with patients, clinicians, social interactions; evidence of compliance with training on how to report AEs. • Performance of safety monitoring, e.g. routine safety outputs or literature from clinical trial or post marketing surveillance, with evidence of assessment and conclusion.

- Risk management, e.g., active membership of product benefit-risk working group, pharmacovigilance working group, benefit- risk committee.
- Take part in quality assessments (e.g. audits) of PV systems.
- Supports or provides training on PV procedures (e.g. to sales reps or new employee induction).
- Contributes to risk minimisation materials.
- Individual patient expert evaluation of risk-benefit profile (regulatory and market access submissions).
- Patient preference studies in evaluation of risk-benefit.
- Risk mitigation plans – co-created and evaluated with patients.
- Examples of reported AEs and follow up.
- Examples of training received and/or delivered on PV.
- Examples of handling of a safety issue (e.g. new emerging AE in clinical trial and communication with regulators and/or patients.

CiP 7

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

What is this CiP about?

This CiP is designed to ensure that trainees can evaluate and communicate the benefit-risk balance of a product, and evaluate the factors that lead to risk-management and mitigation issues providing an evaluation that informs on the continued ethical development, regulation and utilisation of the medicine in the community.

During training, the trainee should, where possible, be engaged in processes and procedures for the collection, analysis and evaluation of data and information to provide explanation of the benefits and risks of a medical product; to perform a patient, product or product development impact assessment to reach decisions on continued product development, on appropriate clinical use and on product management strategies for risk mitigation.

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. • Applies assessments of benefit-risk balance to reach milestone decisions in product development. • Provides clear explanation of the benefits and risks of a medical product to enable appropriate patient engagement. • Proposes product management strategies and risk mitigation.
Core competencies	C2, 16 – 27, 31, 39 and 46.
Practical activities/ examples of evidence	• Renewal applications. • Input and or review common technical document (CTD) from benefit-risk evaluation perspective. • Clinical overview and summaries for the CTD and other relevant regulatory documents. • Input and or review the periodic safety review update reports (PSURs). • Able to identify, propose and execute relevant programmes under early access to medicine scheme (EAMS). • Evidence of any appropriate compassionate use facilitation. • Evidence of involvement in first in human or other relevant early phase clinical studies either in the form of protocol design, clinical trial authorisation (CTA) applications and or execution of the study including any evidence of patient engagement strategies where appropriate. • Project based evidence. • Consultation with patients on elements of benefit and risk from patients' perspectives. • Reflection on benefit–risk from patients' perspective.

CiP 8

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

What is this CiP about?

This CiP is designed to ensure that trainees, during their work in pharmaceutical medicine, acquire the knowledge, skills and behaviour to advise their respective organisations on product and product portfolio strategies, on possible acquisition of products, portfolio growth and internationalisation; providing a medical and clinical perspective and advice on strategy to sustain and develop the organisation's broad business aims and objectives.

During training, the trainee should, where possible, be engaged in activities to develop capability in product profiling and positioning, in medical product lifecycle planning and management, in medical due diligence activities for product acquisition or portfolio expansion; activities to demonstrate abilities to make medical and clinical contributions to facilitate the organisation's business decision-making on the acquisition, development and lifecycle management of medical products.

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. • Provides a medical contribution to due diligence with respect to product profiling, positioning within the market and addressing unmet medical needs. • Identifies the possible position in the portfolio for products in development or during in-licensing. • Involved in medical product lifecycle planning and management. • Demonstrates an ability to facilitate business decision-making during the development and lifecycle of the medical product.
Core competencies	C1, 2, 4, 5, 8, 11, 16, 23, 25, 37, 42 – 48, 51 and 52.
Practical activities/ examples of evidence	• Summary of Product Characteristics (SmPC) – for example list of indications with links to identified unmet medical need or target product claims in the TPP document or Clinical Development Plan, with evidence of input from trainee, e.g. track changes, attendance at planning meeting, drafting text, literature search and summary of current best practice, input into regulatory response documents to achieve the target indication without population limitations due to lack of evidence.

Practical activities/ examples of evidence	• Target Product Profile document- with evidence of attendance at planning meetings, and input into document, such as drafting sections, providing medical and scientific evidence for specific indication, etc. • Clinical Development Plan with evidence of attendance at planning meetings, and input into document, such as drafting sections, providing medical and scientific evidence for specific studies or study design to address collecting data to support business needs such as planned HEOR in order to address anticipated NICE requirements. • Decision to progress to next clinical development stage with evidence of medical input into the commercial aspects of the decision, e.g. with regard to stage of pipeline of competitors, commercial viability, likelihood of success, etc. • Plan to capture Health Economic Outcomes Research data to support post authorization activities e.g. in study design within the clinical development plan, launch activities to engage with KOLs to capture early experience. • Reflections from meetings and correspondence to show influence and impact of medical input into decision making, particularly with respect to the business case and commercial feasibility of a planned project. • Reports and presentations with evidence of authorship or major contribution, reflections and evidence that the presentation or report influenced the business decision. • Consideration of project-based evidence such as a recognised training course, with a workshop demonstrating the skills needed to identify business critical information such as profiling in the market, unmet medical need, competitor intelligence, etc; produce a fictious business case to justify business case to reclassify a mature product which is assessed by ES or an experienced colleague in Commercial planning. • Evidence of being part of a team that writes the business case or dossier for application to reclassify product from prescription only to pharmacist or over-the-counter. • TPP creation & lifecycle planning including obtaining patient input.

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'

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to work to the highest professional standards and integrity in pharmaceutical medicine.

During training, the trainee should be engaged in self-assessment, contribute to the company's output and performance whilst recognising the need to protect patients and clinical trial participants. To be familiar with processes, procedures and tools to manage data and information, and to communicate effectively within a framework of ethical, legal and regulatory standards and requirements.

Descriptors	• Trusted to act honestly, openly and with integrity when interacting with patients, clinical trial participants, colleagues and other stakeholders. • Able to recognise and practise within the limits of own professional competence and knows when to seek advice. • Works within legal and regulatory standards and requirements. • Applies the principles of equality and diversity in all professional interactions. • Ensure that ethical considerations are paramount in medical practice and gain advice when dealing with conflicting ethical challenges. • In all communications apply medical, regulatory, and professional standards, as recognised in the biopharmaceutical industry codes of practice. • Recognises the privacy of any patient information they receive and ensures that patient confidentiality is maintained. • Able to handle, store and transmit records containing personal information in line with data protection requirements.
Core competencies	C3, 5, 10, 12, 14, 17, 18, 21, 24, 25, 33, 34, 37, 44, 46, 48 – 50.
Practical activities/ examples of evidence	• Write/review ABPI compliant marketing materials. • Review compliance aspects of meetings are implemented effectively.

- Author/review company SOP on data protection/ ABPI compliance.
- Design/deliver training on compliance/data protection.
- Contribution to 360 feedback to others.
- Complete training on the General Data Protection Regulation (GDPR).
- Complete training on business ethics.
- Attend courses/undertake e-learning on engaging with patients.
- Author / contribute to charters & process to ensure professional standards are maintained.
- Reflect on published principles and charters on working with and respecting patients.
- Evidence of completion of training (data protection; ethics; patient engagement training).
- Communications (emails, social media posts, presentation slides).
- Feedback from patients, patient experts and clinical trial participants.

CiP 10

Work competently within pharmaceutical organisational and management systems

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to adapt to the culture and practices of their organisation, to contribute independent medical and clinical advice, and work sustainably and flexibly in their roles. To demonstrate continuing and developing professional attitudes and behaviours relating to the application of competency, care and conduct to the work of a practising pharmaceutical physician within their organisations.

During training, the trainee should engage in activities to acquire knowledge for and develop interpersonal, management and leadership skills appropriate to their work as a pharmaceutical physician operating in a managed environment.

Descriptors	• Maintains accountability to the organisation for the scope of their role and for working within the appropriate medical/governance framework. • 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. • Demonstrates appropriate professional values and behaviours in performing the role of a pharmaceutical physician. • Understands the organisation, accountabilities and responsibilities of national and regional regulatory agencies and related bodies. • Understands the legislative framework that the pharmaceutical industry operates in; keeps up to date with legal and regulatory developments and applies these in practice. • 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). • Always performs within regulatory and professional guidelines and codes of practice.
Core competencies	C3, 18 - 20, 25 – 28, 36, 41 – 45, 48 – 57.
Practical activities/ examples of evidence	• Read on PMPCA cases and write reflective commentaries on case decision and relate own products. • Attendance at and reflections on regulatory courses. • Attendance at and reflections patient-themed conferences/meetings. • Attendance at and reflections on relevant FPM events. • Gives clear, accurate and legible written instructions in English. • Identifies information required for decision-making, makes sound ethical decisions and explains and/or documents the rationale to others. • Applies management and team-working skills appropriately, including influencing, negotiating, continuously re-assessing priorities and effectively managing complex, dynamic situations to manage time and other resources effectively. • Demonstrates emotional intelligence and resilience, diligence and thoroughness e.g. personal challenges of coping with uncertainty.

- Demonstrates cultural and social awareness, e.g. appropriate situational awareness and sensitivity to the impact of their comments, attitudes and behaviours on others.
- Understands the similarities and differences in team structure and dynamics between the NHS clinical team and the pharmaceutical multi-professional team.
- Understands local, regional and global pharmaceutical regulations and guidelines, including data protection and confidentiality.
- Aware of employment law, particularly as it relates to them as an employee, including working time regulations and health and safety legislation.
- Read sources of relevant to responsibilities when working with patients, patient experts and clinical trial participants.
- Read sources relevant to patient engagement with Regulatory Authorities & HTA bodies.
- Attendance as observer at NICE and/or NHS Trust meeting.
- Reflection on patient representation with Regulatory Authorities and HTA bodies.

CiP 11

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

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to keep up to date with research methods and practices including ethical clinical trials applicable to the development of medicines and medical products.

During training, the trainee should be engaged in continuing professional development relevant to their job role, participate in multi-source feedback activities, undertake or participate in research and the critical assessment of literature to appraise emerging trends and technologies in pharmaceutical medicine. Develop capability to receive and respond to constructive feedback on their work, to reflect and learn from their own practice and that of others.

Descriptors	• Adapts to the dynamic environment of pharmaceutical medicine and the need to anticipate changes and remain up to date. • Critically appraises emerging trends and technologies in pharmaceutical medicine. • 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. • Able to receive and respond to constructive feedback. • Reflects on and learns from their professional practice and that of others.
Core competencies	C1, 17, 21, 24, 27, 35, 36, 41, 49 – 51, 53 – 55 and 57.
Practical activities/ examples of evidence	• CPD certificates. • Training records. • Evidence of performing roles for both in the wider medical environment (e,g, societies, FPM) and within their company (e.g. trainees'/medical committees, presenting at journal clubs, training colleagues, etc). • Feedback from manager / supervisor. • Reflections from courses and conferences. • Author reflective practice reviews for in job learning. • Explore the emergence of the patient as a stakeholder through review of patient led initiatives such as IMI Paradigm, EUPATI, PFMD and therapy area specific collaborations. • Demonstrate understanding and the potential of an emerging technology (e.g. artificial intelligence, Cell based therapy, vaccine technology etc). • Reflective practice reviews of in job learning. • Reflect on the emergent patient voice in areas of practice.

CiP 12

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

What is this CiP about?

This CiP is designed to ensure that trainees acquire the knowledge, skills and behaviours to engage in collaborative working, leadership when called upon, and in continuing learning, teaching and developing others. This CiP contributes to their development of interpersonal, management and leadership skills.

During training, the trainee should be exposed to and engaged in collaborative working in multidisciplinary teams, learning, teaching and mentoring in pharmaceutical medicine. To engage in activities and situations which illustrate the learning cycle of research and development and the need to progress, develop and improve in personal, product and organisational terms.

Descriptors

- Demonstrates applied knowledge and competence in leadership, teaching and mentoring relevant to the practice of pharmaceutical medicine.
- 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.
- Demonstrates leadership in applying knowledge to decision-making in teams.
- Demonstrates leadership in applying knowledge to educate and develop the capabilities of others.
- Contributes to teaching and training colleagues, including other healthcare professionals and other professionals, e.g. scientists.
- 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.
- Appraises and assesses learning outcomes honestly and objectively.
- 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.

Core competencies	C43, 49 – 55.
Practical activities/ examples of evidence	• Chairing relevant meetings, leading projects and participation in training. • Delivering complex interactions in the field of pharmaceutical medicines successfully, including managing teams where relevant. • Sharing of knowledge and mentoring more junior colleagues and provide evidence of developing others. • Collaborate and deliver training with a patient, patient expert or a clinical trial participant. • Read relevant information about working with patients. • Promote engagement with patients, patient experts and clinical trial participants. • Training materials. • Presentation slides. • Feedback.

CiP 13

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

What is this CiP about?

This CiP is designed to ensure that trainees have the knowledge, skills and behaviours to work within a quality framework of improvement and sustainable development of an organisation: people, products and the organisation's aims and objectives.

During training, the trainee should be engaged in projects and activities with a view to sustaining, maintaining and improving standards and processes in response to feedback from key stakeholders; this with a view to a continuous quality improvement in medical product development in the interests of patient satisfaction and well-being, medical product effectiveness and safety, and organisational business excellence.

Descriptors	• Contributes to the quality assurance of standards in clinical research. • Facilitates regular reviews and audit of work activities and responding constructively to the outcomes. • Identifies need for root cause analysis of problems and delivers amended processes where necessary. • Able to provide further training if appropriate. • Demonstrates engagement in feedback from patients, patient organisations, colleagues, healthcare professionals, regulatory. • Participates in quality improvement activities.
Core competencies	C12, 26 and 52.
Practical activities/ examples of evidence	• Demonstrate reading and comprehension of quality documents e.g. GPMP, ICH quality documents, ICH E6 GMP document, either through audited internal or external certificate, or self-directed reading with reflective learning log. • Contribution to relevant quality activity within relevant function e.g. clinical development, regulatory, safety, healthcare marketplace, clinical pharmacology (PMAT, MSF). • Deliver internal training in quality (SOP rollout, external quality guidelines) (OAT, MSF). • Evidence of being a core reviewer in quality SOPs, potentially co-authorship of quality SOPs (OAT, MSF). • Attend patient-themed conferences and meetings. • Attend courses. • Participate in incident management activities including Direct Health Professional Communication. • Participate in audit and inspection. • Feedback from patients, patient experts or clinical trial participants. • Conference/meeting certificates of attendance. • Participation in a quality improvement activity (e.g. audit) and demonstrate changes implemented as a result.

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

What is this CiP about?

This CiP is designed to ensure that trainees have the knowledge, skills and behaviours to work with patients and clinical trial participants to ensure that their perspectives and needs are taken into account and communicated to relevant colleagues within the business and to external stakeholders.

During training, the trainee should demonstrate actively in projects and activities their respect and concern for the patients / end-users of medical products, and that their interests are at the forefront of decision-making in product development. Further, that patient / consumer active contribution and feedback throughout the product development cycle is to be encouraged, engaged and developed appropriately in the interests of product utility, value to patients and end-users, and organisational relevance and success.

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. • Communicate information clearly, considering the audience that will be receiving it. • 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. • Protects patients and colleagues from any risk posed by own health.
Core competencies	C2, 3, 18, 33, 36 – 38, 40 – 42, 48, 56 and 57.
Practical activities/ examples of evidence	• Managing stakeholder interactions and relationships with key departments and key support functions with emphasis on the needs and well-being of patients. • Participating in or has experience of ethics committee meetings.

- Writing and/or reviewing the format and content of communications.
- Contributing to registering and/or reporting clinical trials, and/or review of promotional material.
- Contributing to the design and/or implementation of risk minimisation measures.
- Recognising the need for and working within an appropriate governance framework when assessing proposals for novel and/or unlicensed use of medicines.
- Participating in or having experience of incident management or safety review process/meetings in which changes to the benefit-risk of a product and consequent actions are considered.
- Read patient related sources of information.
- Attend patient-themed conferences.
- Complete equality and diversity training.
- Promote the importance of patient engagement to colleagues.
- Presentations.
- Event/training programmes.

Useful patient websites

Please see below a list of useful patient websites. This is not an exhaustive list and the links were accessible at the time this document was published.

Clinical Trials Transformation Initiative
www.ctti-clinicaltrials.org/briefing-room/tools

DIA Global Forum
https://globalforum.diaglobal.org/

European Medicines Agency
www.ema.europa.eu/en/partners-networks/patients-consumers

European Patients' Academy on Therapeutic Innovation
www.eupati.eu/

FDA
www.fda.gov/patients/learn-about-fda-patient-engagement

Patient Focused Medicines Development
https://patientfocusedmedicine.org

National Institute for Health Research
www.nihr.ac.uk/patients-carers-and-the-public/

Glossary

Capability

A capability is the possession of personal qualities, competencies, abilities and capacity to get a job done, and have the potential to develop and to meet future needs.

More specifically:

- Part of essential professional work in a given context
- Independently executable, within a time-frame
- Leads to recognised output of professional work
- Observable and measurable in process and outcome, leading to a conclusion ("well done" or "not well done")
- Must require sufficient, specific knowledge, skills and attitudes, generally acquired through training; should reflect competencies, important to be acquired
- Capabilities in practice concept allows competency-based decisions to be made on the level of supervision required by pharmaceutical medicine trainees
- Since capabilities are independently executable, observable and measurable in their process and outcome, they are therefore suitable for entrustment decisions
- Usually confined to qualified personnel only.

Capabilities in practice

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, which use the professional judgement of appropriately trained, expert assessors as a defensible way of forming global judgements of professional performance.

Competency

A competency is the possession of knowledge, skills and behaviours to perform a task or activity effectively to fulfil current needs.

Critical progression point

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 Certificate of Completion of Training (CCT) or its equivalent.

Descriptor

Descriptors are intended to help trainees and trainers recognise the knowledge, skills and attitudes which should be demonstrated. Trainees 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.

Generic capabilities in practice

The six generic CiPs cover the universal requirements of all specialties as described in the GMC' Good Medical Practice and the 'Generic professional capabilities framework'. Assessment of the generic CiPs will be underpinned by the nine GPC domains and evidenced against the expected performance and behaviour for their stage of training.

Specialty capabilities in practice

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.

Specialty knowledge base

FPM's Diploma in Pharmaceutical Medicine (DPM) examination is the specialty knowledge base of the pharmaceutical medicine specialty training programme. A trainee must pass the DPM examination in addition to completing all the generic and specialty CiPs before an ARCP panel can award them an outcome 6.

Workplace-based assessment

A workplace-based assessment (WPBA) is a method for an assessor to determine whether a trainee has reached to the required level to be

judged to have attained the capability. Trainees will be expected to use the full range of WPBAs, which include the:

- Multi-source feedback (MSF)
- Observation assessment Tool (OAT)
- Patient feedback (PF) as applicable
- Pharmaceutical medicine assessment tool (PMAT)
- Quality improvement project assessment tool (QIPAT)

Appendix 1

Mapping of generic and specialty CiPs to the GMC's 'Generic Professional Capabilities Framework'

GPC domains	1	2	3	4	5	6	7	8	9
CiPs									
1	X	X	X	X	X	X	X		X
2	X	X	X		X	X			X
3	X	X	X						X
4		X			X	X			X
5	X	X	X		X	X	X		
6		X	X		X	X	X		X
7	X	X	X	X	X	X			X
8	X	X			X	X	X		X
9	X	X	X		X	X			
10	X	X	X	X	X	X	X	X	X
11	X	X	X		X			X	X
12	X				X			X	
13					X	X		X	
14				X	X	X	X	X	

Appendix 2

The 'Core Competencies in Pharmaceutical Medicine and Medicines Development'[1]

1. Evaluation and analysis of a disease area within the industry clinical development environment and identification of unmet therapeutic needs.
2. Evaluation of the clinical and non-clinical pharmacology and toxicology evidence for a new candidate for clinical development.
3. Evaluation and application of the regulatory and ethical aspects underpinning clinical development
4. Creation of a clinical development plan (CDP) for a new candidate including a target product profile (TPP).
5. The design and execution of exploratory studies and evaluation of the resulting data as applied to the CDP and achieve a TPP.
6. Evaluation of the advances made in the clinical pharmacology of a new medicine in a stepwise manner with the overall CDP and the TPP.
7. Explanation of the statistical principles for the design, conduct and assessment of exploratory studies.
8. Justification for the various end-points used in the CDP.
9. Appraisal of suspected adverse events during exploratory development.
10. Evaluation of the conduct and management of clinical trials within the context of the CDP and working as part of a team.
11. The design and execution of confirmatory studies and evaluation of the resulting data as applied to the CDP and the TPP.
12. Evaluation and interpretation of the principles for the development of a clinical trial protocol applying principles of GCP and clinical pharmacology.
13. Summary of the principles of case report form design and clinical data management, including CDISC, EDC and MedDRA.
14. The activities and processes in the selection and management of site for clinical trials.
15. Provision of the clinical input into the design and review of a statistical analysis plan.

[1]In: Front. Pharmacol. 19 March 2020; **https://doi.org/10.3389/fphar.2020.00282** and at **www.frontiersin.org/articles/10.3389/fphar.2020.00282/full#supplementary-material**.

16. Appraisal and review of relevant literature and other sources in preparation of manuscripts and publication.

17. Interpretation of and explanation for the outcome of clinical studies.

18. Summarises the legislative framework supporting the development and registration of medicines, ensuring their efficacy, safety and quality.

19. The regulations related to post-authorisation safety monitoring and reporting procedures.

20. Explanation for the significance of regular product safety update reports to the regulatory agencies and participate in their preparation and review.

21. Evaluation of the unlicensed use of medicines and ensuring patient safety.

22. Procedures in the development and renewal of marketing authorisations.

23. The design, preparation, review and evaluation of clinical overviews for regulatory submission.

24. The legal framework for clinical trials and the requirements in different regions, and perceived problems associated with global drug development.

25. The mechanisms for wider availability of medicines, and contribution to product deregulation.

26. The organisation of the investigation of product defects, counterfeit products and other miscellaneous pharmaceutical procedures and requirements

27. The principles and process of regulation of medical devices and biotechnology formulations.

28. To contrast the key regulatory requirements for pharmacovigilance, both in the major ICH regions and locally and their historical background.

29. Conduct of the assessments required for drug safety reporting both at the level of the individual patient (case report) and aggregate report.

30. Summarises the spontaneous reporting and signal detection methodologies and medical assessment of adverse event/adverse drug reaction reports as part of causality assessment.

31. Summarises the principles and methods of evaluation of risk-benefit balance and the principles and methods for managing risk to patients and clinical trial participants.

32. Discriminate and explain the variety of regulatory actions possible to address concerns about patient safety.

33. Description of communication of safety issues, the variety of formats required meeting audience needs and medical/scientific contribution to the development of such communications.

34. Evaluation of safety issues and establishment of a crisis management team, with recognition of the key functional areas to be represented and their roles and responsibilities.

35. Appraisal of the areas of progress, likely major advances and challenges in drug safety and pharmacovigilance.

36. Evaluation of the impact of cultural diversity and the need for cultural competence in medicines development

37. Ethical issues associated with clinical research, drug development and commercialisation on the production of scientific knowledge.

38. Significance of historical abuses on the evaluation of principles of human subject protection.

39. Evaluation of the key documents related to the ethical conduct of clinical trials.

40. Describes ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.

41. Comparisons of the requirements for human subject protection and privacy under different national and international regulations.

42. Adoption of the principles of corporate social responsibility.

43. Description of the commercial healthcare environment in which pharmaceutical medicine operates, identifying the contribution of laws and of regulators and other stakeholders in the decision-making for prescribing medicines.

44. The key elements involved in medical-marketing communications in the healthcare environment and explanation of compliance with regulation in this context.

45. Description of the pharmaceutical industry: internal environment, structure and function, key stakeholders and commercial drivers and explanation of how these business elements impact on the broader healthcare marketplace.

46. Description of the information required undertaking a commercial analysis of the market potential for a pharmaceutical product/candidate within the industry business environment.

47. Appraisal of the commercial competitor environment when evaluating the opportunity for a new medicine under development or a currently marketed product.

48. Description of the interface between pharmaceuticals and the external stakeholder environment and the challenges balancing the commercial and professional aspects in making ethical judgements within the legal/ regulatory framework.

49. Description of the principles and practices of people management and leadership and their application within their own working environment; the setting of learning and improvement goals.

50. The communication of knowledge, skills and behaviours associated with the competent practice of pharmaceutical medicine/medicines development science, using the best techniques and practices when participating in the education of colleagues and stakeholders.

51. The organisation of networks and the building and maintenance of relationships, encouraging contribution to and working with inter-professional teams to meet the business objectives.

52. Supporting the success of the organisation through active contribution to develop strategic plans to achieve goals, manage resources and people and leverage performance.

53. Ensuring organisational excellence through development of critical evaluation skills, encouragement for improvement and innovation in managing change.

54. Identification and recognition of strengths, deficiencies and limits to one's knowledge and expertise.

55. Contribution to the effective working of a healthcare team or other professional group.

56. Explanation of his/her accountability to stakeholders, society and the disciples of pharmaceutical medicine/medicines development sciences.

57. Application of quality and performance improvement concepts to address organisational performance issues.