Faculty of
Pharmaceutical
Medicine

Curriculum for Pharmaceutical Medicine Specialty Training August 2021
Mapping of the 2021 curriculum capabilities in practice to the 2010 curriculum modules

Introduction

This mapping document provides trainees already in training and their educational supervisors with a way of identifying how previously achieved competencies could contribute towards progress as defined by the new curriculum.

The new curriculum represents a notable change in how the curriculum content is presented. Mapping from a competency-based framework to capabilities in practice is not straightforward and it is now always possible to map like to like. However, we believe trainees moving to the new curriculum will be able to use this document to identify how their prior learning allows them to meet the requirements of the new curriculum.

July 2021

	2010 curriculum	2021 curriculum	
Module 1 - Medicine Regulation (RGN)	Competency 'The pharmaceutical physician will……	Specialty CiP	Generic CiP
RGN 1	be able to explain the legislative framework supporting the development and registration of medicines, ensuring their safety, efficacy and quality.	2, 5, 7	9, 10
RGN 2	be able to describe the regulations relating to post-authorisation safety monitoring and reporting procedures.	2, 6	10
RGN 3	understand the significance of regular product Safety Update Reports to the regulatory agencies and participate in their preparation and review.	3, 6, 7	
RGN 4	be able to offer advice on the unlicensed uses of medicines and ensure patient safety is paramount.	1, 2, 6, 7	9, 14
RGN 5	be able to describe procedures in the development of Marketing Authorisations, renewal of Marketing Authorisations and demonstrate competence in contributing to the writing and /or reviewing of Clinical Overviews.	2, 3, 6, 7	
RGN 6	be able to describe the legal framework for clinical trials and the requirements in different regions and perceived problems associated with global drug development.	2, 5, 6	9
RGN 7	be able to describe the mechanisms for wider availability of medicines and undertake or contribute to product deregulation.	1, 2, 6, 7, 8	9, 14
RGN 8	be familiar with the investigation of product defects, counterfeit products, and other miscellaneous pharmaceutical procedures & requirements.	2, 6	13

	2010 Curriculum	2021 Curriculum	
Module 2 – Clinical Pharmacology (CLP)	Competency 'The pharmaceutical physician will…	Specialty CiP	Generic CiP
CLP 1	be able to exercise judgement of non-clinical pharmacology and toxicology firstly in deciding to evaluate a new drug candidate in humans, secondly in the initial choice of dosage, and thirdly in planning a progressive development programme leading to marketing authorisation.	4, 5, 6	
CLP 2	have the ability to identify and review relevant literature and other sources and to write manuscripts for publication.	1, 3, 4, 5, 6	
CLP 3	have a working knowledge of the clinical pharmacology and toxicology evidence required in the stepwise regulatory approval process from initiating clinical trials to product licence approval in Europe.	2, 4, 5, 6, 7	
CLP 4	have a thorough knowledge of the design, execution and analysis of early-phase drug studies in man.	1, 2, 4, 5, 6	9
CLP 5	be conversant with the ethical principles and practices governing clinical research with volunteer subjects.	2, 3, 4, 5, 6	9
CLP 6	be able to apply the principles of Good Clinical Practice (GCP) in clinical pharmacology.	1, 2, 4, 5	9, 13
CLP 7	be able to investigate the clinical pharmacology of a new medicine in a stepwise manner within the overall clinical development plan.	4, 8	
CLP 8	be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs.	1, 4, 8	14

	2010 Curriculum	2021 Curriculum	
Module 3 – Statistics and Data Management (SDM)	Competency 'The pharmaceutical physician will…	Specialty CiP	Generic CiP
SDM 1	be able to explain the statistical principles in the design of clinical studies.	2, 3, 5	
SDM 2	be able to provide a clinical input into the construction and review of a Statistical Analysis Plan.	3, 5	
SDM 3	be able to explain the commonly used statistical principles and methods for the analysis and presentation of data in clinical studies; including combining data from across clinical studies as in meta-analyses.	3, 5, 6, 7	
SDM 4	understand the statistical principles for the design, conduct, analysis and reporting of health economic studies, non-interventional studies (such as epidemiological and observational studies), Post-Authorisation Safety Studies (PASS), studies or signal searching work using drug databases.	3, 6, 7	
SDM 5	be able to undertake a constructive review of the statistical methods used and presented in reports and publications.	3, 5, 8	11
SDM 6	be able to understand the principles of Case Report Form design and clinical data management, including CDISC (Clinical Data Interchange Standards Consortium), Electronic Data Capture and MedDRA, and to be able to provide input to the review of clinical data.	2, 3, 5, 6	

	2010 Curriculum	2021 Curriculum	
Module 4 – Clinical Development (CLD)	Competency 'The pharmaceutical physician will…	Specialty CiP	Generic CiP
CLD 1	be able to describe the data required and how to obtain, analyse and apply them in order to undertake an analysis of a disease area within the industry clinical development environment.	3, 4	
CLD 2	understand and be able to evaluate non-clinical and Phase I data as they are applied to a Clinical Development Plan for a new drug.	2, 4, 5, 6, 7	
CLD 3	demonstrate an understanding of the various end-points used in clinical trials, including clinical outcomes, laboratory values, biological markers used as surrogate end-points and imaging techniques.	1, 2, 4, 5, 6	
CLD 4	understand and be able to construct or assess a Clinical Development Plan for the clinical development of a new product.	4, 5, 6	
CLD 5	understand the principles underpinning the development of a clinical trial protocol.	2, 4, 5, 6, 7	9
CLD 6	have a clear understanding of, and be able to apply, the regulatory and ethical aspects underpinning clinical development.	2, 4, 5, 6, 7	9, 10
CLD 7	have a good working knowledge of the management and conduct of clinical trials, working as part of a team.	4, 5	9
CLD 8	be able to provide a full and detailed evaluation of all suspected adverse events occurring in clinical trials.	4, 5, 6, 7	
CLD 9	be able to interpret and explain the results of clinical studies and be able to create and constructively evaluate clinical study reports and manuscripts prepared for publication.	4, 5, 6	9, 11

	2010 curriculum	2021 curriculum	
Module 5 - Healthcare Marketplace (HMP)	Competency 'The pharmaceutical physician will…	Specialty CiP	Generic CiP
HMP 1	demonstrate an understanding of the commercial healthcare environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision making in the use of medicines.	1, 2, 8	10, 13
HMP 2	understand the key elements involved in medical-marketing communication in the healthcare environment, to explain how relevant and legally compliant materials and activities are developed and to recognise the importance of compliance with regulation in this context.	2, 3, 6, 7	9, 10
HMP 3	be able to describe the structure and function of the pharmaceutical industry, and the organisations within it, key stakeholders, the relevance of commercial drivers and how these business elements impact on the broader healthcare marketplace.	3	10
HMP 4	be able to describe the information required and how to analyse and apply it in order to undertake a commercial analysis of potential for a pharmaceutical product within the industry business environment.	3, 8	9
HMP 5	understand the commercial competitor environment when evaluating the opportunity for a new product during development, or a currently marketed product.	8	
HMP 6	demonstrate an understanding of the interface between the pharmaceutical industry and the external healthcare environment, its impact on relationships and interactions with external stakeholders and the challenges faced in balancing the commercial and professional aspects in making ethical judgements within the legal / regulatory framework.	1, 6, 7	9, 10

	2010 Curriculum	2021 Curriculum	
Module 6 – Drug Safety Surveillance (DSS)	Competency 'The pharmaceutical physician will….	Specialty CiP	Generic CiP
DSS 1	understand the key regulatory requirements for pharmacovigilance, both in the major (ICH) regions and locally, and their historical background.	2, 5, 6	
DSS 2	be able to carry out all medical assessments required to meet the requirements for drug safety reporting both at the level of the individual patient (case report) and aggregate report.	3, 5, 6	
DSS 3	have a clear understanding of spontaneous reporting and signal detection methodologies and be able to assess medically AE/ADR reports as part of causality assessment.	3, 5, 6	
DSS 4	understand the principles and methods of evaluation of risk and benefit balance and the principles and methods for managing risk to patients and clinical trial subjects.	5, 7	14
DSS 5	will understand the variety of regulatory actions possible to address concerns about patient safety.	2, 5, 6	
DSS 6	will understand the importance of communication of safety issues, the variety of formats required to meet audience needs and have the ability to contribute to the development of such communications.	3, 5, 6	9
DSS 7	will have the capability to understand an issue and establish a crisis management team, recognising the key functional areas to be represented and their roles and responsibilities.	6, 7	9
DSS 8	demonstrate an understanding of the areas of progress, likely major advances and future challenges in drug safety and pharmacovigilance.		11

	2010 Curriculum	2021 Curriculum	
Module 7 – Interpersonal, Management and Leadership Skills (IML)	Competency 'The pharmaceutical physician will…	Specialty CiP	Generic CiP
IML 1	demonstrate an understanding of the managed environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision-making in the development and commercialisation of medicines.	6	10
IML 2	be able to demonstrate an understanding of the principles and practices of people management and leadership, and competency to apply these within their own working environment.		9, 12
IML 3	be able to demonstrate applied knowledge and competency in a range of interpersonal and communication skills relevant to the practice of pharmaceutical medicine.	3, 6	9, 10, 12
IML 4	ensure that the knowledge, skills and behaviours associated with the competent practice of pharmaceutical medicine are communicated effectively and will acquire the best techniques and practices to achieve this.	3	9, 11, 12