

Pharmaceutical Medicine Specialty Training – Assessment Blueprint

KEY TO ASSESSMENT BLUEPRINT DOCUMENT	
Curriculum Area Column	
K	Knowledge
AK	Application of Knowledge
AB	Attitudes & Behaviour
RGN	Example of a <u>Module</u> (RGN=Medicines Regulation)
RGN 1	Example of a Module <u>Item</u>
RGN 1.1	Example of a Module Item <u>Topic</u>
GPMP 1	Good Pharmaceutical Medical Practice
Unshaded K.AK.AB	Competency Level 1: Core competency; able to perform task alone or as part of a team, in real-life ore simulated exercise
Shaded K.AK.AB	Competency Level 2: Non-core competency; able to demonstrate knowledge / application of knowledge or underlying principles
Column Headings	
MSF	Multi-Source Feedback Assessment
PMAT	Pharmaceutical Medicine Assessment Tool; observe and score generic competencies applied to a task / project (in development) [cf. mini-CEX; DOPS]
PBD	Project-based Discussion (competency based)
DPM EXAM	Specialty Knowledge Base examination in pharmaceutical medicine / Specialty Examination / Diploma in Pharmaceutical Medicine
CBA	Course-based Assignment; assignment(s) set on Approved Module Courses for PMST

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		PMAT	CBA	DPM EXAM	MSF	PBD
Curriculum Area RGN 1	Objective: The registrar will be able to explain the legislative framework supporting the development and registration of medicines and the monitoring of their safety, efficacy and quality.					
GPMP 1						
K	<p>1.1 Describe The Medicines Act 1968 and related Statutory Instruments (SI). Describe European Regulations, Directives & Guidelines relating to medicines' development and monitoring. Describe the ICH process and the significance of ICH Guidelines.</p> <p>1.2 Define the requirements for development and registration of medicines.</p>	✓	✓	✓		✓
AK	<p>1.1, 1.2 Identify, retrieve and assemble documents from all available sources in order to be informed about and to undertake specified regulatory tasks. Discuss the distinction between Regulations, Directives and Guidelines and their implementation.</p>	✓	✓			✓
AB	<p>1.1, 1.2 Recognises the need for the pharmaceutical physician to maintain close contact with the regulatory affairs department. Understands the requirement for physician consultation and participation in appropriate discussion meetings. Recognises that there are regional differences in requirements and participates in meetings and calls upon appropriate resources to</p>				✓	✓

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	address these differences.					
K	1.3 Describe the operational procedures at major national regulatory agencies (e.g. Medicines & Healthcare products Regulatory Agency (MHRA), the European Medicines Agency (EMA), the US Food & Drug Administration (FDA) and The Pharmaceuticals and Medical Devices Agency, Japan (PMDA).	✓	✓	✓		✓
AK	1.3 Discuss the relationship between EMA and national regulatory authorities of the EU.	✓	✓			✓
AB	1.3 Recognises the need for the pharmaceutical physician to interact with different regulatory authorities, endeavouring to find a common ground whenever possible, and advancing solutions for differences that cannot be reconciled.				✓	✓
K	1.4 Describe differences between the EU, US, Japanese Regulations and European requirements for medicines development in the context of the ICH guidelines and their implementation. Describe the registration of pharmaceutical products in international markets.	✓	✓	✓		✓
AK	1.4 Discuss the impact of harmonised and non-harmonised requirements on drug development and registration processes. Differentiate between the requirements for registration of drugs in different regulatory regions. Discuss how and why these requirements have evolved. Discuss how these differences may be accommodated. Initiate and participate in dialogue with different regulatory authorities.	✓	✓			✓
Curriculum	Objective: The registrar will be able to describe and undertake					

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Area RGN 2	post-marketing safety monitoring and reporting procedures.					
GPMP 1						
K	<p>2.1 Describe Adverse Drug Reaction reporting systems (including specially targeted spontaneous reporting schemes).</p> <p>2.2 Describe the drug safety reporting requirements that operate under different jurisdictions.</p> <p>2.3 Submission of reports from marketed products, from clinical trials on marketed products and in registration dossiers for products already on market elsewhere.</p>	✓	✓	✓		✓
AK	<p>2.1, 2.2, 2.3</p> <p>Ability to advise on setting up appropriate post-marketing safety studies, and assess how to conduct market research ethically and safely.</p> <p>Distinguish non-serious from serious safety signals that are likely to be of greatest concern to the regulators and impact the life cycle and use of the drug.</p> <p>Set up systems to ensure that all reports originating from various sources are centrally gathered and assessed.</p> <p>Ability to assess drug safety issues.</p> <p>Initiates internal company meetings and if necessary, a dialogue with the regulators.</p>	✓	✓			✓
AB	<p>2.1, 2.2, 2.3</p> <p>Recognises the need for pharmaceutical physicians to maintain close collaboration with the drug safety department.</p>				✓	✓

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	Recognises the strengths and limitations of in-house systems for assembling safety databases.					
K	2.4 Describe the obligations of the Marketing Authorisation Holder (MAH) with respect to drug safety reporting.	✓	✓	✓		✓
AK	2.4 Collate data from various sources and prepare a safety report (real or hypothetical) for submission to a regulatory authority. From collated safety data identify new safety signals that may concern regulatory authorities or indicate how such signals might be identified. Regularly scan literature to track drug safety issues.	✓	✓			✓
K	2.5 Describe the strengths and limitations of various kinds of reports and approaches to identifying safety issues.	✓	✓	✓		✓
AK	2.5 Is able to commission reports that deal with specific safety issues at the request of regulatory authorities. Ability to write or review safety reports in consultation with experts and regulators to evaluate new signals.	✓	✓			✓
K	2.6 Describe the further investigation and assessment of drug safety alerts.	✓	✓	✓		✓
AK	2.6 Discuss the regulatory approaches to investigation and assessment of drug safety issues. Follow up novel reports for additional details to assess causality.	✓	✓			✓
K	2.7 Describe risk minimisation strategies.	✓	✓	✓	✓	✓
AK	2.7 Identify risk factors and institute measures to promote safe and effective use of medicines.	✓	✓			✓

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	Has endeavoured to find common patterns in drug usage and link these with the safety and known properties of the drug. Devises and writes a risk management plan for a specified product (real or hypothetical).					
AB	2.7 Understands the requirement to propose measures to minimise risk and evaluates critically the effectiveness of these measures.				✓	✓
Curriculum Area RGN 3	Objective: The registrar will understand the significance of Periodic Safety Update Reports (PSURs), and participate in their preparation and review.					
GPMP 1						
K (DSS 3)	3.1 Describe CIOMS and the history of Periodic Safety Update Reports (PSURs). 3.2 Describe the legal requirements for PSURs. 3.3 Describe the contents and format of PSURs. 3.4 Describe periodicity of submission of PSURs. 3.5 Explain the possible outcomes from the review of a PSUR.	✓	✓	✓		✓
AK	3.1, 3.2, 3.3, 3.4, 3.5 Understand template to enable an efficient review of a PSUR. Identify critically all known safety information. Assess the contents of a PSUR in the context of current prescribing information for a product. Identify and appraise the significance of new signals that may emerge from PSURs	✓	✓			✓

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	Update prescribing information to promote safe and effective use of medicines.					
AB	<p>3.1, 3.2, 3.3, 3.4, 3.5</p> <p>Recognises that PSURs are a vital means of reviewing proactively the safety of marketed products.</p> <p>Realises that PSURs enable different authorities to be provided with the same comprehensive information on the safety of the drug from all sources.</p>				✓	✓
Curriculum Area RGN 4	Objective: The registrar will be able to prepare and review ethically acceptable product-related literature.					
GPMP 1						
K	<p>4.1 Describe Regulations, Guidelines, Formats and Contents relating to writing:</p> <ul style="list-style-type: none"> - Summary of Product Characteristics (SmPC); - Patient Information Leaflets (PIL); - Technical Leaflets; - Package Labelling; - Advertisements. <p>4.2 Describe data required to support the contents of these documents.</p>	✓	✓	✓		✓
AK	<p>4.1, 4.2</p> <p>Analyse and discuss the similarities, differences and relationship between these documents, and the legal basis of and requirements for</p>	✓	✓			✓

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	<p>their Formats and Contents.</p> <p>Write and /or review these documents.</p> <p>Ensure that all product-related literature is consistent with the terms of the Summary of Product Characteristics and complies with regulations.</p>					
AB	<p>4.1, 4.2</p> <p>Recognises the significance of these documents.</p> <p>Values the Summary of Product Characteristics as a legally binding document that impacts the contents of other product-related literature.</p> <p>Understands the need to regularly scrutinise these documents for accuracy and their effectiveness in promoting safe and effective use of medicines.</p>				✓	✓
K	<p>4.3 Describe voluntary codes of practice in the context of product-related literature.</p> <p>Discuss penalties for breaches.</p>	✓	✓	✓		✓
AK	<p>4.3 Maintains familiarity with procedures and proceedings of the appropriate responsible bodies for codes of practice.</p>	✓	✓			✓
K	<p>4.4 Describe issues associated with prescribing information, which is different in different countries.</p>	✓	✓	✓		✓
AK	<p>4.4 Understand geographical differences in pattern of drug usage and in the global need for clear and comprehensive prescribing information.</p>	✓	✓			✓
AB	<p>4.4 Recognises the hazards associated with different standards of maintaining accuracy of prescribing information.</p>				✓	✓

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Curriculum Area RGN 5	Objective: The registrar will be able to advise on unlicensed uses of medicines and ensure patient safety is paramount.					
GPMP 1						
K	5.1 Describe legislation that allows for provision of unlicensed medicines for specific uses. 5.2 Describe the types of unlicensed use, including compassionate use / named patient supplies / clinical trial supplies.	✓	✓	✓		✓
AK	5.1, 5.2 Differentiate between use of medicines when off-label and when unlicensed, and between the various types of unlicensed medicines. Discuss conditions attached to the use of various types of unlicensed medicines to protect patients. Conducts scientific arguments supporting the availability of medicines for unlicensed use.	✓	✓			✓
AB	5.1, 5.2 Recognises why unlicensed use is often necessary. Consults and discusses with regulatory affairs department when requested to make available unlicensed medicines. Identifies personal role in compliance.				✓	✓
K	5.3 Describe sources of unlicensed medicines and impact of internet advertising and pharmacies.	✓	✓	✓		✓
AK	5.3 Discuss the duties of the supplier and the prescriber with respect to	✓	✓			✓

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	<p>unlicensed medicines.</p> <p>Discuss procedures for gaining approval for provision of unlicensed medicines.</p> <p>Review applications for making available unlicensed medicines and liaise with regulators.</p> <p>Discuss the risks of internet advertising and procurement of medicines.</p>					
AB	5.3 Maintains regular contact with the prescriber to protect the patient.				✓	✓
K	5.4 Describe safety monitoring requirements and procedures during unlicensed use of medicines.	✓	✓	✓		✓
AK	5.4 Discuss how to avoid unauthorised use of unlicensed medicines.	✓	✓			✓
AB	5.4 Adopts a responsible approach to the availability and the use of unlicensed medicines.				✓	✓
K	<p>5.5 Describe differences between off-label and unlicensed medicines.</p> <p>Describe measures to promote the use of medicines as approved.</p> <p>Describe penalties for promoting off-label use of medicines.</p>	✓	✓	✓		✓
AK	5.5 Critically appraise requests for making available unlicensed medicines and advise on how these requests are dealt with.	✓	✓			✓
AB	5.5 Objectively balances the risks and benefits of making available unlicensed medicines and illustrates the risks associated with the use of unlicensed medicines				✓	✓
K	5.6 Describe country-specific provisions in respect of provision of unlicensed medicines (e.g. the Specials [manufacturing] licence in the	✓	✓	✓		✓

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	UK).					
AK	<p>5.6 Describe attitudes / behaviour of different regulatory agencies in respect of provision of unlicensed medicines.</p> <p>Review applications from different countries for making available unlicensed medicines and maintain a dialogue with the regulatory agencies concerned.</p>	✓	✓			✓
Curriculum Area RGN 6	Objective: The registrar will be able to describe procedures for marketing authorisations, and contribute to writing and/or review Clinical Overviews for a variety of drug applications.					
GPMP 1						
K	<p>6.1 Describe the structure of the Common Technical Document (CTD). Describe the contents of a registration dossier.</p>	✓	✓	✓		✓
AK	<p>6.1 Discuss regulatory evaluation and approval processes.</p> <p>Understand the rationale behind CTD and its relationship to data normally required for registration.</p>	✓	✓			✓
AB	6.1 Displays an understanding of how the procedures have evolved.				✓	✓
K	6.2 Describe national procedures in major EU Member States.	✓	✓	✓		✓
AK	6.2 Discuss differences in approval procedures operating in EU Member States.	✓	✓			✓

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AB	6.2 Participates in strategic meetings to influence in-house approaches to submission of applications.				✓	✓
K	6.3 Describe European centralised, decentralised & mutual recognition procedures for Marketing Authorisation, and the: - significance of Rapporteur(s); - significance of Reference Member State (RMS).	✓	✓	✓		✓
AK	6.3 Differentiate between the different European procedures for applications and discuss their advantages and disadvantages. Discuss the statutory requirements for different European procedures.	✓	✓			✓
AB	6.3 Appraises the advantages and disadvantages of different procedures with regard to specific therapeutic classes of drugs. Expresses views on the impact, if any, of different procedures on success rates.				✓	✓
K	6.4 Describe clinical development guidelines and the significance of scientific advice from regulators. Describe scientific advice procedures. Describe the role of advisory bodies.	✓	✓	✓		✓
AK	6.4 Discuss the value and timing of scientific advice. Write and / or review briefing package for scientific advice. Review scope of scientific advice by selected therapeutic areas. Participate in scientific advice meetings.	✓	✓			✓

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AB	6.4 Recognises the advantages and disadvantages of scientific advice.				✓	✓
K	6.5 Describe the structure and contents of a Clinical Overview.	✓	✓	✓		✓
AK	6.5 Write and / or appraise Clinical Overviews especially for a new drug application (or variations, line extensions, abridged documents).	✓	✓			✓
AB	6.5 Recognises the significance of a well-written Clinical Overview.					
K	6.6 Summarise US FDA procedures. Have a working knowledge of Japanese procedures.	✓	✓	✓		✓
AK	6.6 Identify procedural needs specific to each regulatory region. Discuss the major differences between various regulatory zones, especially the EU and the US.	✓	✓			✓
AB	6.6 Recognises the impact of differences between different regions, and the merits and demerits of these differences.				✓	✓
K	6.7 Appeal or arbitration procedures.	✓	✓	✓		✓
AK	6.7 Discuss differences in appeal procedures operating in EU Member States.	✓	✓			✓
Curriculum Area RGN 7	Objective: The registrar will be able to describe the legal framework for clinical trials and requirements in different regions and problems associated with global drug development.					
GPMP 1						
K	7.1 Describe the European Clinical Trials (CT) Directive.	✓	✓	✓		✓

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AK	7.1 Discuss the impact of European CT Directive on academic research.	✓	✓			✓
AB	7.1 Recognises the need to regulate clinical trials.				✓	✓
K	7.2 Describe the contents of the Investigators Brochure (IB).	✓	✓	✓		✓
AK	7.2 Discuss the data required before a clinical trial in man can be conducted.	✓	✓			✓
AB	7.2 Recognises that for safety of subjects, the data requirements vary depending on the duration of the trial and the populations studied. Recognises that investigators need up-to-date safety information for safe conduct of clinical trials.				✓	✓
K	7.3 Describe the Clinical Trials Application (CTA) System. Describe ICH Good Clinical Practice (GCP) and its impact upon the validity of a licence application. Describe the principles of GCP and reporting safety data from clinical trials. Describe the principles and practices of Ethics Committee review.	✓	✓	✓		✓
AK	7.3 Discuss the obligations of the sponsors of clinical trials.	✓	✓			✓
AB	7.3 Adopts a highly ethical and scientific approach to setting up clinical trials.				✓	✓
K	7.4 Describe the structure and contents of a clinical trial protocol	✓	✓	✓		✓
AK	7.4 Contribute to writing protocols for clinical trials.	✓	✓			✓

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AB	7.4 Recognises the risks associated with poorly designed clinical trials (ethical and clinical as well as regulatory).				✓	✓
K	7.5 Describe US Investigational New Drug (IND) procedures.	✓	✓	✓		✓
AK	7.5 Discuss FDA's 'clinical hold' on INDs.	✓	✓			✓
AB	7.5 Maintains close collaboration with investigators and regulatory authorities on progress of clinical trials.				✓	✓
K	7.6 Summarise procedures for clinical trials in Japan.	✓	✓	✓		✓
AK	7.6 Discuss problems associated with global drug development. Display the ability to set up multicentre international clinical trials.	✓	✓			✓
AB	7.6 Recognises the reasons for global and trans-cultural differences in procedures for regulation of clinical trials.				✓	✓
Curriculum Area RGN 8	Objective: The registrar will be able to describe and undertake or contribute to various regulated activities and procedures following the approval of a product.					
GPMP 1						
K	8.1 Describe the types of post-approval applications (abridged, generic, variation, line extensions and change of legal classification) and the requirements and procedures for these applications.	✓	✓	✓		✓
AK	8.1 Discuss the data requirements for different types of post-approval applications. Discuss the procedures for extending the indication or target population	✓	✓			✓

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	and amending dose schedules and safety information. Explore the market potential of a product.					
AB	8.1 Recognises that a marketing authorisation is an evolving document and participates in this evolution. Recognises the limitations of pre-approval safety data. Recognises the need to monitor opportunities for and threats to a marketed medicine.				✓	✓
K	8.2 Differences in the requirements for renewal of a marketing authorisation in different zones.	✓	✓	✓		✓
AK	8.2 Discuss the merits and demerits of different formulations and drug combinations.	✓	✓			✓
AB	8.2 Recognises the regulatory options to protect public safety and to promote safe and effective use of medicines.				✓	✓
K	8.3 Describe pharmacovigilance requirements and activities at national, regional and international levels. 8.4 Describe post-marketing safety studies.	✓	✓	✓		✓
AK	8.3, 8.4 Able to set up appropriate studies to proactively characterise specific risks.	✓	✓			✓
AB	8.3, 8.4 Recognises that the safety of drugs in routine clinical use is frequently different from that in clinical trials. Recognises the strengths and limitations of various post-marketing				✓	✓

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	safety studies. Explores ways of promoting safe and effective use of medicines.					
Curriculum Area RGN 9	Objective: The registrar will be able to describe the mechanisms for wider availability of medicines, and undertake or contribute to product deregulation.					
GPMP 1						
K	9.1 Describe requirements and procedures for change in legal classification of medicines. Describe local national classification systems for availability of medicines (e.g. POM / P / GSL criteria). Describe Patient Group Directions.	✓	✓	✓		✓
AK	9.1 Discuss the data required for change in legal classification. Discuss the effect of change in legal classification on: - public safety; - public health. Draft and / or critically assess an outline of a clinical overview for a legal status reclassification application. Discuss the safety of drugs available over-the-counter.	✓	✓			✓
AB	9.1 Recognises the advantages and potential disadvantages of deregulation of medicines. Chooses to consult relevant stakeholders when considering deregulation of medicines. Monitors the safety of medicines available without a prescription.				✓	✓

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K	9.2 Explain controls over the use and promotion of non-prescription drugs. Describe monitoring safety of non-prescription drugs.	✓	✓	✓		✓
AK	9.2 Discuss advertising of non-prescription drugs. Discuss the merits and demerits of direct-to-consumer advertising.	✓	✓			✓
AB	9.2 Ensures that promotion of the product to the public is responsible.				✓	✓
Curriculum Area RGN 10	Objective: The registrar will be familiar with investigation of product defects, counterfeit products, miscellaneous pharmaceutical procedures & requirements.					
GPMP 1						
K	10.1 Describe regulatory requirements for dealing with product defects. Describe the causes of product defect and how to deal with counterfeits. Describe the investigation of product defects.	✓	✓	✓		✓
AK	10.1 Detail batch & product recall procedures. Evaluate whether procedures are in compliance with GLP or GMP standards.	✓	✓			✓
AB	10.1 Recognises the significance of inspections. Relates product defects to failure in standards. Consults with regulatory authorities on potential clinical significance of				✓	✓

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	defects.					
K	10.2 Describe manufacturers and wholesalers licences and inspection.	✓	✓	✓		✓
AK	10.2 Summarise the requirements and significance of manufacturers' and wholesalers' licences and inspections.	✓	✓			✓
AB	10.2 Displays an understanding of manufacture and distribution of medicines.				✓	✓
K	10.3 Outline import licences and parallel import licences.	✓	✓	✓		✓
AK	10.3 Discuss the requirements and procedures for parallel importation of medicines.	✓	✓			✓
AB	10.3 Contributes to the evaluation of the risks, benefits and economic impact of parallel importation of medicines.				✓	✓
K	10.4 Describe Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).	✓	✓	✓		✓
AK	10.4 Discuss why GLP and / or GMP standards are necessary and summarise these standards.	✓	✓			✓
AB	10.4 Recognises the sources of defects in manufacturing and distribution of medicines.				✓	✓
K	10.5 Describe the background to regulation and content of pharmacopoeias.	✓	✓	✓		✓
AK	10.5 Discuss why pharmacopoeial standards are necessary.	✓	✓			✓
AB	10.5 Displays knowledge of the problems arising from failure to comply				✓	✓

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	with pharmacopoeial standards.					
K	10.6 Describe the regulation of herbal medicines.	✓	✓	✓		✓
AK	10.6 Discuss regulatory procedures for approval of herbal remedies.	✓	✓			✓
AB	10.6 Recognises the established use of herbal remedies, their risks and benefits in the context of diseases and other medicines to treat these.				✓	✓
Curriculum Area CLP 1	Objective: To be able to exercise judgement of non-clinical pharmacology and toxicology firstly in deciding to evaluate a new drug candidate, secondly in the initial choice of dosage, and thirdly in planning a progressive development programme leading to marketing authorisation.					
GPMP 1						
K	<p>1.1 Be conversant with the principles and purposes of pre-clinical tests of a candidate drug's pharmacology and toxicology.</p> <p>1.2 Be conversant with the pre-clinical data currently required for early human studies and of long-term toxicology required for the perceived clinical uses.</p> <p>1.3 Be familiar with the clinical significance of in vitro and in vivo animal pharmacology and, for example, of P450 studies.</p> <p>1.4 Be familiar with standard animal toxicology study designs and toxicokinetics.</p> <p>1.5 Be familiar with the potential differences, particularly safety issues, of administering new biological compounds to man for the first time compared with other new chemical entities.</p>	✓	✓	✓		✓
AK	1.1, 1.2, 1.3, 1.4	✓	✓			✓

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	<p>Ability to understand the evidence of a candidate drug's potential value from pre-clinical studies in various species, either whole animal or isolated organ and tissue models, and in models of disease.</p> <p>Relate longer-term animal toxicology to the potential therapeutic indications and dosages.</p> <p>Use preclinical metabolism data to identify necessary clinical drug interaction studies.</p>					
AB	<p>1.1, 1.2, 1.3, 1.4</p> <p>As a therapeutic/development team member, contributes to the stepwise decisions being made based on pre-clinical pharmacology and toxicology from the perspective of therapeutic needs and patient safety.</p> <p>Recognises the benefits and pitfalls of extrapolating preclinical data to the predictions of drug effects in man.</p> <p>Communicates the relevance of the preclinical data to others working on the drug's development.</p>				✓	✓
Curriculum Area CLP 2	Objective: The registrar will have the ability to identify and review relevant literature and other sources and to write manuscripts for publication.					
GPMP 1						
K	<p>2.1 Thorough reading of other work in the field and of important requirements to meet clinical needs.</p> <p>2.2 Be fully conversant with all relevant publications.</p>	✓	✓	✓		✓
AK	<p>2.1, 2.2</p> <p>Provide a comprehensive review of a therapeutic field and the met and</p>	✓	✓			✓

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	<p>unmet needs.</p> <p>Prepare a clinical development plan in conjunction with others.</p> <p>Critically review relevant publications.</p> <p>Prepare a manuscript or document as a joint author on clinical studies for submission to a peer-reviewed journal or a regulatory authority.</p>					
AB	<p>2.1, 2.2</p> <p>Maintains knowledge of current literature in the relevant therapeutic field and familiarity with recent advances in clinical pharmacology and therapeutics.</p> <p>Encourages other colleagues to write impartial critiques of recent publications.</p>				✓	✓
K	<p>2.3 Knowledge of relevant statistical methods and analyses.</p> <p>2.4 Understanding of pharmacokinetic analyses and modelling.</p>	✓	✓	✓		✓
Curriculum Area CLP 3	<p>Objective: To have a working knowledge of the clinical pharmacology and toxicology evidence required in the stepwise regulatory approval process from initiating clinical trials to product licence approval in Europe.</p>					
GPMP 1						
K	<p>3.1 Working knowledge of the relevant and current regulations.</p> <p>3.2 Working knowledge of how, in particular, the pharmacology and toxicology data necessary for Phase 1 studies must be designed, reviewed and approved in readiness for clinical trials.</p> <p>3.3 Components of clinical development plan required in Europe.</p> <p>3.4 Components of a regulatory licensing (marketing) submission</p>	✓	✓	✓		✓

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	required in Europe. 3.5 Appreciation of any differences in US and Japanese regulatory needs.					
AK	3.1, 3.2, 3.3, 3.4, 3.5 Define the planned clinical pharmacology of the candidate drug before clinical trials are begun. Anticipate possible disease-related variations in drug handling in patients compared with normal healthy subjects. React to unexpected findings promptly and, if necessary, suspend further work while other expert opinions are obtained and the issue is clarified. Have an awareness of past problems in this clinical or therapeutic area that have led to regulatory refusal of trials or their modification. Write expert reports, clinical overviews and product information.	✓	✓			✓
AB	3.1, 3.2, 3.3, 3.4, 3.5 Accepts pivotal role in preparation of a development plan that requires knowledge and judgement. Recognises the value of liaison with other experts in related fields in the design and interpretation of studies. Exhibits strict compliance with regulations and guidelines. Understands the need to keep senior management informed.				✓	✓
Curriculum Area CLP 4	Objective: To have a thorough knowledge of the design, execution and analysis of early-phase drug studies in man.					

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		PMAT	CBA	DPM EXAM	MSF	PBD
GPMP 1						
K	<p>4.1 Understand the purpose of and methods for investigation of a candidate drug in healthy human subjects.</p> <p>4.2 Define the objectives and limits to be applied in order to maximise the information obtained and to avoid or minimise risks to study subjects.</p> <p>4.3 Have knowledge of human pharmacokinetics, pharmacodynamics and pharmacogenetics.</p> <p>4.4 Have a working knowledge of selecting dose range and increments, of minimum effective and maximum tolerated doses.</p> <p>4.5 Be fully aware of regulatory and legal requirements in human studies.</p> <p>4.6 Knowledge of the degree of biological variation seen in a normal population.</p> <p>4.7 The reasons and need for full screening of healthy volunteers.</p>	✓	✓	✓		✓
AK	<p>4.1, 4.2, 4.3, 4.4, 4.5</p> <p>Contribute to the design of human studies in order to fulfil their aims.</p> <p>Define the subsequent aims and safeguards in healthy volunteer studies and early patient trials; instil these and monitor compliance.</p> <p>Select safety measures based on pre-clinical data and related drugs.</p> <p>Check and interpret any physiological changes observed.</p> <p>Propose any dosing changes or limits for subsequent Phase 2 or Phase 3 studies.</p>	✓	✓			✓
AB	4.1, 4.2, 4.3, 4.4, 4.5				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Recognises one’s responsibilities to study volunteers and ensure their safety.</p> <p>Imparts this ethos to others and monitor that safeguards are being applied.</p> <p>Recommends any actions needed as studies progress, such as stopping planned dose escalation or introducing new safety checks.</p> <p>Consults with other company experts in related fields and outside advisers and investigators with expertise and knowledge of clinical pharmacology.</p>					
Curriculum Area CLP 5	Objective: The registrar will be conversant with the ethical principles and practices governing clinical research with healthy volunteer subjects.					
GPMP 1						
K	<p>5.1 Basic principles of the protection of research subjects.</p> <p>5.2 Practical procedures in providing full information to participants and their doctors and in obtaining and recording their informed and continuing consent.</p> <p>5.3 Ethical review of studies from first-time-in-human to large-scale clinical trials.</p>	✓	✓	✓		✓
AK	<p>5.1, 5.2, 5.3</p> <p>Maintain these ethical principles and practices in the setting up and regular inspections of investigator sites.</p> <p>Involvement in writing and approving clinical study information sheets and consent forms.</p> <p>Ideally, have experience of Ethics Committee meetings, as an applicant</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	and / or as a member. Skill in using appropriate lay language for study subjects and their relatives. Over-see the outcomes of site inspections and audits and make personal visits to sites as required.					
AB	5.1, 5.2, 5.3 Regards human research with new drug candidates as imposing the same and at times even greater responsibilities as those required in routine medical practice. Instils these principles and practices within the research organisation and local investigating teams.				✓	✓
Curriculum Area CLP 6	Objective: The registrar will be able to apply the principles of Good Clinical Practice (GCP) in clinical pharmacology.					
GPMP 1						
K	6.1 The ICH Good Clinical Practice (GCP) principles and practices must be known and applied throughout the development programme. 6.2 Up-to-date procedures (e.g. ICH Guidelines) must be known and fulfilled. 6.3 Safeguards for volunteer participants in early-phase studies and those for patients that must be followed.	✓	✓	✓		✓
AK	6.1, 6.2, 6.3 Within the GCP framework, plan a series of clinical pharmacology investigations in a sensible stepwise sequence in order to characterise the compound's properties and to allow critical judgements to be made	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	on its therapeutic potential and safety. Ensure that quality assurance checks are made and acted upon.					
AB	6.1, 6.2, 6.3 Recognises that as a team member and often the only medical graduate, the welfare of subjects in clinical studies must be paramount, as often no personal benefit for them is implied but risk is possible. Recognises the need for stringent adherence to procedures and maintenance of full and accurate records.				✓	✓
Curriculum Area CLP 7	Objective: To be able to investigate the clinical pharmacology of a new medicine in a stepwise manner within the overall clinical development plan.					
GPMP 1						
K	7.1 Understand the clinical pharmacology requirements in a regulatory submission for approval of a new drug and in a Summary of Products Characteristics (SmPC). 7.2 Apply clinical pharmacological knowledge and methodology in the development programme from choice of a candidate entity through its full characterisation and key decisions on its therapeutic potential and any limitations on its clinical use.	✓	✓	✓		✓
AK	7.1, 7.2 Establish in a logical and stepwise manner the main pharmacological actions of a new medicine in healthy people and in those with the target disease. In doing so, identify the likely dose range and, early on in the	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>programme, measure its clinical effects (proof of concept).</p> <p>Identify further studies with other drugs in that therapeutic class aimed to determine their comparative efficacy and ADME profiles.</p> <p>Judge real and potential benefits of the new medicine and likely safety problems to be encountered.</p> <p>Anticipate possible adverse interactions with other drugs, which are likely to be co-prescribed for other medical conditions in routine clinical practice, and of impaired ADME due to co-existing medical conditions.</p>					
AB	<p>7.1, 7.2</p> <p>Recognises the need to characterise in ADME studies how a new medicine is handled in the human body.</p> <p>Realises that impairment of normal ADME may be caused by the disease itself and/or other drugs likely to be given to treat the disease.</p> <p>Communicates the importance of clinical pharmacology to other members of the development team.</p>				✓	✓
Curriculum Area CLP 8	<p>Objective: The registrar will be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs.</p>					
GPMP 1						
K	<p>8.1 Knowledge of the causative factors, pathophysiology and main therapeutic options in one major organ-based disease.</p> <p>8.2 Within that framework, understand the benefits and shortcomings of current therapy, and thereby identify new therapeutic needs.</p> <p>8.3 Understand how advancing knowledge, such as</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	pharmacogenomics and pharmacogenetics, may tailor therapy.					
AK	<p>8.1, 8.2, 8.3</p> <p>Bring together scientists working on the underlying disease process, including academic and company experts on treatment options, and chemists developing new compounds that may fulfil unmet needs.</p> <p>Similarly, contribute to proposed investigations and profiling of a new theoretical agent by applying key principles of efficacy, safety and economic value.</p>	✓	✓			✓
AB	<p>8.1, 8.2, 8.3</p> <p>As part of a research team, consults with academic and clinical experts in the therapeutic area to learn therapeutic aims, achievements and needs.</p> <p>Creates an idealised drug profile and, in doing so, recognises constraints in clinical practice and in health service provisions.</p>				✓	✓
Curriculum Area SDM 1	Objective: To be able to explain the statistical principles in designing clinical studies.					
GPMP 1						
K	1.1 Explain the use of control, blinding, randomisation and other methods for the reduction of bias in clinical trials.	✓	✓	✓		✓
AK	1.1 Select the most appropriate design structure; superiority, equivalence, non-inferiority, dose-response to meet the needs of the drug development programme.	✓	✓			✓
AB	1.1 Recognises the importance of working with a statistician in the				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	design of clinical studies.					
K	<p>1.2 Explain the principles of power and sample size, the reduction of variation and other methods for increasing precision in clinical studies.</p> <p>1.3 Outline methods for the interim analysis of clinical trial data and the management of those analyses, through an Independent Data Monitoring Committee, for the evaluation of efficacy, harm and futility.</p>	✓	✓	✓		✓
AK	<p>1.2, 1.3</p> <p>Provide clinical input into sample size calculations, the selection of primary and secondary endpoints, choice of comparator and methods of interim analysis.</p>	✓	✓			✓
K	<p>1.4 Define case-control and cohort studies and describe their role in pharmacovigilance.</p>	✓	✓	✓		✓
Curriculum Area SDM 2	<p>Objective: The registrar will be able to provide clinical input into and review a Statistical Analysis Plan.</p>					
GPMP 1						
K	<p>2.1 Outline the structure of a Statistical Analysis Plan.</p>	✓	✓	✓		✓
AK	<p>2.1 Review Statistical Analysis Plan.</p> <p>Document the reasons for the inclusion/exclusion of patients.</p> <p>Identify the reasons for the inclusion of patients in samples for analysis.</p> <p>Plan the presentation of the results of the statistical analysis in the clinical study report.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	2.1 Recognises the role of the pharmaceutical physician in the construction and review of a Statistical Analysis Plan.				✓	✓
Curriculum Area SDM 3	Objective: The registrar will be able to explain the commonly used statistical principles and methods for the analysis and presentation of data in clinical studies.					
GPMP 1						
K	3.1 Explain the thinking behind statistical methods, such as the pre-specification of methods of analysis, the control of type I error and the principle of intention-to-treat to reduce bias. 3.2 Describe the role of hypothesis testing, p-values, summary statistics, confidence intervals and modelling in the statistical analysis of data.	✓	✓	✓		✓
AK	3.1, 3.2 Interpret the results of a statistical analysis of data based on methods including; survival analysis, analysis of covariance, logistic regression, meta-analysis.	✓	✓			✓
AB	3.1, 3.2 Recognises the importance of the use of appropriate statistical methodology for the correct interpretation of clinical studies.				✓	✓
K	3.3 Explain the principles behind statistical methods, such as the analysis of covariance and the choice of statistical test, for maximising precision when analysing data. 3.4 Explain the methods of statistical analysis for investigating the homogeneity of the treatment effect.	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	3.5 Explain the methods of statistical analysis for the detection of fraud and misconduct.					
Curriculum Area SDM 4	Objective: To understand the statistical principles for the design, conduct, analysis and reporting of clinical studies from a regulatory perspective.					
GPMP 1						
K	4.1 Outline the key principles for the design, conduct, analysis and reporting of clinical trials contained in the ICH E9 guideline ‘Statistical Principles for Clinical Trials’. 4.2 Identify the key safety questions for a Clinical Development Plan and the trials and data which relate to those questions.	✓	✓	✓		✓
AK	4.1, 4.2 Compile a complete list of data to be included in the integrated report of safety for a Clinical Development Plan.	✓	✓			✓
AB	4.1, 4.2 Recognises the importance of ICH E9 in ensuring that clinical trials are designed, conducted, analysed and reported in a scientifically valid way				✓	✓
K	4.3 Identify the role of meta-analysis in the analysis and presentation of results from a series of clinical studies.	✓	✓	✓		✓
AK	4.3 Identify the criteria for the inclusion of trials in a meta-analysis to answer key questions and present the results of such an analysis.	✓	✓			✓
Curriculum Area	Objective: To be able to undertake a critical review of the statistical methods used and presented in reports and publications.					

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		PMAT	CBA	DPM EXAM	MSF	PBD
SDM 5						
GPMP 1						
K	5.1 Describe the key statistical aspects of a clinical study that should be included in a publication or report.	✓	✓	✓		✓
AK	5.1 Interpret the results of a statistical analysis based on commonly used statistical procedures presented in a publication or report. Critically appraise a meta-analysis.	✓	✓			✓
AB	5.1 Recognises the need to be able to critically review published clinical studies and the importance in the publication of a full description of statistical methodology.				✓	✓
Curriculum Area SDM 6	Objective: To be able to undertake a critical review of the statistical methods used and presented in reports and publications.					
GPMP 1						
K	6.1 Identify the key areas where data management contributes to the clinical trial process.	✓	✓	✓		✓
AK	6.1 List the key areas where data management contributes to the clinical trial process.	✓	✓			✓
AB	6.1 Recognises the need to involve data management in all phases of a clinical trial to ensure efficient data collection and robust data for analysis.				✓	✓
K	6.2 Understand the impact of poor CRF design on the conduct of the	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	clinical trial.					
AK	6.2 Identify examples of good CRF design practice and examples of poor CRF design.	✓	✓			✓
AB	6.2 Recognises the importance of physicians contributing to reviews of CRF design.				✓	✓
K	6.3 Understand common issues with CRF completion at the study site and the importance of training site staff and CRAs.	✓	✓	✓		✓
AK	6.3 Identify common problem areas in CRF completion.	✓	✓			✓
AB	6.3 Recognises the need for data management to be involved in training site staff and CRAs during study set-up.				✓	✓
K	6.4 Understand the data cleaning process (relevant to both electronic and paper CRF) and where physicians should review the Data Validation plan, the clinical data, and provide support.	✓	✓	✓		✓
AK	6.4 Be able to describe the data cleaning process post data-entry in a paper environment. Describe the typical contents of a Data Validation plan. List examples of areas where physicians can provide consultative advice to resolve data issues.	✓	✓			✓
AB	6.4 Recognises the importance of physicians participating in data review, and providing advice to teams, to ensure a clinically correct database for analysis.				✓	✓
Curriculum Area SDM 7	Objective: To understand the principles of CDISC*, Electronic Data Capture (EDC) and MedDRA and their impact on data management activities. (*CDISC=Clinical Data Interchange Standards Consortium).					

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		PMAT	CBA	DPM EXAM	MSF	PBD
GPMP 1						
K	7.1 Understand the principles of CDISC.	✓	✓	✓		✓
AK	7.1 Describe the principles of CDISC. List some of the benefits of CDISC. Know whether CDISC standards have been implemented in own company.	✓	✓			✓
AB	7.1 Recognises the benefits of CDISC and the need for FDA submissions.				✓	✓
K	7.2 Understands the EDC process and the differences in data cleaning activities and role of data management.	✓	✓	✓		✓
AK	7.2 Describe the expectations for EDC and the actual benefits. Describe the considerations that need to be made to implement at the study site. Describe differences in study team roles (data manager and CRA) when utilising EDC compared with conventional studies.	✓	✓			✓
AB	7.2 Recognises the benefits of EDC and the differences in team roles when utilising the technology.				✓	✓
K	7.3 Explain MedDRA structure, uses and support and how coding is performed.	✓	✓	✓		✓
AK	7.3 Describe the MedDRA structure hierarchy. Perform allocation of Primary SOC to medical terms. Describe the roles of the individual performing coding and physician	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	review.					
AB	7.3 Recognises the importance of accurate MedDRA coding in the product labelling.				✓	✓
Curriculum Area CLD 1	Objective: To be able to describe the data required and how to obtain, analyse and apply them in order to undertake an analysis of a therapy area within the industry clinical development environment.					
GPMP 1						
K	1.1 Explain how to conduct a clinical literature search. 1.2 Describe how to evaluate and interpret the findings in the clinical development environment.	✓	✓	✓		✓
AK	1.1, 1.2 Prepare a literature review of a specified therapy area. Write a brief report describing: a. the epidemiology and pathophysiology of the diseases that occur in this area; b. therapies available and their mechanisms of action; c. a summary of drugs under development in this area; d. unmet medical / therapeutic need in this area.	✓	✓			✓
AB	1.1, 1.2 Recognises the breadth and depth of data requirements and the inherent limitations of information freely available in the public domain when making appropriate clinical development judgements.				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	Works as part of a team to ensure the fullest understanding of pre-clinical, clinical and commercial data and their relevance to the therapy area review.					
Curriculum Area CLD 2	Objective: To understand and be able to evaluate preclinical and Phase I data as they are applied to a Clinical Development Plan for a new drug.					
GPMP 1						
K	<p>2.1 Describe what research, studies and data should be available to make an informed decision to proceed to clinical efficacy studies (Phase II).</p> <p>2.2 Describe the topics and the data which would explain why a drug development should not proceed further.</p> <p>2.3 Describe what types of adverse effects are likely to be encountered in clinical trials.</p>	✓	✓	✓		✓
AK	<p>2.1, 2.2, 2.3</p> <p>Write a reasoned critique on whether there are appropriate data to proceed into clinical efficacy trials for a new drug (real or hypothetical).</p>	✓	✓			✓
AB	<p>2.1, 2.2, 2.3</p> <p>Recognises the importance of a medical input to the evaluation of early development data, and share this with the drug development team.</p>				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Recognises the value of healthy volunteer studies in drug development and participates actively in their evaluation.</p> <p>Consults with colleagues in the drug development team on the impact of early development data on the direction and design of Phase II studies.</p>					
K	2.4 Describe the Phase 1 data that would be gathered in clinical pharmacology for a potential new medicine.	✓	✓	✓		✓
AK	2.4 Evaluate the clinical pharmacology data for a new drug real or hypothetical.	✓	✓			✓
K	2.5 Justify the preclinical safety and toxicology data required for a new drug development.	✓	✓	✓		✓
AK	<p>2.5 Evaluate and discuss the safety and toxicology data for a new drug (real or hypothetical).</p> <p>On the basis of preclinical and Phase I data, recommend, with reasons, a range of doses to be studied in Phase II.</p>	✓	✓			✓
K	<p>2.6 Outline the main imaging techniques used currently in clinical trials.</p> <p>2.7 Outline the main laboratory methods used in clinical trials.</p>	✓	✓	✓		✓
AB	2.6, 2.7 Recognises the time-limitation of publications in a rapidly developing technical field.				✓	✓
Curriculum Area CLD 3	Objective: To understand and be able to construct or assess a Clinical Development Plan for the clinical development of a new drug.					

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		PMAT	CBA	DPM EXAM	MSF	PBD
GPMP 1						
K	3.1 Describe the elements of a Clinical Development Plan, including: - the key studies required for registration; - the primary endpoints; - timelines for study and programme completion; - possible risks that would threaten the plan.	✓	✓	✓		✓
AK	3.1 Write a Clinical Development Plan for a new drug (real or hypothetical).	✓	✓			✓
AB	3.1 Recognises the role, value and benefit of the team approach to clinical development and recognises the contribution of others to the successful Clinical Development Plan.				✓	✓
K	3.2 Describe the Objectives of marketing support studies.	✓	✓	✓		✓
Curriculum Area CLD 4	Objective: To understand the principles underpinning the development of a clinical trial protocol.					
GPMP 1						
K	4.1 Describe the required critical data in a study.	✓	✓	✓		✓
AK	4.1 Design and prepare a study protocol for a new drug (real or hypothetical). Write a reasoned critique of the outline protocols considering: - how they achieve the aims of the Clinical Development Plan;	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<ul style="list-style-type: none"> - how they comply with ethical requirements; - how they can be conducted in the real world; - how they reach achievable timelines; - how they can be conducted within the allocated budget. 					
AB	4.1 Recognises the value of carefully thought out protocols in clinical development and participates actively in their development				✓	✓
K	4.2 Describe the design of Case Report Forms (CRFs) and their key features to ensure that data is collected in a practical and unambiguous way.	✓	✓	✓		✓
Curriculum Area CLD 5	Objective: To have a clear understanding of, and be able to apply, the regulatory and ethical aspects underpinning clinical drug development.					
GPMP 1						
K	5.1 Predict and address the ethical issues arising from clinical studies. 5.2 Describe the principles of the Declaration of Helsinki. 5.3 Describe the requirements of ICH Good Clinical Practice. 5.4 Have a working knowledge of and describe: <ul style="list-style-type: none"> - the regulatory requirements for clinical trials in UK, EU and USA; - Clinical Trial Application procedures (UK). 	✓	✓	✓		✓
AK	5.1, 5.2, 5.3, 5.4 Draft an informed consent form that includes all the required elements.	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	<p>5.1, 5.2, 5.3, 5.4</p> <p>Recognises the ethical environment in which clinical trials are conducted and the contribution made by patients in agreeing to participate in clinical research.</p> <p>Recognises that clinical development is a global process regulated by differing regional frameworks.</p>				✓	✓
Curriculum Area CLD 6	<p>Objective: To have a good working knowledge of the management and conduct of clinical trials, working as part of a team.</p>					
GPMP 1						
K	<p>6.1 Describe the time required and project management skills needed to set up a study, identify, assess and recruit investigators and gain their cooperation.</p> <p>6.2 Describe how to arrange appropriate legal and ethical clearance for clinical drug trial supplies, Case Report Forms (CRFs) and other relevant materials.</p> <p>6.3 Describe the practicalities essential to the conduct of clinical trials, for example, pre-study site assessment, study start-up visits, how to start a study on time and run it to schedule, routine site monitoring visits, site close-out procedures, CRF correction, source data verification, GCP documentation, investigator payments, checks for fraud.</p>	✓	✓	✓		✓
AK	<p>6.1, 6.2, 6.3</p> <p>Draw up a project management plan for the clinical development of a new drug (real or hypothetical). This should include key milestones.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	<p>6.1, 6.2, 6.3</p> <p>Recognises that successful drug development requires a multi-disciplinary team approach to which the physician must make timely and effective contributions.</p> <p>Consults with colleagues in the drug development team on the impact of delays to the project plan and how these may be minimised or compensated.</p>				✓	✓
K	<p>6.4 Describe the requirements for:</p> <ul style="list-style-type: none"> - financial disclosure; - data protection. <p>6.5 Describe audit and inspection procedures applied to studies before, during and after their conduct.</p> <p>6.6 Describe why internal QA procedures are needed and the possibilities for mandated external audits and inspections.</p> <p>6.7 Outline the role and responsibilities of the QA department.</p>	✓	✓	✓		✓
Curriculum Area CLD 7	Objective: The registrar will be able to provide a full and detailed evaluation of all suspected adverse events occurring in clinical trials.					
GPMP 1						
K	<p>7.1 Define and classify (describe) adverse events.</p> <p>7.2 Describe the working requirements for adverse event reporting each stage of drug development in UK, EU, USA, Japan and non-ICH countries.</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	<p>7.1, 7.2</p> <p>Evaluate adverse events for severity and causality.</p> <p>Categorise and 'report' some hypothetical examples of adverse events based on patient case histories.</p>	✓	✓			✓
AB	<p>7.1, 7.2</p> <p>Recognises the importance of a thorough evaluation of all emerging safety data as part of the developing safety profile of a drug, in order to identify adverse safety signals early and avoid exposing patients to unnecessary risk.</p>				✓	✓
Curriculum Area CLD 8	<p>Objective: The registrar will be able to interpret and explain the results of clinical studies and be able to create and critically evaluate clinical study reports and manuscripts prepared for publication.</p>					
GPMP 1						
K	<p>8.1 Explain the process involved in the preparation of manuscripts reporting clinical studies for submission for publication to a peer-reviewed journal, the key issues which must be addressed, and the typical structure of such a manuscript.</p> <p>8.2 Explain the scientific and ethical imperative to submit the results of scientific research to peer review.</p> <p>8.3 Describe the establishment and use of clinical trial registries.</p>	✓	✓	✓		✓
AK	<p>8.1, 8.2, 8.3</p> <p>Interpret and explain the results of clinical studies.</p> <p>Write clear, coherent and comprehensive reports of clinical research</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>undertaken.</p> <p>Summarise the results of a programme of clinical research.</p> <p>Assess the design and conduct of studies of a drug (real or hypothetical).</p> <p>Critically review the results to determine the clinical significance of the data.</p> <p>Assess the risks and benefits of a potential new medicine.</p>					
AB	<p>8.1, 8.2, 8.3</p> <p>Recognises the need to interpret and disseminate clinical research data within the team, company and scientific community via peer-reviewed publication in a timely and effective manner.</p> <p>Consults with colleagues on the interpretation of clinical research data.</p> <p>Recognises the need for timely and accurate interpretation of study data.</p> <p>Understands the importance of disseminating the data in a timely and effective manner.</p> <p>Recognises the impact of clinical trial data on the stock market.</p>				✓	✓
Curriculum Area HMP 1	<p>Objective: To demonstrate an understanding of the broader healthcare environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision making in prescribing medicines.</p>					
GPMP 1						
K	<p>1.1 Describe the various components of the legal and regulatory framework in which pharmaceutical medicine needs to operate:</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<ul style="list-style-type: none"> -UK Medicines Act; UK Advertising Regulations; -EU Advertising Directive;- -The Code of Practice for the Pharmaceutical Industry; -Other regulations, codes and guidelines applying to registrar’s country(ies) of operation e.g. IFPMA International Code of Pharmaceutical Marketing Practices; EFPIA European Code of Practice for the promotion of medicines; WHO ethical criteria for medicinal promotion;-Role of the MHRA and other regulatory bodies. 					
AK	<p>1.1 Analyse the roles, importance relative contribution and interactions of these components in supporting the legal and regulatory framework within which pharmaceutical medicine operates.</p>	✓	✓			✓
AB	<p>1.1 Recognises the significance and authority of different levels of the law/regulation in the interpretation and operation of the legal and regulatory framework.</p>				✓	✓
K	<p>1.2 Identify the key stakeholders and the main elements within the healthcare market in which the registrar works (e.g. UK NHS, Department of Health, NICE, MHRA) and in other key markets.</p> <p>1.3 Describe the contribution and decision making processes within the healthcare market in relation to prescribing:</p> <ul style="list-style-type: none"> - The National Institute for Health and Clinical Excellence (NICE) or equivalent; - value assessments of pharmaceuticals;- disease management guidelines; - Drugs and Therapeutics Committees; - computerised prescribing systems (e.g. PRODIGY). 	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	<p>1.2, 1.3</p> <p>Evaluate the major interactions between the key stakeholders in the healthcare market.</p> <p>Interpret the interactions between the different groups and processes and how they can affect prescribing practices.</p>	✓	✓			✓
AB	<p>1.2, 1.3</p> <p>Recognises how these groups influence prescribing practices within the healthcare environment.</p> <p>Recognises how these interactions influence the provision of healthcare in the market.</p>				✓	✓
K	<p>1.4 Explain the principles of marketing research and profiling in the context of regulations with regard to:</p> <ul style="list-style-type: none"> - competition in the healthcare market; - segmentation of customers and markets; - customer targeting; - methods of promotion; - activities of public and professional relations companies. 	✓	✓	✓		✓
AK	<p>1.4 Evaluate how market research and profiling data can contribute to effective promotional activities and the constraints of regulation in this context.</p>	✓	✓			✓
AB	<p>1.4 Recognises the contribution and constraints of marketing data in the promotion of medicines.</p>				✓	✓
K	<p>1.5 Describe the role of the Prescription Pricing Authority (PPA).</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	1.5 Interpret PPA data and demonstrate how it may be used in the healthcare market.	✓	✓			✓
AB	1.5 Recognises the role of PPA data in the prescribing environment.				✓	✓
K	1.6 Outline distribution channels for medicines, including parallel importing.	✓	✓	✓		✓
AK	1.6 Analyse the effects of distribution channels on the availability and cost of medicines.	✓	✓			✓
AB	1.6 Recognises the impact of distribution channels on availability of medicines in the healthcare market.				✓	✓
Curriculum Area HMP 2	Objective: To understand the key elements involved in medical-marketing communication in the healthcare environment, to explain how relevant and legally compliant materials and activities are developed and to recognise the importance of compliance with regulation in this context.					
GPMP 1						
K	<p>2.1 Describe the process involved in the preparation and production of legally compliant documentation to support medical marketing activities:</p> <ul style="list-style-type: none"> - briefing documents; - presentations & publications; - therapeutic training to medical representatives and other non-medically qualified staff; - materials for communications e.g. publications / presentations made by third parties. <p>2.2 Explain the relevance of targeting materials to the appropriate</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	audiences e.g. journals / conferences and ensuring consistency with commercial messages.					
AK	<p>2.1, 2.2</p> <p>Construct medical marketing materials/documents (e.g. briefing materials, relevant publications and presentations) appropriate for the audience and consistent with commercial messages.</p> <p>Evaluate a range of medical marketing materials for scientific accuracy, legal and regulatory compliance and comprehension by the reader.</p>	✓	✓			✓
AB	<p>2.1, 2.2 Recognises the importance and challenges of operating within a legal framework for medical marketing communication and the consequences of non-compliance.</p> <p>Recognises the importance of ensuring the compliance of all product-related documentation with the content of the SmPC.</p>				✓	✓
K	2.3 Identify the breadth of medical marketing activities and materials, how to determine whether they are promotional and when and how they should be assessed for legal / regulatory compliance.	✓	✓	✓		✓
AK	2.3 Analyse selected materials and activities (e.g. media communications, professional and public relations, pre-launch activities) with regard to scientific, educational and promotional content.	✓	✓			✓
AB	2.3 Recognises the importance and consequences of differentiating medical communications as promotional within a defined therapeutic area.				✓	✓
Curriculum Area HMP 3	Objective: The registrar will be able to describe the pharmaceutical industry internal environment, structure and function, key stakeholders, the relevance of commercial drivers and how these business elements impact on the broader					

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		PMAT	CBA	DPM EXAM	MSF	PBD
	healthcare market.					
GPMP 1						
K	3.1 Describe the pharmaceutical industry internal environment: <ul style="list-style-type: none"> - structure and function of pharmaceutical companies; - product life-cycle management including impact of clinical studies; - portfolio management; - return on investment; - corporate communications and reputation. 	✓	✓	✓		✓
AK	3.1 Evaluate how internal business operations and drivers impact the interactions with and relationship between the pharmaceutical industry and the wider healthcare environment.	✓	✓			✓
AB	3.1 Recognises the relevance of the internal pharmaceutical industry environment in determining the nature of the industry's interactions in the healthcare market.				✓	✓
Curriculum Area HMP 4	Objective: The registrar will be able to describe the information required and how to analyse and apply it in order to undertake a commercial analysis of product potential for a pharmaceutical product within the industry business environment.					
GPMP 1						
K	4.1 Identify the elements involved in the commercial assessment of a pharmaceutical product: <ul style="list-style-type: none"> - profiling and positioning; - clinical data; - pricing; 	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<ul style="list-style-type: none"> - products and services; - intellectual property (IP); - others, for example, health economics, costs of promotion, PPRS, reimbursement and implications of formulary listing / delisting, licensing and impact of cost of goods / royalties, break even and net present value (NPV), co-marketing, co-promotion and co-development, products and services as part of the 'augmented brand', implications of patent expiry, issues surrounding generic medicines. 					
AK	4.1 Evaluate the commercial potential for a pharmaceutical product, real or hypothetical.	✓	✓			✓
AB	4.1 Recognises the breadth and depth of data requirements and the inherent limitations in the commercial analysis of pharmaceutical product potential.				✓	✓
K	4.2 Describe the components required for the evaluation of an in-licensing/collaboration option: <ul style="list-style-type: none"> - identifying candidates; - portfolio fit and management; - due diligence; - product efficacy and safety; - intellectual property (IP); - commercial assessment (see Topic 4.1 above). 	✓	✓	✓		✓
AK	4.2 Evaluate the commercial potential for an in-licensing opportunity for a pharmaceutical product, real or hypothetical.	✓	✓			
AB	4.2 Recognises the commercial potential and limitations of in-licensing				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	and collaborative options.					
K	4.3 Define the clinical and commercial aspects of a pharmaceutical reclassification: - Prescription Only Medicine (POM) to Pharmacy (P); - Pharmacy (P) to General Sales List (GSL).	✓	✓	✓		✓
AK	4.3 Evaluate the commercial potential for a pharmaceutical product reclassification	✓	✓			✓
AB	4.3 Recognises the clinical and commercial implications of pharmaceutical reclassifications.				✓	✓
Curriculum Area HMP 5	Objective: To understand the need to have knowledge of the wider competitor environment in the therapy area when evaluating the commercial opportunity for products at different stages in their development.					
GPMP 1						
K	5.1 Describe the key components of a competitive commercial product analysis for a: - marketed product; - pipeline product; - therapy area; - competitor product.	✓	✓	✓		✓
AK	5.1 Perform a competitive product analysis for a product, real or hypothetical, at two different stages in its development. Evaluate the promotional platform of a competitor product.	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	Construct objection handling statements.					
AB	5.1 Recognises the value of a robust competitive commercial product analysis for products at different stages in their development.				✓	✓
Curriculum Area HMP 6	Objective: To demonstrate an understanding of the interface between the pharmaceutical industry and the external healthcare environment, its impact on relationships and interactions with external stakeholders and the challenges faced in balancing the commercial and professional aspects in making ethical judgements within the legal/regulatory framework.					
GPMP 1						
K	<p>6.1 Identify who the industry’s key stakeholders are in the external environment and how the industry’s activities impacts on them, including the general public.</p> <p>6.2 Describe the ethical issues which arise and approaches considered in reaching a judgement in:</p> <ul style="list-style-type: none"> - the investigation and management of fraud and misconduct e.g. in clinical research; - particular patient use of medicines e.g. compassionate use; - Phase IV studies; - Post-Marketing Surveillance studies; - individual patients adverse events or compassionate use); - open label clinical trial extensions; - investigator-initiated studies; - charging for named patient supplies; - giving a balanced and Objective: clinical / scientific view / response in 	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>keeping with company strategy and professional ethics;</p> <p>- creating a policy on patient information provided by medical information within regulation;</p> <p>- developing a Data on File statement.</p>					
AK	<p>6.1, 6.2 Perform an industry key stakeholder analysis.</p> <p>Analyse the important relationships and interactions between the key stakeholders.</p> <p>Discuss how ethical judgments are made and relevant guidelines applied in the different scenarios outlined in HMP 6.2.</p> <p>Perform ethical evaluations in the areas outlined in HMP 6.2.</p>	✓	✓			✓
AB	<p>6.1, 6.2 Recognises the relevance of a stakeholder analysis and how it can contribute to the impact of developing better relationships and improving communication of the industry's activities.</p> <p>Exhibits the ability to distinguish between different ethical approaches in different situations and recognise the personal and professional challenges involved when making ethical judgements in the commercial environment.</p>				✓	✓
K	<p>6.3 Describe the roles of and relationship between the relevant trade and professional organisations, including Association of the British Pharmaceutical Industry (ABPI), British Medical Association (BMA), medical Royal Colleges, and others.</p>	✓	✓	✓		✓
AK	<p>6.3 Discuss the function, context and relevance of the interactions between these bodies.</p>	✓	✓			✓
AB	<p>6.3 Recognises the different and complementary contribution made by the various bodies</p>				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
Curriculum Area DSS 1	Objective: To understand the historical background that has led to the present day pharmacovigilance regulations and systems.					
GPMP 1						
K	<p>1.1 Be aware of the major past ‘landmark’ safety issues with major products (e.g. thalidomide, benoxaprofen, Vioxx) and drug classes (e.g. oral contraceptives, inhaled anti-asthma products), their investigations and outcomes.</p> <p>1.2 Understand the evolution of drug surveillance methods, of pharmacovigilance (PhV) regulations worldwide and their harmonisation, and of inter- and intra-company reporting systems for assembling and reporting adverse events.</p>	✓	✓	✓		✓
AB	<p>1.1, 1.2</p> <p>Recognises the importance of these ‘landmark’ cases in bringing about change including increased regulation and more sophisticated reporting systems worldwide</p>				✓	✓
Curriculum Area DSS 2	Objective: To understand the key regulatory requirements for pharmacovigilance, both in the major regions and locally.					
GPMP 1						
K	<p>2.1 Understand the responsibilities and liabilities of investigators, clinicians, study monitors and manufacturers in the pre- and post-marketing phases to detect, assess and report adverse events associated with medicines (in the country where registrar operates).</p> <p>2.2 Be conversant with the requirements and processes for reporting to</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	the MHRA in the UK and to the EMEA. 2.3 Understand the requirements for informing prescribers, investigators, ethics committees and regulatory agencies of important safety concerns.					
AK	2.1, 2.2, 2.3 Communicate and discuss this knowledge of regulations with colleagues. Locate the relevant sources of information on these regulations and identify any new requirements. Evaluate whether these have implications in terms of revising processes to ensure compliance.	✓	✓			✓
AB	2.1, 2.2, 2.3 Is fully aware of the broader ethical, moral and professional responsibilities of pharmaceutical physicians with regard to drug safety, e.g. the GMC description of the duties of doctors. Recognises the importance of adherence to these regulations and the need to stay fully aware of updates / changes to regulations and guidelines.				✓	✓
K	2.4 Understand the PhV operation of the MHRA and of the EMEA. 2.5 Understand the PhV operation of the FDA in the USA and of its requirements for reporting. 2.6 Outline the relevant sections of the UK Medicines Act (1968) and subsequent Statutory Instruments relating to drug safety and PhV. 2.7 Recall the relevant ICH provisions for safety surveillance.	✓	✓	✓		✓
AK	2.4, 2.5, 2.6, 2.7	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Communicate and discuss this knowledge of regulations with colleagues.</p> <p>Locate the relevant sources of information on these regulations and identify any new requirements. Evaluate whether these have implications in terms of revising processes to ensure compliance.</p>					
AB	<p>2.4, 2.5, 2.6, 2.7</p> <p>Recognises the importance of adherence to these regulations and the need to stay fully aware of updates / changes to regulations and guidelines.</p>				✓	✓
K	<p>2.8 Be aware of the PhV operation of the drug regulatory authority in Japan (PDMA) and its requirements for reporting.</p>	✓	✓	✓		✓
Curriculum Area DSS 3	<p>Objective: The registrar will be able to carry out all medical assessments required to meet the requirements for drug safety reporting.</p>					
GPMP 1						
K	<p>3.1 Define the regulations relating to the collection and reporting of suspected Adverse Drug Reactions (ADR) in local country where registrar works.</p>	✓	✓	✓		✓
AK	<p>3.1 Review and make a medical assessment of case reports and clinical study reports in the current literature mentioning suspected ADRs and transfer relevant information to report formats for submission to relevant regulatory agencies.</p> <p>Apply ethical judgements and ensure adherence to appropriate guidelines when carrying out post-marketing surveillance studies.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	3.1 Recognises the importance of meeting the requirements for reporting of ADRs.				✓	✓
K	3.2 Describe the requirements regarding safety issues in the Summary of Product Characteristics (SmPC).	✓	✓	✓		✓
AK	3.2 Review SmPCs of company products to ensure all safety issues are covered appropriately as regards clarity and completeness.	✓	✓			✓
AB	3.2 Contributes to ensuring that the SmPC appropriately reflects the safety profile of the drug in question.				✓	✓
K (RGN 3)	3.3 Outline the contents of a Periodic Safety Update Report (PSUR).	✓	✓	✓		✓
AK	3.3 Evaluate an existing PSUR. Write the overall safety evaluation section of a real or simulated PSUR.	✓	✓			✓
AB	3.3 Recognise the overall function of the PSUR in terms of updating any safety concerns re drug.				✓	✓
K	3.4 Describe the contents of safety sections of Patient Information Leaflets (PIL) and package information.	✓	✓	✓		✓
AK	3.4 Write and be able to critically review the safety section of a PIL and package information.	✓	✓			✓
AB	3.4 Recognise how important it is to ensure that the PIL is written considering its target audience to aid compliance.				✓	✓
K	3.5 Outline product recall procedures, including communications to doctors and patients.	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	3.5 Evaluate and discuss issues around product recall and be able to write a Dear Doctor letter for Healthcare Professionals (HCP) and also patient communications.	✓	✓			✓
AB	3.5 Participates actively in the medical discussions around product recall.				✓	✓
K	3.6 Describe the role of the Qualified Person in Pharmacovigilance (QPPV).	✓	✓	✓		✓
AK	3.6 Discuss interactions a QPPV is most likely to have with a pharmaceutical physician and the actions required by the pharmaceutical physician.	✓	✓			✓
AB	3.6 Recognises importance of the QPPV role.				✓	✓
K	3.7 Relevant pharmacovigilance sections from: a) EU Directives and Regulations; b) ICH and CHMP Guidelines. 3.8 Be aware of the CIOMS Working Groups and Reports I-VI.	✓	✓	✓		✓
AK	3.7, 3.8 Apply guidelines and directives and ensure compliance to them in all aspects of pharmacovigilance with particular focus on Volume 9A.	✓	✓			✓
AB	3.7, 3.8 Recognises importance of these regulations and guidelines.				✓	✓
Curriculum Area	Objective: The registrar will have a clear understanding of spontaneous reporting and signal generation methodology and be able to assess medically AE/ADR reports.					

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		PMAT	CBA	DPM EXAM	MSF	PBD
DSS 4						
GPMP 1						
K	4.1 Describe the characteristics that make an ADR reportable according to international guidelines.	✓	✓	✓		✓
AK	<p>4.1 Apply the definitions of adverse event, serious adverse event, unexpected / unlabelled adverse event, suspected adverse reaction and clinically significant abnormal laboratory test value; discuss the differences between them.</p> <p>Assess adverse event / reaction reports and be able to evaluate the importance of temporal relationships, concomitant medications, pre-existing or concurrent illnesses and patient characteristics.</p> <p>Formulate appropriate follow-up questions to reporting healthcare professionals and specify the data that are important in the assessment of adverse event/reaction reports.</p>	✓	✓			✓
AB	4.1 Recognise the need for clear definitions and procedures / guidelines for adverse event reporting.				✓	✓
K	4.2 Understand the application of epidemiological methods to spontaneous reporting.	✓	✓	✓		✓
AK	<p>4.2 Assess medically post-marketing suspected ADR reports and determine seriousness, causal relationship to suspect drug and expectedness.</p> <p>Assess medically serious adverse events (SAEs) from clinical trials and determine their causal relationship to the study drug and expectedness.</p> <p>Assess ADRs and other relevant benefit-risk information reported in the literature.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	4.2 Recognises the importance of medical assessment of adverse events from all potential sources and its potential future use in treating or advising patients.				✓	✓
K	4.3 Be aware of coding systems for drug safety (e.g. MedDRA). 4.4 Understand the methods and applications of all signal generation methods in pharmacovigilance and the processes required for prioritisation and evaluation of detected signals.	✓	✓	✓		✓
Curriculum Area DSS 5	Objective: The registrar will be able to interrogate a database or review published data to evaluate for signals and assess causality.					
GPMP 1						
K	5.1 Explain the major pharmaco-epidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases. 5.2 Identify the major methods of post-marketing surveillance. 5.3 Understand the application of the Safety Assessment of Marketed Medicines (SAMM) and the requirements for Post-Authorisation Safety Studies (PASS) in the UK. 5.4 Understand the common causal mechanisms for ADRs. 5.5 Understand the mechanisms of drug interactions. 5.6 Describe the principles of causality assessment and causality algorithms to classify events as to their likely causal attribution to a particular medicine.	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
S	5.1, 5.2, 5.3, 5.4, 5.5, 5.6 Perform relevant searches on a database. Critically evaluate published research data.	✓	✓			✓
AB	5.1, 5.2, 5.3, 5.4, 5.5, 5.6 Recognises the importance of signal evaluation, causality assessment and the communication of relevant findings as a key responsibility in helping to safeguard future patients.				✓	✓
Curriculum Area DSS 6	Objective: To understand the principles and methods of evaluation of risk and benefit balance and the principles and methods for risk management.					
GPMP 1						
K	6.1 Understand the principles and methods for risk / benefit evaluation and related decisions during pre-marketing development. 6.2 Understand the principles and process for development of safety specifications documents. 6.3 Be familiar with the CIOMS VI report in respect of safety in clinical trials. 6.4 Understand the structure, roles and responsibilities of data safety monitoring committees. 6.5 Describe the principles of risk and benefit assessment. 6.6 Recall the CIOMS IV – Report of CIOMS Working Group IV.	✓	✓	✓		✓
AK	6.1, 6.2, 6.3, 6.4, 6.5, 6.6 Critically review relevant documents (e.g. protocol, PIL, safety	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	specifications, risk management plan) for appropriate risk and benefit statements.					
AB	6.1, 6.2, 6.3, 6.4, 6.5, 6.6 Recognises the importance of the physician's role in risk and benefit assessment and risk management and share this with colleagues.				✓	✓
K	6.7 Understand the principles and methods of post-marketing risk management plans (ICH E2E) and be able to provide medical input into such plans. 6.8 Be aware of the options and mechanisms for optimising safety in relation to benefit.	✓	✓	✓		✓
AK	6.7, 6.8 Make appropriate medical contributions for effective risk management plans.	✓	✓			✓
Curriculum Area DSS 7	Objective: The registrar will understand the variety of regulatory actions possible to address drug safety signals.					
GPMP 1						
K	7.1 Understand the key regulatory actions including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension and withdrawal. 7.2 Explain the European procedures for reassessment of risk: benefit (Articles 31 & 36 of Directive 2001/83/EEC).	✓	✓	✓		✓
AK	7.1, 7.2 Be able to review any of these documents before regulatory submission to ensure accuracy from a medical perspective.	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AB	7.1, 7.2 Recognises the importance of these regulatory actions to help ensure patient safety.				✓	✓
Curriculum Area DSS 8	Objective: The registrar will understand the importance of communication of safety issues, the variety of formats required to meet audience needs and be able to contribute to the development of such communications.					
GPMP 1						
K	8.1 Outline the safety aspects of the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL). 8.2 Understand the availability of urgent communication tools; the opportunities and pitfalls of their use. 8.3 Understand about communications planning and the need for coordination with key stakeholders in handling a drug safety issue.	✓	✓	✓		✓
AK	8.1, 8.2, 8.3 Contribute to the drafting of ‘Dear Doctor’ letters. Contribute to the drafting of press briefings.	✓	✓			✓
AB	8.1, 8.2, 8.3 Recognises the importance of communication of safety issues and the need for a variety of formats to meet different customer needs.				✓	✓
Curriculum Area DSS 9	Objective: The registrar will have the capability to understand an issue and establish a crisis management team, recognising the key functional areas to be represented and their roles and responsibilities.					
GPMP 1						

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		PMAT	CBA	DPM EXAM	MSF	PBD
K	9.1 Explain the organisation and conduct of a crisis management team.	✓	✓	✓		✓
AK	9.1 Identify the key individuals to be included in a crisis management team. Identify the main steps involved in assessing and reacting to a potential crisis situation.	✓	✓			✓
AB	9.1 Recognises the need for planned procedures to be in place and the urgency required to implement these plans appropriately.				✓	✓
K	9.2 Be conversant with the legal responsibilities and liabilities of pharmaceutical companies and pharmaceutical physicians in respect of drug safety issues.	✓	✓	✓		✓
AK	9.2 Describe the appropriate response to various simulated drug safety issues.	✓	✓			✓
AB	9.2 Consults effectively with all relevant parties.				✓	✓
K	9.3 Understand the role of the pharmaceutical company, the regulatory agencies, the media and the legal profession in the evolution of drug safety issues. 9.4 Define the external factors affecting response to drug safety issues (e.g. public freedom, political agendas etc).	✓	✓	✓		✓
AK	9.3, 9.4 Approve product briefing documents for the media.	✓	✓			✓
AB	9.3, 9.4 Recognises the need for appropriate training of all relevant staff in issue / crisis management.				✓	✓
Curriculum Area	Objective: To demonstrate an understanding of the areas of progress, likely major advances and future challenges in drug safety and pharmacovigilance.					

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		PMAT	CBA	DPM EXAM	MSF	PBD
DSS 10						
GPMP 1						
K	<p>10.1 Define the key markers of progress – examination of evidence that the output from existing safety surveillance systems has improved health.</p> <p>10.2 Outline safety aspects of gene therapy and other new technologies.</p> <p>10.3 Explain the potential for pharmacogenomics / pharmacogenetics to enhance the safety of medicines.</p> <p>10.4 Describe the CYP450 isoenzymes and their role in safety aspects of medicines’ development and surveillance.</p> <p>10.5 Outline the future challenges for pharmacovigilance</p>	✓	✓	✓		✓
AK	<p>10.1, 10.2, 10.3, 10.4, 10.5</p> <p>Evaluate how these advances may impact on drug safety surveillance in the future.</p>	✓	✓			✓
AB	<p>10.1, 10.2, 10.3, 10.4, 10.5</p> <p>Demonstrates a willingness to remain abreast of advances in research and technology and apply new knowledge and learn new skills.</p>				✓	✓
<p>Curriculum Area</p> <p>IPM 1</p>	<p>Objective: To demonstrate an understanding of the managed environment in which pharmaceutical medicine operates, identifying the contribution of the law and regulation, and the interactions of key stakeholders and how these various components influence decision-making in the development and commercialisation of medicines.</p>					

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		PMAT	CBA	DPM EXAM	MSF	PBD
GPMP 1						
K	<p>1.1 To identify and explain the components of employment legislation that are of relevance to the operation of a Medical Department and other areas of the pharmaceutical managed environment.</p> <p>Explain the importance of relationships and interactions between Medical and other key Departments e.g. marketing, sales, R&D, consumer products (Over-The-Counter medicines).</p> <p>Understand roles, responsibilities and relationships with key support functions e.g. finance, legal, human resources departments.</p> <p>1.2 Describe the elements of Health & Safety Executive legislation that have importance in the pharmaceutical environment.</p>	✓	✓	✓		✓
AK	<p>1.1, 1.2 Discuss current UK employment legislation as it applies to a growing Medical Department.</p> <p>Identify differences between UK practices and those in other European and non-UK countries in the research-based pharmaceutical industry.</p>	✓	✓			✓
AB	<p>1.1, 1.2 Recognises the legal framework of modern employment in the UK and its impact on the work of drug development and commercialisation.</p>				✓	✓
K	<p>1.3 Describe the principles of financing within the pharmaceutical sector as it applies to the industry, companies, departments and projects.</p>	✓	✓	✓		✓
AK	<p>1.3 Manage a budget and its accounts within a company, department or project.</p>	✓	✓			✓
AB	<p>1.3 Recognises the importance and impact of fiscal management in determining goals, priorities and outcomes in the pharmaceutical business environment.</p>				✓	✓
Curriculum	<p>Objective: The registrar will be able to demonstrate an understanding of the principles and practices of people</p>					

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Area IPM 2	management and leadership, and competency to apply these within their own working environment.					
GPMP 1						
K	2.1 Describe the general principles of people management.	✓	✓	✓		✓
K	2.2 List the principles and practices of conducting competitive employment interviews and of selecting new staff.	✓	✓	✓		✓
K	2.3 Describe methods of performance management and appraisal, their purpose, application and outcomes	✓	✓	✓		✓
AK	2.3 Differentiate between educational and performance appraisal. Describe principles of effective Objective: setting, sources of appropriate feedback and their relative importance, and measurement of outcomes	✓	✓			✓
K	2.4 Outline motivational techniques.	✓	✓	✓		✓
AK	2.4 Apply motivational techniques in reaching a project outcome.	✓	✓			✓
K	2.5 Describe methods used to retain and develop staff to their full potential including the role of personal development plans.	✓	✓	✓		✓
AK	2.5 Differentiate between specialist training and management skills and how they can be complementary. Outline appropriate specialist training and management training plans and how they can be incorporated within the pharmaceutical physician's organisational roles and responsibilities.	✓	✓			✓
K	2.6 Outline the principles and common practices of managing a team in line or as a matrix.	✓	✓	✓		✓
AK	2.6 Apply leadership and motivational skills to management of	✓	✓			✓

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	<p>multidisciplinary teams in one of the following areas:</p> <ul style="list-style-type: none"> - in line - in matrix - local - international 					
AB	Recognises the importance of management / leadership style and influence on team dynamics and reaching departmental / project goals.				✓	✓
Curriculum Area IPM 3	Objective: The registrar will be able to demonstrate applied knowledge and Objective in a range of interpersonal and communication skills relevant to the practice of pharmaceutical medicine.					
GPMP 1						
K	<p>3.1 Negotiating.</p> <p>3.2 Influencing.</p> <p>3.3 Networking.</p>	✓	✓	✓		✓
AK	<p>3.1, 3.2, 3.3</p> <p>Use negotiating skills to reach an outcome.</p> <p>Use influencing skills to construct a committee / advisory board to meet defined Objectives.</p> <p>Use networking skills to build a build a database of key influencers, opinion leaders or experts in a product / therapy area.</p> <p>Demonstrate an understanding of the importance of personal styles and preferences in approaches to interpersonal interactions and communication with colleagues and how these may be determined and acted upon (e.g. Myers Briggs and other similar psychometric</p>	✓	✓			✓

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	methods).					
AB	3.1, 3.2, 3.3 Recognises the importance of interpersonal skills for pharmaceutical physicians to influence / drive project / team outcomes.				✓	✓
K	3.4 Describe the critical role of IT and communications technology management in contributing to efficiency and effectiveness within an organisation.	✓	✓	✓		✓
AK	3.4 Outline the principles of knowledge management and its importance in the pharmaceutical organisational context.	✓	✓			✓
K	3.5 Describe the principles applied by an effective meeting chair.	✓	✓	✓		✓
AK	3.5 Chair meetings effectively to reach timely outcomes in at least one of: - development projects; - management projects; - committees; - speaker meetings.	✓	✓			✓
K	3.6 Outline the principles of effective presentations.	✓	✓	✓		✓
AK	3.6 Make effective AV presentations (in at least one of): - product related; - therapy area related; - project related; - case study feedback.	✓	✓			✓

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K	3.7 Describe the principles of effective time management.	✓	✓	✓		✓
AK	3.7 Project planning and meeting allocated timelines for multidisciplinary roles. Relate time and time management to opportunity costs and other determinants of successful and timely project completion and outcome.	✓	✓			✓
AB	3.7 Recognise the importance of effective time management to meet project and personal goals				✓	✓
Curriculum Area IPM 4	Objective: The registrar will demonstrate working to the tenets of Good Pharmaceutical Medical Practice.	PMAT	CBA	DPM EXAM	MSF	PBD
K GPMP 1	4.1 Refer to PMST Modules: RGN 2,4,6 CLP 8 SDM 5 CLD 1,7,8 HMP 2 DSS 3,8	✓	✓	✓		✓
AK	4.1 Refer to PMST Modules.	✓	✓			✓
AB	4.1 Refer to PMST Modules.				✓	✓
K GPMP 2	4.2 Outline the principles of adult learning theory. Define the principles of Continuing Professional Development (CPD).	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	<p>4.2 Identify gaps in knowledge and plan actions to fill them.</p> <p>Translate knowledge and new learning into practice.</p> <p>Maintain a portfolio of CPD.</p> <p>Model and promote CPD within the multi-disciplinary team.</p>	✓	✓			✓
AB	<p>4.2 Strives to enhance professional Objective: with active involvement in CPD activities.</p> <p>Recognises the moral and professional obligation to maintain Objective: and be accountable.</p> <p>Reflects on all aspects of practice.</p>				✓	✓
<p>K</p> <p>GPMP 4</p>	<p>4.3 Recall and build upon the competencies defined in the Foundation Curriculum:</p> <ul style="list-style-type: none"> - interview structure; - effective listening; - clarify information given by patients and research subjects; - use comprehensible language tailored to subject; - use open and closed questions appropriately; - gauge subjects' ideas, concerns, expectations and comprehension; - appropriate use of written materials and interpreters; - act in a courteous, polite and professional manner. 	✓	✓	✓		✓
AK	<p>4.3 Demonstrate good communication skills to others in team.</p> <p>Manage subject follow up effectively (e.g. with GPs).</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Accurately record details of discussions with subjects over care.</p> <p>Identify and manage communication barriers while respecting confidentiality, language, cultural differences, hearing impairment, poor literacy etc.</p>					
AB	<p>4.3 Shows willingness to provide subjects with a second opinion.</p> <p>Shows willingness to provide other sources of information for subjects (printed literature, support societies etc).</p> <p>Ensures the subject is well informed and central to the discussion making process.</p> <p>Identifies significant others and recognise their role in the management of information to subjects and patients.</p>				✓	✓
K GPMP 6	<p>4.3 In respect of complaints and medical error recall and build upon competencies defined in the foundation programme:</p> <ul style="list-style-type: none"> - awareness of complaints procedures; - factors likely to lead to complaints (poor communication, dishonesty etc); - adopt behaviour likely to prevent complaints; - deal with dissatisfied subjects; - recognise when something has gone wrong and identify appropriate staff with whom to communicate this; - act with honesty and sensitivity in a non-confrontational manner. <p>Define local complaints procedures.</p> <p>Identify sources of help when advice is made about yourself or a colleague.</p>	✓	✓	✓		✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
AK	<p>4.3 In respect of complaints and medical error, contribute to processes whereby complaints are reviewed and learned from.</p> <p>Explain comprehensively to the subject the events leading up to a medical error.</p> <p>Deliver an appropriate apology.</p> <p>Distinguish between system and individual errors.</p>	✓	✓			✓
AB	<p>4.3 Takes leadership over complaints issues.</p> <p>Recognises the impact of complaints and medical error on staff, subjects and the pharmaceutical industry.</p> <p>Contributes to a fair and transparent culture around complaints and errors.</p> <p>Recognises the rights of subjects and others to make a complaint.</p>				✓	✓
K GPMP 5	<p>4.4 Outline the features of an effective comprehensive handover.</p> <p>Identify the important roles played by all members of a multi-disciplinary team.</p> <p>Outline feature of good team dynamics.</p> <p>Outline the principles of effective inter-professional collaboration to optimise subject care.</p>	✓	✓	✓		✓
AK	<p>4.4 Establish effective communication with relevant teams by means appropriate to the situation.</p> <p>Delegate to members of the medical department team and members of the multi-disciplinary team whilst maintaining appropriate supervision.</p> <p>Take responsibility as appropriate for accurate and prompt information distribution within and between teams.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Utilise the expertise of the multi-disciplinary team.</p> <p>Communicate effectively with administrative bodies and support organisations.</p> <p>Employ collaborative negotiation to prevent and resolve conflict.</p>					
AB	<p>4.4 Fosters a supportive and respectful environment where there is open and transparent communication.</p> <p>Respects opinions and encourage open communication with all members of the multi-disciplinary team to improving learning.</p> <p>Shows willingness to participate in multi-disciplinary team meetings.</p>				✓	✓
K GPMP 3	<p>4.5 Outline adult learning principles relevant to medical education, including:</p> <ul style="list-style-type: none"> - identification of learning styles; - Construction of educational objectives. <p>Describe the use of effective questioning techniques.</p> <p>Describe how to vary teaching format and stimulus.</p> <p>Outline the structure of effective appraisal interview.</p> <p>Define the work-based assessments in use.</p> <p>Differentiate appraisal and assessment.</p> <p>Identify an appropriate course of action to assist the failing registrar.</p>	✓	✓	✓		✓
AK	<p>4.5 Vary teaching format and stimulus, appropriate to the situation and subject.</p> <p>Provide effective feedback after teaching and promote learner reflection.</p>	✓	✓			✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>Conduct effective appraisal.</p> <p>Demonstrate effective lecture, presentation, small group and 1-to-1 teaching sessions.</p> <p>Provide appropriate career advice or refer registrar to an alternative effective source of career information.</p> <p>Participate in strategies aimed at improving subject / patient / lay education e.g. talking at support group meetings.</p> <p>Recognise the failing registrar.</p>					
AB	<p>4.5 Recognises the importance of the role of the physician as educator.</p> <p>Demonstrates willingness to teach registrars and other professional colleagues in a variety of settings.</p> <p>Encourages discussions with colleagues to share knowledge and understanding.</p> <p>Shows willingness to participate in work base assessments.</p> <p>Maintains honesty and objectivity during appraisal and assessment.</p> <p>Shows willingness to take up formal tuition in medical education.</p> <p>Recognises the importance of personal development as a role model to guide registrars in aspects of good professional behaviour.</p>				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
K GPMP 6	<p>4.6 Define the concept of modern medical professionalism (ref). Recall and build on the competencies defined in the Foundation programme:</p> <ul style="list-style-type: none"> - respect the rights of children, elderly, people with physical, mental, learning or communication difficulties; - adopt a non-discriminatory approach; - behave with honesty and probity; - act with honesty and integrity in a non-confrontational manner. <p>Outline the relevance of professional bodies (Royal Colleges, Faculty of Pharmaceutical Medicine, GMC, Deanery, BMA, Specialist Societies, MDU).</p>	✓	✓	✓		✓
AK	<p>4.6 Practise pharmaceutical medicine with:</p> <ul style="list-style-type: none"> - integrity - compassion - altruism - continuous improvement - excellence - working in partnership with members of the wider team. <p>Promote awareness of the pharmaceutical physician in the best use of healthcare resources.</p> <p>Recognise and respond to unprofessional behaviour in others.</p>	✓	✓			✓
AB	<p>4.6 Recognises the need to use all healthcare resources prudently and appropriately.</p> <p>Recognises the need to improve clinical leadership and management</p>				✓	✓

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		PMAT	CBA	DPM EXAM	MSF	PBD
	<p>skill.</p> <p>Recognises the situations where it is appropriate to involve professional bodies.</p> <p>Shows willingness to act as mentor and educator.</p> <p>Participates in professional regulation.</p> <p>Recognises the right for equity of access to healthcare for minority groups.</p>					
K GPMP 7	<p>4.7 Define health problems affecting doctors and other professionals that impact work, professional behaviour and the safety of patients, research subjects and others.</p>	✓	✓	✓		✓
AK	<p>4.7 Show vigilance regarding health issues in self and colleagues which impact work, professional behaviour and the safety of patients, research subjects and others.</p> <p>Be willing to deal openly and supportively with problems in the performance, conduct or health of team members.</p>	✓	✓			✓
AB	<p>4.7 Recognises that systems are in place for dealing supportively with problems in the performance, conduct or health of team members when they come to light.</p>				✓	✓