

**JOINT COMMITTEE ON
HIGHER MEDICAL TRAINING**

and

**FACULTY OF
PHARMACEUTICAL MEDICINE**



**CURRICULUM FOR
HIGHER MEDICAL TRAINING
IN**

PHARMACEUTICAL MEDICINE

PHARMACEUTICAL MEDICINE

Pharmaceutical Medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of the marketing of medicines for the benefit of patients and the health of the community. The Faculty of Pharmaceutical Medicine is responsible for ensuring and maintaining standards in the discipline and, as such, has developed a curriculum for higher medical training to equip specialists with the comprehensive skills and competence increasingly demanded by the industry for the public good.

Entry requirements

The requirements for entry to specialist training in pharmaceutical medicine are as follows:

1. a minimum of two years of General Professional Training (GPT) in approved training posts, which should normally involve direct patient care and experience of prescribing at SHO level. Multidisciplinary rotations in approved SHO posts are highly recommended, but not required.
2. appointment through a transparent system to a post within the pharmaceutical industry, the regulatory authorities, or academia wherein a Faculty-approved training programme can be undertaken. Approval of both the post and the training programme will be required for enrolment.
3. a scientific qualification (e.g. BSc) and/or postgraduate medical or scientific diploma or degree (e.g. MSc, PhD, MD, MRCP, MRCPATH) is desirable but not essential
4. registration with the Faculty

EEA or Overseas Doctors

The entry requirements for EEA or overseas doctors are the same as those outlined above with the following amendments:

- the basic medical qualification must be recognised by and be registrable with the GMC. GMC registration will be required for recommendation of a CCST.
- GPT training must have been supervised to the same extent as approved posts in the UK and entrants must be able to provide evidence of suitable knowledge and experience. This is subject to approval by the Lead Postgraduate Dean
- appointment to posts must be consistent with UK employment law and good practice in selection and recruitment. The applicant must be in post prior to enrolling for HMT.

Duration and Organisation of Training

The programme will take a minimum of four and a maximum of eight years (FTE) and comprises basic and advanced training modules. The basic training follows the syllabus for the Diploma in Pharmaceutical Medicine examination and normally takes two years. Passing the Diploma examination is required before a CCST can be recommended. Basic training is largely knowledge based and ensures a breadth of knowledge appropriate to a specialist in pharmaceutical medicine.

The advanced training follows seven modules, which extend from this basic knowledge base and ensure depth of knowledge and competence in application appropriate to a specialist in pharmaceutical medicine. Three of the advanced modules, including *Interpersonal and Management Skills*, must be acquired through in-work experience. The additional four modules may be acquired in work or may be acquired by means of Faculty-approved interactive taught courses. In-work modules may begin prior to passing the Diploma examination, but taught courses will require evidence of Diploma level knowledge prior to enrolment on the course. Assessments are required for all modules and will normally be competence-based.

The Syllabus for the Diploma in Pharmaceutical Medicine and the Curriculum for the Advanced Modules follow this section.

Training Record

A Training Record will be maintained by the specialist trainee, remaining the property of the trainee and produced at the annual assessments. It will be counter-signed by the Educational Supervisor to confirm satisfactory fulfilment of the required training experience and the acquisition of the competence levels enumerated in the Specialty curricula.

Flexible Training

Trainees who are unable to work full-time are entitled to opt for flexible training programmes as per EC Directive 93/16/EEC:

- i. Part-time training shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities to a period of at least half of that provided for full-time trainees;
- ii. The competent authorities shall ensure that the total duration and quality of part-time training of specialists are not less than those of full-time trainees.

The above provisions must be adhered to in pharmaceutical medicine.

Assessment

Annual assessment of specialist trainees will be based upon the standard format of annual review, including the Penultimate Year Assessment (PYA) which is particularly important. Full details can be found in the JCHMT Training Handbook. The Award of the CCST will be based on satisfactory completion of the entire series of annual assessments.

Training Programme

Higher Medical Training in Pharmaceutical Medicine consists of a basic component, which forms the knowledge base and follows the syllabus of the Diploma in Pharmaceutical Medicine, and an advanced component, which builds on and applies this knowledge following seven curriculum modules. The details of both the basic and the advanced training programmes are outlined below.

Basic Higher Medical Training in Pharmaceutical Medicine

**The Diploma in Pharmaceutical Medicine is a requirement of Higher Medical Training in Pharmaceutical Medicine and must be passed before a CCST can be recommended.*

Introduction

The syllabus for the Diploma in Pharmaceutical Medicine is composed of nine modules:

1. Medicines Regulation
2. Clinical Pharmacology
3. Statistics and Data Management
4. Clinical Development
5. Healthcare Marketplace
6. Drug Safety
7. Role of the Medical Department
8. Discovery of New Medicines
9. Therapeutics

The scope and content of the syllabus for the Diploma is largely unchanged from that prior to 2003 but its presentation has been updated to bring it in line with recent developments in Higher Medical Training and to take account of advances and changes in the practice of pharmaceutical medicine. The first six modules listed correspond to the advanced training modules for Higher Medical Training (HMT). In addition, 'Discovery of New Medicines' is considered an essential area of knowledge for physicians entering a career in pharmaceutical medicine. Similarly, 'Therapeutics' has always been included in the syllabus but its importance to the practice of all areas of pharmaceutical medicine is emphasised by its designation as a separate module.

The content of the syllabus is listed under the separate modules below. There is a considerable degree of overlap and some topics appear under more than one module though it is not intended to imply that any topic is restricted only to those modules under which it is listed. The order of listing does not reflect importance.

1. Medicines Regulation

The general principles of medicines regulation

Medicines regulation in UK, EU, USA, Japan

Activities and contribution of International Conference on Harmonisation

Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices

Clinical Trials regulations – IND, CTX, EU Directives etc
Common Technical Document, Expert Reports / Overviews
Reporting of adverse drug reactions, periodic safety update reports
Product information – Summary of Product Characteristics, Patient Information Leaflets
Licensing – MAA, NDA, abridged applications, updating and maintaining licences
Orphan drugs
Provisions for and use of unlicensed medicines
Drug abuse and dependence
Non-prescription drugs and reclassification of Prescription Only and Pharmacy only medicines
Codes of practice, industry self regulation, advertising
Fraud and professional misconduct
Patents, legal issues, parallel imports
Ethics and Ethics Committees
Pharmacopoeias

2. Clinical Pharmacology

PRE-CLINICAL DEVELOPMENT TO SUPPORT TESTING IN HUMANS

Safety testing – acute, subacute toxicology, genotoxicology, reproductive toxicology, topical irritation and hypersensitivity, safety pharmacology, immunotoxicology

Pharmacokinetics and metabolism

Pharmaceutical Development - formulations, manufacture and supply of materials, labelling and presentation, stability and storage, purity, compatibility, disposal

EXPLORATORY CLINICAL DEVELOPMENT

Assessment of preclinical data

Planning of studies in Exploratory Development

Populations for exploratory studies - healthy volunteers and patients

Ethics – principles, peer review, informed consent, Declaration of Helsinki

Regulation

Studies - objectives, design, conduct and analysis, choice of site

Tolerability and safety

Use of biomarkers and pharmacodynamic endpoints, dose-response

Pharmacokinetics, ADME and pharmacokinetic/pharmacodynamic models

Interpretation of study design, analysis and results

CLINICAL PHARMACOKINETICS

Concepts – half-life, volume of distribution, clearance

Bioavailability and Bioequivalence

Drug-Drug and Drug-Disease Interactions (Extrinsic factors)

Studies in different populations (Intrinsic factors)

Pharmacogenetics

Population pharmacokinetics

Applicability of pharmacokinetics to dosage regimen and study design

3. Statistics and Data Management

THE PURPOSE AND FUNDAMENTALS OF STATISTICS

TRIAL DESIGN, HYPOTHESIS TESTING, POWER

Pre-trial decisions and specification

Risk factors, confounding variables

The null hypothesis, Type I and II errors, significance, power

MEASUREMENT AND TYPES OF DATA

Standardisation

Variations in biometry in population, in disease

DATA COLLECTION AND MANAGEMENT

Options for data collection (manual and electronic)

Creation, maintenance and security of databases, software validation and archiving

Data management from clinical trials: corrections, computer capture, verifications and extraction

Within-trial decisions, data management, extraction and manipulation

TYPES OF ANALYSIS

Analysis of efficacy end-points and of safety

Paired and non-paired tests, parametric and non-parametric tests, confidence limits

Handling of rating and visual analogue scales, patient diaries and laboratory values

INTERPRETATION OF STUDY DESIGN, ANALYSIS AND RESULTS

Assessment of violations, withdrawals, errors, bias

Statistical principles and issues in report writing: data manipulation, transposition, merging

Clinical interpretation of trial

Final report writing and formatting for registration dossier and publications

4. Clinical Development

PLANNING AND ORGANISATION

Organisation and operation of project teams

Objective and target setting

Integrated project planning

Requirements for licensing of new medicines

Budgeting and costs control

REGULATION AND ETHICS

EU Directives

ICH –Good Clinical Practices

Ethics – principles, peer review, informed consent, Declaration of Helsinki

Regulatory review
Indemnity
Confidentiality and Data Protection

CLINICAL TRIALS

Planning of Clinical Trial programme – use of preclinical and Phase I data
Study types and designs
Documentation - protocols, reports, source documents, case report forms, study master file, investigator's brochure
Contractual arrangements with investigators and contract research organisations
Study conduct
Quality control and quality assurance
Adverse Events and Serious Adverse Events – definitions, collection, reporting, assessment, coding
Interpretation of study design, analysis and results
Formulations, manufacture and supply of materials, labelling and presentation, stability and storage, purity, compatibility, disposal
Data management and statistical analysis

5. Drug Safety

PRECLINICAL

In vitro and *in vivo* testing.
Toxicology: dose-range finding, GLP studies, requirements to support exposure in humans, safety testing of topicals, immunotoxicity, genotoxicity, carcinogenicity, reproductive toxicity
Safety Pharmacology
Studies of drug metabolism to predict interactions
Implications of findings to studies in humans

CLINICAL TRIALS

Adverse Events and Serious Adverse Events – definitions, collection, reporting, assessment, coding, ICH and CIOMS

ADVERSE DRUG REACTIONS

Classification of Adverse Reactions, idiosyncrasy, accidents
Mechanisms, predisposing factors in health and disease
Dosage, Cumulation, Interactions
Assessment of evidence and management
Reporting
Carcinogenicity and Genotoxicity
Prevention

REGULATION

Dear Dr letters and Withdrawal of products

SmPCs and PILs
Drug abuse and dependence
Non-therapeutic drug use
Life and Storage Safety of Medicinal Products

PHARMACOVIGILANCE

Methods and ethics of adverse event monitoring, post-marketing surveillance, spontaneous reporting, Safety Assessment of Marketed Medicines, Periodic Safety Update Reports
Benefit-risk assessment
Issue and Crisis management

PHARMACOEPIDEMOLOGY

Databases
Signal generation
True and apparent incidence and prevalence data
Sensitivity and specificity of indices

6. Healthcare Marketplace

Quality of Life
Marketing structure and competition, price negotiations,
National and local formularies.
Product information, advertising and claims
Product support and promotion
Product life-cycle management
Product liability
Codes of practice
Principles and practice of marketing
Measurement of healthcare, governmental policy and third-party reimbursement.
Principles of health economics
Pharmacoepidemiology
Competition, in-licensing, co-marketing

7. Role of Medical Department

Clinical Research
Regulatory submissions
Pharmacovigilance
Quality Assurance
Information services
Data Management
Financial control
Legal compensation

Crisis management

8. Discovery of New Medicines

The philosophy behind and organisation of research

Disease target identification and selection

Patenting new active substances

Receptor-based approaches, agonists, antagonists, enzyme inhibitors, genomics, proteomics

Lead optimisation and candidate selection of molecules for exploratory human investigation

In vitro and *in vivo* testing of new compounds

Relationship between animal and human pharmacology

9. Therapeutics

Management of common acute and chronic diseases

Major drug classes

Measurement of drug effects

Adverse drug reactions

Benefit:risk

Drug interactions

Prescribing for particular populations e.g. children, elderly, pregnant and breast feeding women, patients with renal or hepatic impairment

Controlled drugs and drug dependence

Overdosage and treatment of poisoning

Patient compliance and information

Therapeutic Drug Monitoring

Advanced Higher Medical Training in Pharmaceutical Medicine

**Competence in all seven modules must be successfully demonstrated and assessed before a CCST can be recommended.*

Advanced Higher Medical Training comprises a modular programme with continuous and performance-based assessment in seven fields of practice in pharmaceutical medicine, which are:

- | | |
|--|-----------------------------|
| 1. Medicines Regulation | 4. Clinical Development |
| 2. Clinical Pharmacology | 5. Healthcare Marketplace |
| 3. Statistics and Data Management | 6. Drug Safety Surveillance |
| 7. Interpersonal and Management Skills | |

Key to Levels of competence: 1 = Be fully conversant
2 = Have a working knowledge of
3 = Be aware of

MEDICINES REGULATION RGN 1-10			
Topic ref	Objective	Description	Competence Level required
RGN 1	Working knowledge of UK and EU medicines regulation and familiarity with ICH and other international initiatives	To have a working knowledge and understanding of: <ul style="list-style-type: none"> • Medicines Act 1968 and subsequent Statutory Instruments (SI) • European Regulations, Directives and Guidelines and UK enactment of such • the operation of a national regulatory agency, e.g. the European Medicines Evaluation Agency, FDA • <i>In principle</i> the International Conference on Harmonisation (ICH) including the parties concerned, procedures (including electronic submissions and the areas covered) To have an awareness of: <ul style="list-style-type: none"> • Ministry of Health and Welfare, Japan • registration of Pharmaceutical Products in international markets 	2
RGN 2	Knowledge of requirements for ADR reporting and options for regulatory action on safety signals	Be fully conversant with adverse drug reaction reporting, including spontaneous reporting, yellow card system and MAH obligations	1
RGN 3 Links to DSS 3	Knowledge of periodic safety update reports	Be fully conversant with principles of periodic safety updates and possible outcomes of their assessment.	1
RGN 4	Writing and/or reviewing product information	Be fully conversant with product information <ul style="list-style-type: none"> • European SmPC • Patient information leaflet • Technical leaflet • Package labelling 	1

RGN 5	Be fully conversant with provisions for use of unlicensed medicines.	Be fully conversant with : <ul style="list-style-type: none"> the responsibilities/liabilities imposed by the provision of unlicensed medicines Type DDX compassionate use/named patient supplies Have a working knowledge/ awareness of <ul style="list-style-type: none"> The origin investigation and management of cases of fraud and misconduct Special licences. 	1
RGN 6	Writing and/or reviewing expert reports for new drug applications.	Have a working knowledge of <ul style="list-style-type: none"> UK and European procedures The structure of an MAA Expansion of the EU market and impact on procedures To be able to contribute to the writing and/or appraisal of expert reports (These may be new drug applications, variations or abridged documents.) Availability and use of CPMP guidelines 	2
RGN 7 Links to CLD	Understand the principles of clinical trials regulation, GCP and its regulatory impact. (This is mainly covered by Dip Pharm Med and in Clinical Devel. module.)	To have a working knowledge of: <ul style="list-style-type: none"> CTX/CTC system DDX Have an awareness of: <ul style="list-style-type: none"> Ethics Committee review IND procedures European clinical trial directive To be able to demonstrate knowledge of principles of : <ul style="list-style-type: none"> GCP, as laid down by ICH. How GCP affects validity of MAA. GCP and Medicines in Children 	2
RGN 8 Links with DSS	Working knowledge of post licensing regulatory procedures	To have a working knowledge of: <ul style="list-style-type: none"> Type I Type II Type II urgent safety Abridged applications Marketing authorisation renewal Legal classification Drug safety issues <ul style="list-style-type: none"> pharmacovigilance Prescription Event Monitoring pharmacoepidemiology Type II urgent safety restriction	1
RGN 9	Working knowledge of mechanisms for wider availability of medicines	Be aware of POM/GSL criteria, patient group directives etc. Draft/critically assess an outline of a clinical expert report for a legal status reclassification application.	3
RGN 10	Be able to advise on investigation of defects	To have a working knowledge of <ul style="list-style-type: none"> defect investigation batch and product recall To have awareness of <ul style="list-style-type: none"> manufacturers and wholesalers licences and inspection import licences parallel import licences Good Manufacturing Practice (GMP) Good Laboratory Practice (GLP) Pharmacopoeias 	2

CLINICAL PHARMACOLOGY

CLP 1-9

Topic ref	Objective	Description	Competence Level required
CLP 1 Links with CLD 2 and CLD 3	Working knowledge/awareness of relevant pre-clinical science	K Have a working knowledge of basic clinical pharmacological concepts (agonist/antagonist inhibition potency selectivity) of preclinical toxicology tests and long term toxicity/ carcinogenicity reports of the preclinical data required to support initiation of clinical development and to support significant steps in clinical development such as progression to long-term studies.	2
		K Have an awareness of potential clinical significance of in vitro and in vivo pharmacology, of standard toxicological study designs, of the concepts of toxicokinetics and of the potential value of in vitro and in vivo P450 preclinical data in predicting likely drug interactions.	3
		S Be able to contribute to identifying additional preclinical evaluation required before first time in man studies, derivation of risk benefit ratios and to use preclinical metabolism data to identify necessary clinical drug interaction studies.	2
CLP 2 Links with SDM 1 and with SDM 5	Be able to understand standard statistical methods and interpret results of standard statistical analysis	K Fully understand statistical significance, confidence intervals, null hypothesis power, type 1 and type 2 errors, meta-analysis, evidence based medicine, odds ratio. Appreciate the relative merits of parametric and nonparametric statistical tests. S Be able to find relevant references and source information for study design. Be able to critically appraise publications in a given therapeutic area and to write an abstract and full paper to a standard acceptable for publication and a peer review journal	1
CLP 3 Links with RGN 1, RGN 6 and RGN 7 and with CLD 9	Have a working knowledge of regulatory authority controls relevant to clinical pharmacology studies	Have a working knowledge of clinical pharmacology contribution and toxicology in phase I requirements for regulatory submission for initiating clinical trials in Europe, of clinical pharmacology components of a regulatory submission for approval in Europe and of the clinical pharmacology component of a clinical development plan to satisfy regulatory requirements in Europe. Have an awareness of the regulatory procedures (as above) of clinical pharmacology studies in USA and Japan	2
CLP 4 Links with CLD 3	Have working knowledge of design of and be able to use the data generated by a first into man study.	K Have a working knowledge of the objectives of first studies in man, of the main kinds of designs for phase I studies and their relative merits, of the value of placebo, stopping rules and safety evaluation, of the principles of selection of dose range and dose increments during dose escalation, of minimum effective and maximal tolerated doses, of a degree biological variation seen in a normal population and of the reasons and need for full screening of healthy volunteers. S Be able to contribute the use of pharmacokinetic data and the design of first time in man studies, the selection of safety measures in first time in man studies on the basis of preclinical data, to define relevant pharmacodynamic measures for first into man studies on the basis of preclinical data and to interpret the changes seen in tests of physiological function in healthy subjects in studies of a new chemical entity.	2
CLP 5 Links with CLD 7 and with CLD 8	Be fully conversant with the basic ethical principles involved in clinical research in healthy individuals	K Know the principles essential for protection of healthy subjects in clinical trials, the Ethics Committee requirements for approving a first into man study and the indications for contacting general practitioners of individuals participating in healthy volunteer studies. S Be able to write a subject information sheet and consent form in appropriately lay language and yet incorporating all elements of informed consent as specified in ICH guidelines on GCP.	1

CLP 6 Links with CLD 9	Be fully aware of the relevant aspects of good clinical practice.	K Be fully aware of the central documents to be maintained in a clinical trial file and have a working knowledge of the principles of good clinical practice, the roles and responsibilities of Investigator and co-investigator as laid out in the ICH regulations.	1
CLP 7 Links with CLD 3 and with CLD 4	Have a working knowledge of the role of clinical pharmacology and the creation and implementation of a clinical development plan	S Be able to contribute to defining the implications of changing clinical development plan for resourcing studies and revising time-frames for submission to regulatory authorities, contribute to assessment of the impact of ADME data on a development plan and help to identify the need for interaction special patient group, etc. studies and understand interdependencies of studies and thus contribute to appropriate timing of studies within the overall development timetable	2
CLP 8 Links with CLD 1	Have a working knowledge of one major organ based disease area.	K Preferably physiology of major diseases and of the mode of action of the major drug classes used in treatment, of the criteria of efficacy, safety and value to be met by a new treatment in this area. S Be able to contribute a clinical development plan for a candidate drug in the organ based area.	2
CLP 9	Have an awareness of new knowledge emerging in the area of pharmacogenomics		3

STATISTICS AND DATA MANAGEMENT SDM 1- 7			
Topic ref	Objective	Description	Competence Level required
SDM 1 Links with CLP 2	Be able to apply the principles of statistics in clinical trials.	Have sufficient familiarity of statistical principles to enable effective collaborative work with professional statisticians, ensuring that design and analysis of clinical trials meets scientific and regulatory requirements.	2
SDM 2	Be able to contribute to planning and review of statistical analysis.	Understand the requirements of a statistical analysis plan, ensuring effective clinical input to development of the plan (by a statistician) and effective review of its content.	1
SDM 3	Be able to contribute to planning and execution of meta analysis	Identify the key questions to be answered by an Integrated Summary of Efficacy. Consider how individual study results could be presented to answer the questions.	2
SDM 4	Be able to plan and contribute to execution of Integrated Summary of Safety.	Identify the key questions to be answered by an Integrated Summary of Safety. Consider how individual study results could be presented to answer the questions.	1 – planning 2 – execution
SDM 5	Be able to collaborate with a statistician on design and analysis of clinical trials.	Understand issues arising in design and analysis of trials and how they may be addressed effectively.	2
SDM 6	Be able to work with a data manager to manage clinical trial data.	Understand the principles of clinical data management and methods used to ensure the integrity of clinical trial data.	2
SDM 7	Be able to work with a data manager on review and validation of clinical trial data.	Contribute to development of data validation plan, ensuring the provision of high quality data within the regulatory framework.	2

CLINICAL DEVELOPMENT

CLD 1- 16

Topic ref	Objective	Description	Competence Level required
CLD 1	Research and write a report on a therapy area	Find out about a relevant therapy area, and existing therapies in that area. Be able to critically review the area, identify unmet medical need, new therapies in development, and potential new therapeutic strategies. Integrate these into a report	1
CLD 2	Review of Preclinical and Phase1 data	Be able to review Phase 1 (tolerance) and late phase preclinical data.	2
CLD 3	Assessment of Preclinical and Phase1 data	Determine their adequacy for Phase 2 and 3, and anticipate their impact on the design of the program and its likelihood of success	2
CLD 4	Constructing or Assessing Clinical Development Plan	Be able to suggest a program of clinical trials that will produce the quality, safety and efficacy data to support worldwide registration of the product, and the pricing, outcome and commercialisation data to support the drug in the global market.	2
CLD 5	Developing study protocols	Identify a study design that will produce critical data specified in a clinical development plan and	1
CLD 6	Write a Study Protocol	Produce a practical, ethical, study protocol.	1
CLD 7	Understand the Ethical Issues pertaining to Clinical Trials	Demonstrate an understanding of the ethical issues relating to clinical trials.	2
CLD 8	Drafting consent forms	Draft an informed consent form	2
CLD 9	Understand the regulations and ethical guidelines governing Clinical trials	Declaration of Helsinki, GCP etc	1
CLD 10	Setting up clinical studies	An understanding of the principles of time and project management and the practicalities essential to the conduct of clinical trials	2
CLD 11	Conducting a study	Have an understanding of the purpose and practicalities of Setting up a study, identifying and assessing investigators, monitoring, and closing down a study	2
CLD 12	Handling adverse effects	Be able to identify, evaluate, classify and categorise clinical trial adverse events.	2
CLD 13	Reporting Adverse Events	Be able to determine how to report events of different types, dependent on the status of the drug and the location of the event, in accordance with UK, European, US and Japanese regulations.	2
CLD 14	Report writing	Be able to interpret clinical trial data and write clear reports that adequately summarise the trial.	1
CLD 15	Manuscript Writing	Be able to write a manuscript that will be accepted by a peer-reviewed journal.	2
CLD 16	Interpreting study results	Be able to summarise the results of a research program, assessing the design and conduct of the studies, and critically reviewing their results in order to make an assessment of risk/benefit	2

HEALTHCARE MARKETPLACE		HMP 1- 6	
Topic ref	Objective	Description	Competence Level required
HMP 1 Links to RGN 7 and DSS 2	Be fully conversant with product information legislation contained in the UK Medicines Act and the ABPI Code of practice including its application to conferences and symposia	To develop an understanding of the legal framework in which Pharmaceutical Medicine needs to operate including the ABPI code of practice and the UK Medicines Act, and any other regulations applying to the candidates country(ies) of operation.	1
HMP 2	Be fully competent to construct and approve product briefing materials for the media	To be able to develop and recognise legally compliant documentation in support of marketing activities	1
HMP 3	Be fully competent to manage the process to successful publications/presentations by others	To be able to draft publications and presentations for external authors, adapt inputs, reconcile multiple views, and produce final draft documentation	1
HMP 4	Have a working knowledge of in-licensing and co-marketing, <u>and</u> be fully competent to assess an in-licensing candidate	To understand how to evaluate the clinical potential of an in-licensing opportunity	1
HMP 5	Have a working knowledge of how to critically evaluate the promotional platform of a competitive product	To be able to understand the competitor environment fully, both marketed products and pipeline, in the relevant therapeutic area, and be able to compare one's own current and future promotional platform with that of others	2
HMP 6 Links to RGN 4	Be fully competent to apply ethical judgements and apply the relevant guidelines on a range of issues	To understand the impact of our activities on the external environment and appreciate how our actions are seen by the general public. To appreciate the relevant safeguards on ethical behaviour	1

DRUG SAFETY SURVEILLANCE		DSS 1 - 10	
Topic ref	Objective	Description	Competence Level required
DSS1	Basic understanding of adaptation of man to use pharmaceuticals and awareness of historical background and evolution of ADR reporting systems.	<ul style="list-style-type: none"> • Sociological context of drug safety in different populations • Landmark safety cases. • Evolution of methods, regulations and reporting systems 	3
DSS 2	Conversant with the regulatory framework for pharmacovigilance and the role of ICH and CIOMS	<ul style="list-style-type: none"> • Operational aspects of MCA, EMEA, FDA • Relevant sections of UK/EU legislation and ICH provisions 	2

DSS 3	Fully conversant with the UK/EU requirements for drug safety reporting	<ul style="list-style-type: none"> Regulations in own country on ADR reporting, on provision and content of PSURs. Ability to review PSUR and write Overall Safety Evaluation section of PSUR. Requirements for SmPCs, PILs and package information Definition of Qualified Person in Pharmacovigilance. EU, ICH and CPMP regulations and guidelines. 	1
DSS 4	Spontaneous reporting and signal generation methods	<ul style="list-style-type: none"> Features of an adverse event that make it reportable Definitions of AE, ADR ,seriousness, labelled/expectedness Initial assessment, follow-up and reporting of adverse events Assess submitted ADR's and ADRs in the literature. Application of epidemiological methods to spontaneous reporting 	2
DSS 5	Signal evaluation and causality assessment	<ul style="list-style-type: none"> Major pharmaco-epidemiological methods and databases. Common causal mechanisms Mechanisms of drug interactions, causality algorithms and drug safety coding systems Critical evaluation of published research data Present and appraise analysed safety studies to answer key questions Apply guidelines for SAMM studies. 	1
DSS 6	Risk:Benefit assessment	<ul style="list-style-type: none"> Principles of risk:benefit assessment Familiarity with CIOMS IV Reducing risk/increasing benefit. Implications for stakeholders of (unfavourable) risk:benefit assessment. 	2
DSS 7	Options for regulatory action to address drug safety signals	<ul style="list-style-type: none"> Variations, urgent safety restrictions, licence suspension and withdrawal. European procedures for reassessment of Risk:Benefit (Article 12 and 15A) 	3
DSS 8	Communication of safety issues to health professionals and the public	<ul style="list-style-type: none"> SPCs and PILs Drafting Dear Doctor letters Urgent communication tools Drafting press briefings 	2
DSS 9	Issue and crisis management	<ul style="list-style-type: none"> Organisation and conduct of a crisis management team. Assessing and reacting to a potential crisis. Responding appropriately to various simulated safety issues. Legal responsibilities of company, or pharmaceutical physicians. Other external participants in crisis management External factors affecting the response to drug safety issues 	2
DSS 10	Drug safety surveillance in the 21 st century	<ul style="list-style-type: none"> Markers of success-examination of evidence that the output from existing safety surveillance systems has improved health. Safety aspects of gene therapy and other new technologies. The potential for pharmacogenomics to enhance drug safety. CYP450 isoenzymes.....what will be the next important enzymes to be mapped? Future challenges for pharmacovigilance 	3

INTERPERSONAL AND MANAGEMENT SKILLS IPM 1- IPM 9

Topic ref	Objective	Description	Competence Level required
IPM 1 Links to DSS 5	Be fully conversant with the general principles and practice of leadership and management	To understand the practice of leadership and management, including the legal framework, Health and Safety law, legal privilege, due diligence, and employment law	1
IPM 2	Be fully competent to manage staff performance	To understand appraisal techniques, giving and receiving feedback	1
IPM 3	Be fully competent to negotiate with others	Develop negotiation, influencing and networking skills	1
IPM 4	Be fully conversant with the general principles of people management	Understand how to interview and select new staff, and motivate retain and develop them to their full potential	1
IPM 5	Be fully competent to chair meetings	Chair a meeting effectively	1
IPM 6	Be fully competent to manage a team in line or matrix	Leadership and motivation of multidisciplinary teams	1
IPM 7	Be fully competent to manage time	Manage time effectively	1
IPM 8	Be fully competent to make effective presentations	To develop excellent presentation skills	1
IPM 9	Be fully competent to manage budgets and accounts	Finance for financial managers	1