



**INSTITUTE  
OF MEDICINE**

ROYAL COLLEGE OF  
PHYSICIANS OF IRELAND

HIGHER SPECIALIST TRAINING IN

# PHARMACEUTICAL MEDICINE



**This curriculum of training in Pharmaceutical Medicine was developed in 2017 and undergoes an annual review by Dr Mary Teeling, National Specialty Directors, Colm Small, Head of Postgraduate Training and Education, and by the Pharmaceutical Medicine Training Committee. The curriculum is approved by the Institute of Medicine.**

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## Introduction

Pharmaceutical Medicine is the medical specialty which encompasses the discovery, development, evaluation and licensing of medicines together with their appropriate marketing and ongoing monitoring of their safety in clinical practice (lifecycle management of medicines). The specialty has been evolving over the past 50 years and was recognised as a medical specialty in the UK in 1989 and in Switzerland and Ireland (since 2005); other EU countries are currently in the process of approving the specialty. More recently the EU 7<sup>th</sup> Framework Programme (which supports scientific research and development activities within Europe) has recognised the importance of appropriate training in the area of pharmaceutical medicine by including several training programmes in its Joint Technology Initiative on Innovative Medicines (IMI JTI).

Although pharmaceutical medicine shares some common themes with clinical pharmacology, it has unique features including the clinical research aspects of drug development, the licensing procedures of medicines and the monitoring of their safety profile in clinical practice (so-called pharmacovigilance). It also includes the provision of accurate and timely medical and technical information to assist healthcare professionals and patients in the appropriate use of medicines and the implementation of regulatory compliance (i.e. adherence to the legal and ethical aspects of medicine usage and promotion) throughout the lifecycle of a medicine. Medical practitioners who work as pharmaceutical physicians undertake these activities in many different areas within the healthcare system and allied services including clinical trial units, academic departments, contract research organisations, national agencies, such as the Health Products Regulatory Authority (formally the Irish Medicines Board), NSAI or National Medicines Information Centre in Ireland as well as the pharmaceutical industry. Although the majority of pharmaceutical physicians (with the possible exception of those undertaking clinical trials) have no direct contact with patients, they are required to be fully registered with the Medical Council of Ireland in order to fulfil their duties.

Pharmaceutical physicians are involved in activities on a daily basis (e.g. evaluating ongoing safety with medicines in practice and promoting evidence-based prescribing) to reduce medication errors, maximise patient benefit and minimise harm with use of medicines. Pharmaceutical physicians interact with other healthcare professionals on a regular basis - on medical information enquiries, in clinical trial activities, in preparing educational materials, including journal articles, textbooks, reference books, formularies, pharmaco-economic assessments and e-learning materials – all of which encourage rational use of medicines in the interest of patient safety. Pharmaceutical physicians from either the pharmaceutical industry or national agencies may also be called upon by the media to give guidance on drug-related events of public interest.

This training programme will provide the knowledge and competence for a doctor to be trained in all aspects of drug development, the regulation and safe use of medicines, and with good communication skills who will be able to assist healthcare professionals, as well as Pharmacoeconomic and regulatory competent authorities in the rational use of medicines, in the interest of public health.

## Aims

Upon satisfactory completion of specialist training in Pharmaceutical Medicine a doctor will be **competent** to undertake comprehensive medical practice in that specialty in a **professional** manner, unsupervised and independently and/or within a team, in keeping with the needs of the healthcare system in which the specialist operates.

**Competencies**, at a level consistent with practice in the specialty of Pharmaceutical Medicine, will include the following:

- Enabling healthcare professionals to provide patient care that is appropriate, effective and compassionate in dealing with health problems and health promotion
- Medical knowledge in the basic biomedical, behavioural and clinical sciences, medical ethics and medical jurisprudence and application of such knowledge to their practice.
- Interpersonal and communication skills that ensure effective information exchange with other health professionals, individual patients and their families, the scientific community and the public.
- Appraisal and utilisation of new scientific knowledge to update and continuously improve professional practice.
- The ability to function as a supervisor, trainer and teacher in relation to colleagues, medical students and other health professionals as appropriate.
- Capability to be a scholar, contributing to development and research in the field of Pharmaceutical Medicine.
- Professionalism.
- Knowledge of public health and health policy issues: awareness and responsiveness in the larger context of the health care system, including e.g. the organisation of health care, partnership with health care providers and managers, the practice of cost-effective health care, health economics and resource allocations.
- Ability to understand health care and identify and support system-based improvement of care.

## Professionalism

Being a good doctor is more than technical competence. It involves values – putting patients and patient safety first, safeguarding their interests, being honest, communicating with accuracy, and being committed to lifelong learning and continuous improvement. Developing and maintaining values are important; however, it is only through putting values into action that doctors demonstrate the continuing trustworthiness that the public legitimately expect. According to the Medical Council, Good Professional Practice involves the following aspects:

- Effective communication
- Respect for autonomy and shared decision-making
- Maintaining confidentiality
- Honesty, openness and transparency (especially around mistakes, near-misses and errors)
- Raising concerns about patient safety
- Maintaining competence and assuring quality of medical practice

## Entry Requirements

Applicants for Higher Specialist Training (HST) in Pharmaceutical Medicine must have a certificate of completion Basic Specialist Training (BST) in General Internal Medicine and obtained the MRCPI.

Other entrants with appropriate higher examinations (including MICGP, MRCSI) may be considered.

All applicants must be employed in a position that is within a national regulatory agency such as the Health Products Regulatory Authority (HPRA) or a Pharmaceutical Company e.g. Pfizer. The applicant's employment location must be listed as an approved training site for Pharmaceutical Medicine. Applicants to the training programme must be supported by their employer organisation and will be required to supply evidence of this at application stage.

Those that do not hold a BST Certificate and MRCPI must provide evidence of equivalency.

Entry on the training programme is at year 1. Deferrals are not allowed on entry to the Higher Specialty Training Programme.

## Duration and Organisation of Training

Whilst the curriculum is competency-based, the duration of training must meet the European minimum of 4 years for full-time speciality training adjusted accordingly for flexible training.

The programme has a modular structure, which takes into account the major areas of competence required by the pharmaceutical medicine (PM) specialist. There are 6 core modules, in addition to the generic components module. Trainees must complete each of these core modules during their period of training.

In addition, each trainee must complete a postgraduate course (diploma / MSc) in pharmaceutical medicine / drug development sciences, by the end of year 3 of the training programme (see figure 1). This is funded by the trainee's employer or self-funded. This will enable trainees to demonstrate that they have a broad understanding of the various areas of pharmaceutical medicine and its overarching public health role in the promotion of the rational use of medicines.

The curriculum incorporates the European harmonised curriculum for pharmaceutical medicine, formally approved by the European Commission recognised Innovative Medicines Initiative Joint Undertaking (IMI JU) PharmaTrain project and by the UK Faculty of Pharmaceutical Medicine. Each trainee will complete a 4-year training programme, in order to acquire practical competency-based training.

Trainees in the Pharmaceutical Medicine HST programme are encouraged to spend time in research. However due to the nature of the specialty there is no period of research or out of programme experience that will count towards the completion of the training program. Many of the core programme modules already incorporate significant research elements. If trainees express an interest in undertaking research during the training programme they can do as part of the specialty module: New Medicines Development. The Pharmaceutical Medicine NSD and Dean of Postgraduate Medical Education & Training will review the application prospectively for appropriateness of the research topic and the candidate to undertake the work. For those intending to pursue an academic path, an extended period of research may be necessary in order to explore a topic fully or to take up an opportunity of developing the basis of a future career. Such extended research may continue after the CSCST is gained.

The earlier years of training will usually be directed towards acquiring a broad general experience of Pharmaceutical Medicine under appropriate supervision.

An increase in the content of hands-on experience follows naturally, and, as confidence is gained and abilities are acquired, the trainee will be encouraged to assume a greater degree of responsibility and independence.

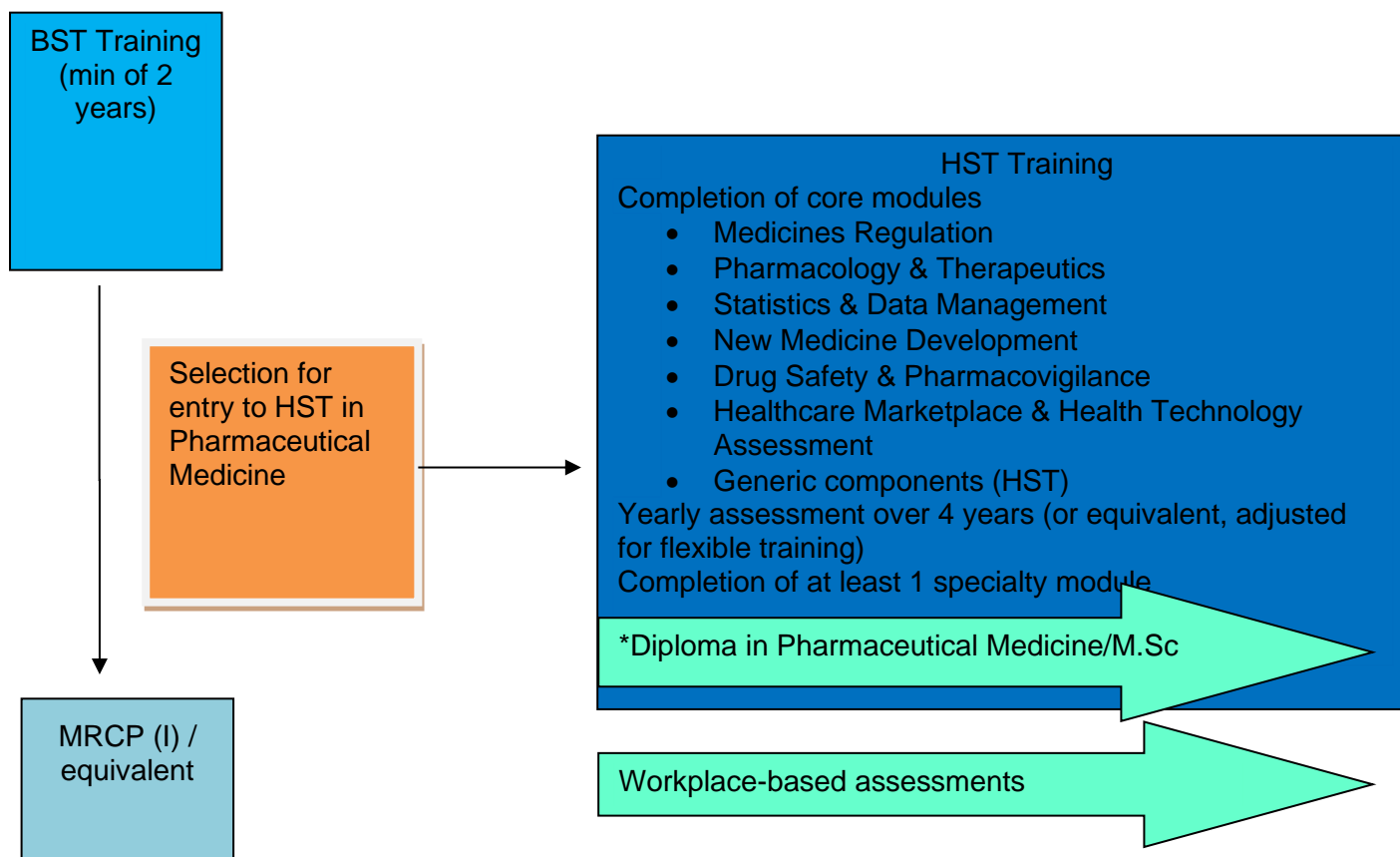
“Generic” knowledge, skills and attitudes support competencies which are common to good medical practice in all the Medical and related specialties. It is intended that all Specialist Registrars should reaffirm relevant competencies during Higher Specialist Training. No time-scale of acquisition is offered, but failure to make progress towards meeting these important objectives **at an early stage** would cause concern about a Trainee's suitability and ability to become independently capable as a specialist.



## Training Pathway

Figure 1 below outlines the training pathway for HST in pharmaceutical medicine. Because of the nature of the speciality and in particular the lack of direct patient contact involved in the majority of pharmaceutical medicine posts, trainees will only be eligible for entry to the HST programme upon completion of their Basic Specialist Training. Similarly, it is not envisaged that trainees will combine the HST programme within a dual training structure (further clinical training).

**Figure 1: Training Pathway**



\*Completion of a recognised postgraduate academic training course in pharmaceutical medicine/drug development sciences or an M.Sc is mandatory before the end of year three on the training programme. This is funded by the trainee's employer or self-funded.

## Training Programme

Because of the nature of the specialty and in particular the confidential nature of much of the work undertaken by professionals working in the various strands of pharmaceutical medicine, it will not usually be possible for trainees to routinely rotate between training sites. Where the potential training site is within a large organisation (e.g. large pharmaceutical companies, national regulatory agencies such as the HPRA), it may be possible for the trainee to gain workplace experience in most of the areas listed as core pharmaceutical medicine competences within the training programme at their training site. Moreover, many of the smaller potential training sites are affiliates of larger EU-based institutions, therefore the trainee may be able to access experience from within the larger organisation; however, the trainee may still be required to participate in external practical workshops to acquire competence as per curricular requirements.

All potential training sites will be approved prior to start of training. This will involve a site visit by the RCPI to the training site and require a signed commitment by the employer to ensure that the trainee's role and responsibilities will be compatible with his/her training role in Pharmaceutical Medicine. This includes adequate time for study and periods of study leave. The elements of the programme which can be delivered by "On Site Experience" will be identified; those that will require external training will also be identified and trainee and Trainer will work towards a solution that will be agreed with the Specialty Training Committee. Trainees will also be required to complete all of the mandatory RCPI HST courses as listed in the minimum requirements section of the curriculum e.g. Study Days, such as Protocol Development and Good Clinical Practice Course.

Any deficiencies arising from the lack of rotation will be overcome by (1) requiring each trainee to successfully complete a recognised postgraduate course in pharmaceutical medicine / drug development sciences and (2) the use of problem-based learning workshops / practical sessions. Trainees, whose employment site precludes / offers limited workplace experience in a specific competence, will be required to complete a workshop / practical session in that area of competence. These will be run by the various training sites where such competences are available or in approved academic institutions and will be approved by the Specialty Training Committee. All trainees can attend these sessions which will help to develop an in-depth understanding of the area through problem-based learning activities and will promote interactive learning relationships between the trainees on the programme.

## **Assessment Process**

The methods used to assess progress through training must be valid and reliable. The current Pharmaceutical Medicine Curriculum describes the levels of competence which can be recognised. The assessment grade will be awarded on the basis of observation in the workplace by the Trainer. Time should be set aside for appraisal following the assessment e.g. of case presentations, PSUR reviews, critical events management, project completion reports / presentations, clinical study report critiques etc.

As progress is being made, the lower levels of competence will be replaced progressively by those that are higher. Where the grade for an item is judged to be deficient for the stage of training, the assessment should be supported by a detailed note which can later be referred to at the annual review. Assessment will also be supported by the trainee's portfolio of achievements and performance at relevant meetings, presentations, audit, in tests of knowledge, attendance at courses and educational events.

## **Generic Components**

**This chapter covers the generic components which are relevant to HST trainees of all specialties but with varying degrees of relevance and appropriateness, depending on the specialty.**

**As such, this chapter needs to be viewed as an appropriate guide of the level of knowledge and skills required from all HST trainees with differing application levels in practice.**

## Good Professional Practice

**Objective:** Trainees must appreciate that medical professionalism is a core element of being a good doctor and that good medical practice is based on a relationship of trust between the profession and society, in which doctors are expected to meet the highest standards of professional practice and behaviour.

**Medical Council Domains of Good Professional Practice:** Relating to Patients, Communication and Interpersonal Skills, Professionalism, Patient Safety and Quality of Patient Care.

### KNOWLEDGE

#### Effective Communication

- How to listen to patients and colleagues
- The principles of open disclosure
- Knowledge and understanding of valid consent
- Teamwork
- Continuity of care

#### Ethics

- Respect for autonomy and shared decision making
- How to enable patients to make their own decisions about their health care
- How to place the patient at the centre of care
- How to protect and properly use sensitive and private patient information in accordance with data protection legislation and how to maintain confidentiality
- The judicious sharing of information with other healthcare professionals where necessary for care following Medical Council Guidelines
- Maintaining competence and assuring quality of medical practice
- How to work within ethical and legal guideline when providing clinical care, carrying research and dealing with end of life issues

#### Honesty, openness and transparency (mistakes and near misses)

- Preventing and managing near misses and adverse events.
- When and how to report a near miss or adverse event
- Incident reporting; root cause and system analysis
- Understanding and learning from errors
- Understanding and managing clinical risk
- Managing complaints
- Following open disclosure practices
- Knowledge of national policy and National Guidelines on Open Disclosure

#### Raising concerns about patient safety

- Safe working practice, role of procedures and protocols in optimal practice
- The importance of standardising practice through the use of checklists, and being vigilant
- Safe healthcare systems and provision of a safe working environment
- Awareness of the multiple factors involved in failures
- Knowledge and understanding of Reason's Swiss cheese model
- Understanding how and why systems break down and why errors are made
- Health care errors and system failures
- Human and economic costs in system failures
- The important of informing a person of authority of systems or service structures that may lead to unsafe practices which may put patients, yourself or other colleagues at risk
- Awareness of the Irish Medical Councils policy on raising concerns about safety in the environment in which you work

**SKILLS**

- Effective communication with patients, families and colleagues
- Co-operation and collaboration with colleagues to achieve safe and effective quality patient care
- Being an effective team player
- Ethical and legal decision making skills
- Minimising errors during invasive procedures by developing and adhering to best-practice guidelines for safe surgery
- Minimising medication errors by practicing safe prescribing principles
- Ability to learn from errors and near misses to prevent future errors
- Managing errors and near-misses
- Using relevant information from complaints, incident reports, litigation and quality improvement reports in order to control risks
- Managing complaints
- Using the Open Disclosure Process Algorithm

**ASSESSMENT & LEARNING METHODS**

- Consultant feedback at annual assessment
- Workplace based assessment e.g. Mini-CEX, DOPS, CBD
- Educational supervisor's reports on observed performance (in the workplace): prioritisation of patient safety in practice
- RCPI HST Leadership in Clinical Practice
- RCPI Ethics programmes
- Medical Council Guide to Professional Conduct and Ethics
- Reflective learning around ethical dilemmas encountered in clinical practice
- Quality improvement methodology course - recommended

## Infection Control

**Objective:** To be able to appropriately manage infections and risk factors for infection at an institutional level, including the prevention of cross-infections and hospital acquired infection

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care; Management (including Self-Management).

### KNOWLEDGE

#### Within a consultation

- The principles of infection control as defined by the HIQA
- How to minimise the risk of cross-infection during a patient encounter by adhering to best practice guidelines available, including the 5 Moments for Hand Hygiene guidelines
- The principles of preventing infection in high risk groups e.g. managing antibiotic use to prevent *Clostridium difficile*
- Knowledge and understanding of the local antibiotic prescribing policy
- Awareness of infections of concern, e.g. MRSA, *Clostridium difficile*
- Best practice in isolation precautions
- When and how to notify relevant authorities in the case of notifiable infectious disease
- Understanding the increased risk of infection to patients in surgery or during an invasive procedure and adhering to guidelines for minimising infection in such cases
- The guidelines for needle-stick injury prevention and management

#### During an outbreak

- Guidelines for minimising infection in the wider community in cases of communicable diseases and how to seek expert opinion or guidance from infection control specialists where necessary
- Hospital policy/seeking guidance from occupational health professional regarding the need to stay off work/restrict duties when experiencing infections the onward transmission of which might impact on the health of others

### SKILLS

- Practicing aseptic techniques and hand hygiene
- Following local and national guidelines for infection control and management
- Prescribing antibiotics according to antibiotic guidelines
- Encouraging staff, patients and relatives to observe infection control principles
- Communicating effectively with patients regarding treatment and measures recommended to prevent re-infection or spread
- Collaborating with infection control colleagues to manage more complex or uncommon types of infection including those requiring isolation e.g. transplant cases, immunocompromised host
- In the case of infectious diseases requiring disclosure:
  - Working knowledge of those infections requiring notification
  - Undertaking notification promptly
  - Collaborating with external agencies regarding reporting, investigating and management of notifiable diseases
  - Enlisting / requiring patients' involvement in solving their health problems, providing information and education
  - Utilising and valuing contributions of health education and disease prevention and infection control to health in a community

**ASSESSMENT & LEARNING METHODS**

- Consultant feedback at annual assessment
- Workplace based assessment e.g. Mini-CEX, DOPS, CBD
- Educational supervisor's reports on observed performance (in the workplace): practicing aseptic techniques as appropriate to the case and setting, investigating and managing infection, prescribing antibiotics according to guidelines
- Completion of infection control induction in the workplace
- Personal Protective Equipment Training Course (In hospital)



## Self-Care and Maintaining Well-Being

### Objectives:

1. To ensure that trainees understand how their personal histories and current personal lives, as well as their values, attitudes, and biases affect their care of patients so that they can use their emotional responses in patient care to their patients' benefit
2. To ensure that trainees care for themselves physically and emotionally, and seek opportunities for enhancing their self-awareness and personal growth

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care, Relating to Patients, Communication and Interpersonal Skills, Collaboration and Teamwork, Management (including self-management).

### KNOWLEDGE

- Self-awareness including preferences and biases
- Personal psychological strengths and limitations
- Understand how personality characteristics, such as need for approval, judgemental tendencies, needs for perfection and control etc., affect relationships with patients and others
- Knowledge of core beliefs, ideals, and personal philosophies of life, and how these relate to own goals in medicine
- Know how family-of-origin, race, class, religion and gender issues have shaped own attitudes and abilities to discuss these issues with patients
- Understand the difference between feelings of sympathy and feelings of empathy
- Know the factors between a doctor and patient that enhance or interfere with abilities to experience and convey empathy
- Understanding of own attitudes toward uncertainty and risk taking and own need for reassurance
- How own relationships with certain patients can reflect attitudes toward paternalism, autonomy, benevolence, non-maleficence and justice
- Recognise own feelings in straightforward and complex patient-doctor interactions
- Recognising the symptoms of stress and burn out

### SKILLS

- Exhibiting empathy and showing consideration for all patients, their impairments and attitudes irrespective of cultural and other differences
- Ability to create boundaries with patients that allow for therapeutic alliance
- Challenge authority appropriately from a firm sense of own values and integrity and respond appropriately to situations that involve abuse, unethical behaviour and coercion
- Recognise own limits and seek appropriate support and consultation
- Work collaboratively and effectively with colleagues and other members of health care teams
- Manage effectively commitments to work and personal lives, taking the time to nurture important relationship and oneself
- Ability to recognise when falling behind and adjusting accordingly
- Demonstrating the ability to cope with changing circumstances, variable demand, being prepared to re-prioritise and ask for help
- Utilising a non-judgemental approach to patient's problem
- Recognise the warning signs of emotional ill-health in self and others and be able to ask for appropriate help
- Commitment to lifelong process of developing and fostering self-awareness, personal growth and well being
- Be open to receiving feedback from others as to how attitudes and behaviours are affecting their care of patients and their interactions with others
- Holding realistic expectations of own and of others' performance, time-conscious, punctual
- Valuing the breadth and depth of experience that can be accessed by associating with professional colleagues

**ASSESSMENT & LEARNING METHODS**

- On-going supervision
- RCPI Ethics programmes
- Wellness Matters Course
- RCPI HST Leadership in Clinical Practice course

## Communication in Clinical and Professional Setting

**Objective:** To demonstrate the ability to communicate effectively and sensitively with patients, their relatives, carers and with professional colleagues in different situations.

**Medical Council Domains of Good Professional Practice:** Relating to Patients; Communication and Interpersonal Skills.

### KNOWLEDGE

#### Within a consultation

- How to effectively listen and attend to patients
- How to structure an interview to obtain/convey information; identify concerns, expectations and priorities; promote understanding, reach conclusions; use appropriate language.
- How to empower the patient and encourage self-management

#### Difficult circumstances

- Understanding of potential areas for difficulty and awkward situations
- How to negotiate cultural, language barriers, dealing with sensory or psychological and/or intellectual impairments and how to deal with challenging or aggressive behaviour
- Knowing how and when to break bad news
- How to communicate essential information where difficulties exist, how to appropriately utilise the assistance of interpreters, chaperones, and relatives.
- How to deal with anger and frustration in self and others
- Selecting appropriate environment; seeking assistance, making and taking time

#### Dealing with professional colleagues and others

- How to communicate with doctors and other members of the healthcare team
- How to provide a concise, written, verbal, or electronic, problem-orientated statement of facts and opinions
- The legal context of status of records and reports, of data protection confidentiality
- Freedom of Information (FOI) issues
- Understanding of the importance of legible, accessible, records to continuity of care
- Knowing when urgent contact becomes necessary and the appropriate place for verbal, telephone, electronic, or written communication
- Recognition of roles and skills of other health professionals
- Awareness of own abilities/limitations and when to seek help or give assistance, advice to others; when to delegate responsibility and when to refer

#### Maintaining continuity of care

- Understanding the relevance of continuity of care to outcome, within and between phases of healthcare management
- The importance of completion of tasks and documentation, e.g. before handover to another team, department, specialty, including identifying outstanding issues and uncertainties
- Knowledge of the required attitudes, skills and behaviours which facilitate continuity of care including, being available and contactable, alerting others to avoid potential confusion or misunderstanding through communications failure

#### Giving explanations

- The importance of possessing the facts, and of recognising uncertainty and conflicting evidence on which decisions have to be based
- How to secure and retain attention avoiding distraction
- Understanding how adults receive information best, the relative value of the spoken, written, visual means of communication, use of reinforcement to assist retention
- Knowledge of the risks of information overload
- Tailoring the communication of information to the level of understanding of the recipient
- Strategies to achieve the level of understanding necessary to gain co-operation and partnership; compliance, informed choice, acceptance of opinion, advice, recommendation

**Responding to complaints**

- Value of hearing and dealing with complaints promptly; the appropriate level, the procedures (departmental and institutional); sources of advice, and assistance available
- The importance of obtaining and recording accurate and full information, seeking confirmation from multiple sources
- Knowledge of how to establish facts, identify issues and respond quickly and appropriately to a complaint received

**SKILLS**

- Ability to appropriately elicit facts, using a mix of open and closed-ended questions
- Using “active listening” techniques such as nodding and eye contact
- Giving information clearly, avoiding jargon, confirming understanding, ability to encourage co-operation, compliance; obtaining informed consent
- Showing consideration and respect for other’s culture, opinions, patient’s right to be informed and make choices
- Respecting another’s right to opinions and to accept or reject advice
- Valuing perspectives of others contributing to management decisions
- Conflict resolution
- Dealing with complaints
- Communicating decisions in a clear and thoughtful manner
- Presentation skills
- Maintaining (legible) records
- being available, contactable, time-conscious
- Setting realistic objectives, identifying and prioritising outstanding problems
- Using language, literature (e.g. leaflets) diagrams, educational aids and resources appropriately
- Establish facts, identify issues and respond quickly and appropriately to a complaint received
- Accepting responsibility, involving others, and consulting appropriately
- Obtaining informed consent
- Discussing informed consent
- Giving and receiving feedback

**ASSESSMENT & LEARNING METHODS**

- Mastering Communication course (Year 1)
- Consultant feedback at annual assessment
  - Workplace based assessment e.g. Mini-CEX, DOPS, CBD
  - Educational supervisor’s reports on observed performance (in the workplace): communication with others e.g. at handover. ward rounds, multidisciplinary team members
- Presentations
- RCPI Ethics programmes
- RCPI HST Leadership in Clinical Practice Course

## Leadership

**Objective:** To have the knowledge, skills and attitudes to act in a leadership role and work with colleagues to plan, deliver and develop services for improved patient care and service delivery.

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care; Communication and Interpersonal Skill; Collaboration and Teamwork; Management (including Self-Management); Scholarship.

### KNOWLEDGE

#### Personal qualities of leaders

- Knowledge of what leadership is in the context of the healthcare system appropriate to training level
- The importance of good communication in teams and the role of human interactions on effectiveness and patient safety

#### Working with others

- Awareness of own personal style and other styles and their impact on team performance
- The importance of good communication in teams and the role of human interactions on effectiveness and patient safety

#### Managing services

- The structure and function of Irish health care system
- Awareness of the challenges of managing in healthcare
  - Role of governance
  - Clinical directors
- Knowledge of planning and design of services
- Knowledge and understanding of the financing of the health service
  - Knowledge of how to prepare a budget
  - Defining value
  - Managing resources
- Knowledge and understanding of the importance of human factors in service delivery
  - How to manage staff training, development and education
- Managing performance
  - How to perform staff appraisal and deal effectively with poor staff performance
  - How to rewards and incentivise staff for quality and efficiency

#### Setting direction

- The external and internal drivers setting the context for change
- Knowledge of systems and resource management that guide service development
- How to make decisions using evidence-based medicine and performance measures
- How to evaluate the impact of change on health outcomes through ongoing service evaluation

**SKILLS**

- Effective communication with patients, families and colleagues
- Co-operation and collaboration with others; patients, service users, carers colleagues within and across systems
- Being an effective team player
- Ability to manage resources and people
- Managing performance and performance indicators

**Demonstrating personal qualities**

- Efficiently and effectively managing one-self and one's time especially when faced with challenging situations
- Continues personal and professional development through scholarship and further training and education where appropriate
- Acting with integrity and honesty with all people at all times
- Developing networks to expand knowledge and sphere of influence
- Building and maintaining key relationships
- Adapting style to work with different people and different situations
- Contributing to the planning and design of services

**ASSESSMENT & LEARNING METHODS**

- Mastering Communication course (Year 1)
- RCPI HST Leadership in Clinical Practice (Year 3 – 5)
- Consultant feedback at annual assessment
- Workplace based assessment e.g. Mini-CEX, DOPS, CBD
- Educational supervisor's reports on observed performance (in the workplace): on management and leadership skills
- Involvement in hospital committees where possible e.g. Division of Medicine, Drugs and Therapeutics, Infection Control etc.

## Quality Improvement

**Objective:** To demonstrate the ability to identify areas for improvement and implement basic quality improvement skills and knowledge to improve patient safety and quality in the healthcare system.

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care; Communication and Interpersonal Skills; Collaboration and Teamwork; Management; Relating to Patients; Professionalism

### KNOWLEDGE

#### Personal qualities of leaders

- The importance of prioritising the patient and patient safety in all clinical activities and interactions

#### Managing services

- Knowledge of systems design and the role of microsystems
- Understanding of human factors and culture on patient safety and quality

#### Improving services

- How to ensure patient safety by adopting and incorporating a patient safety culture
- How to critically evaluate where services can be improved by measuring performance, and acting to improve quality standards where possible
- How to encourage a culture of improvement and innovation

#### Setting direction

- How to create a 'burning platform' and motivate other healthcare professionals to work together within quality improvement
- Knowledge of the wider healthcare system direction and how that may impact local organisations

### SKILLS

- Improvement approach to all problems or issues
- Engaging colleagues, patients and the wider system to identify issues and implement improvements
- Use of quality improvement methodologies, tools and techniques within every day practice
- Ensuring patient safety by adopting and incorporating a patient safety culture
- Critically evaluating where services can be improved by measuring performance, and acting to raise standards where possible
- Encouraging a culture of improvement and innovation

#### Demonstrating personal qualities

- Encouraging contributions and involvement from others including patients, carers, members of the multidisciplinary team and the wider community
- Considering process and system design, contributing to the planning and design of services

### ASSESSMENT & LEARNING METHODS

- RCPI HST Leadership in Clinical Practice
- Consultant feedback at annual assessment
- Involvement in hospital committees where possible e.g. Division of Medicine, Drugs and Therapeutics, Infection Control etc.

## Scholarship

**Objective:** To develop skills in personal/professional development, teaching, educational supervision and research

**Medical Council Domains of Good Professional Practice:** Scholarship

### KNOWLEDGE

#### Teaching, educational supervision and assessment

- Principles of adult learning, teaching and learning methods available and strategies
- Educational principles directing assessment methods including, formative vs. summative methods
- The value of regular appraisal / assessment in informing training process
- How to set effective educational objectives and map benefits to learner
- Design and delivery of an effective teaching event, both small and large group
- Use of appropriate technology / materials

#### Research, methodology and critical evaluation

- Designing and resourcing a research project
- Research methodology, valid statistical analysis, writing and publishing papers
- Ethical considerations and obtaining ethical approval
- Reviewing literature, framing questions, designing a project capable of providing an answer
- How to write results and conclusions, writing and/or presenting a paper
- How to present data in a clear, honest and critical fashion

#### Audit

- Basis for developing evidence-based medicine, kinds of evidence, evaluation; methodologies of clinical trials
- Sources from which useful data for audit can be obtained, the methods of collection, handling data, the audit cycle
- Means of determining best practice, preparing protocols, guidelines, evaluating their performance
- The importance of re-audit

### SKILLS

- Bed-side undergraduate and post graduate teaching
- Developing and delivering lectures
- Carrying out research in an ethical and professional manner
- Performing an audit
- Presentation and writing skills – remaining impartial and objective
- Adequate preparation, timekeeping
- Using technology / materials

### ASSESSMENT & LEARNING METHODS

- An Introduction to Health Research (online)
- Performing audit course (online)
- Effective Teaching and Supervising Skills course (online) - recommended
- Educational Assessment Skills course - recommended
- Health Research Methods for Clinicians - recommended



## Management

**Objective:** To understand the organisation, regulation and structures of the health services, nationally and locally, and to be competent in the use and management of information on health and health services, to develop personal effectiveness and the skills applicable to the management of staff and activities within a healthcare team.

**Medical Council Domains of Good Professional Practice:** Management.

### KNOWLEDGE

#### Health service structure, management and organisation

- The administrative structure of the Irish Health Service, services provided in Ireland and their funding and how to engage with these for best results
- Department of Health, HSE and hospital management structures and systems
- The national regulatory bodies, health agencies and patient representative groups
- Understanding the need for business plans, annual hospital budgets, the relationship between the hospital and PCCC

#### The provision and use of information in order to regulate and improve service provision

- Methods of collecting, analysing and presenting information relevant to the health of a population and the apportionment of healthcare resources
- The common ways in which data is presented, knowing of the sources which can provide information relevant to national or to local services and publications available

#### Maintaining medical knowledge with a view to delivering effective clinical care

- Understanding the contribution that current, accurate knowledge can make to establishing clinical effectiveness, best practice and treatment protocols
- Knowledge of sources providing updates, literature reviews and digests

#### Delegation skills, empowerment and conflict management

- How to assess and develop personal effectiveness, improve negotiating, influencing and leadership skills
- How to manage time efficiently, deal with pressure and stress
- How to motivate others and operate within a multidisciplinary team

### SKILLS

- Chairing, organising and participating in effective meetings
- Managing risks
- Managing time
- Delegating tasks effectively
- Managing conflicts
- Exploring, directing and pursuing a project, negotiating through the relevant departments at an appropriate level
- Ability to achieve results through an understanding of the organisation and its operation
- Ability to seek / locate information in order to define an issue needing attention e.g. to provide data relevant to a proposal for change, establishing a priority, obtaining resources
- Ability to make use of information, use IT, undertake searches and obtain aggregated data, to critically evaluate proposals for change e.g. innovative treatments, new technologies
- Ability to adjust to change, apply management, negotiating skills to manage change
- Appropriately using management techniques and seeking to improve these skills and personal effectiveness

**ASSESSMENT & LEARNING METHODS**

- Mastering Communication course
- Performing audit course (online)
- RCPI HST Leadership in Clinical Practice
- Annual audit
- Consultant feedback on management and leadership skills
- Involvement in hospital committees

## Standards of Care

**Objective:** To be able to consistently and effectively assess and treat patients' problems

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care; Relating to Patients; Communication and Interpersonal Skills; Collaboration and Teamwork: Management (including Self-Management); Clinical Skills.

### KNOWLEDGE

#### Diagnosing Patients

- How to carry out appropriate history taking
- How to appropriately examine a patient
- How to make a differential diagnosis

#### Investigation, indications, risks, cost-effectiveness

- The pathophysiological basis of the investigation
- Understand the clinical significance of reference ranges, positive and negative predictive value and potential risks of inappropriate tests
- The procedures for commonly used investigations, common or/and serious risks
- Understanding of the sensitivity and specificity of results, artefacts, PPV and NPV
- Understanding significance, interpreting and explaining results of investigations
- Logical approach in choosing, sequencing and prioritising investigations

#### Treatment and management of disease

- Natural history of diseases
- Quality of life concepts
- How to accurately assess patient's needs, prescribe, arrange treatment, recognise and deal with reactions / side effects
- How to set realistic therapeutic goals, to utilise rehabilitation services, and use palliative care approach appropriately
- Recognising that illness (especially chronic and/or incapacity) has an impact on relationships and family, having financial as well as social effects e.g. driving

#### Disease prevention and health education

- Screening for disease: methods, advantages and limitations
- Health promotion and support agencies; means of providing sources of information for patients
- Risk factors, preventive measures, and change strategies applicable to smoking, alcohol, drug abuse, and lifestyle
- Disease notification; methods of collection and sources of data

#### Notes, records, correspondence

- Functions of medical records, their value as an accurate up-to-date commentary and source of data
- An understanding of the need and appropriate use of problem-orientated discharge notes, letters, more detailed case reports, concise out-patient reports and focused reviews
- Appreciating the importance of up-to-date, easily available, accurate information, and the need for communicating promptly e.g. with primary care

#### Prioritising, resourcing and decision taking

- How to prioritise demands, respond to patients' needs and sequence urgent tasks
- Establishing (clinical) priorities e.g. for investigations, intervention; how to set realistic goals; understanding the need to allocate sufficient time, knowing when to seek help
- Understanding the need to complete tasks, reach a conclusion, make a decision, and take action within allocated time
- Knowing how and when to conclude

**Handover**

- Know what are the essential requirements to run an effective handover meeting
  - Sufficient and accurate patients information
  - Adequate time
  - Clear roles and leadership
  - Adequate IT
- Know how to prioritise patient safety
  - Identify most clinically unstable patients
  - Use ISBAR (Identify, Situation, Background, Assessment, Recommendations)
  - Proper identification of tasks and follow-ups required
  - Contingency plans in place
- Know how to focus the team on actions
  - Tasks are prioritised
  - Plans for further care are put in place
  - Unstable patients are reviewed

**Relevance of professional bodies**

- Understanding the relevance to practice of standards of care set down by recognised professional bodies – the Medical Council, Medical Colleges and their Faculties, and the additional support available from professional organisations e.g. IMO, Medical Defence Organisations and from the various specialist and learned societies

**SKILLS**

- Taking and analysing a clinical history and performing a reliable and appropriate examination, arriving at a diagnosis and a differential diagnosis
- Liaising, discussing and negotiating effectively with those undertaking the investigation
- Selecting investigations carefully and appropriately, considering (patients') needs, risks, value and cost effectiveness
- Appropriately selecting treatment and management of disease
- Discussing, planning and delivering care appropriate to patient's needs and wishes
- Preventing disease using the appropriate channels and providing appropriate health education and promotion
- Collating evidence, summarising, recognising when objective has been met
- Screening
- Working effectively with others including
  - Effective listening
  - Ability to articulate and deliver instructions
  - Encourage questions and openness
  - Leadership skills
- Ability to prioritise
- Ability to delegate effectively
- Ability to advise on and promote lifestyle change, stopping smoking, control of alcohol intake, exercise and nutrition
- Ability to assess and explain risk, encourage positive behaviours e.g. immunisation and preventive measures
- Involve patients' in solving their health problems, by providing information and education
- Availing of support provided by voluntary agencies and patient support groups, as well as expert services e.g. detoxification / psychiatric services
- Act in accordance with, up to date standards on palliative care needs assessment
- Valuing contributions of health education and disease prevention to health in a community
- Compile accurate and appropriate detailed medical notes and care reports including the results of examinations, investigations, procedures performed, sufficient to provide an accurate, detailed account of the diagnostic and management process and outcome, providing concise, informative progress reports (both written and oral)
- Transfer information in an appropriate and timely manner

- Maintaining legible records in line with the Guide to Professional Conduct and Ethics for Registered Medical Practitioners in Ireland
- Actively engaging with professional/representative/specialist bodies

#### **ASSESSMENT & LEARNING METHODS**

- Consultant feedback
- Workplace based assessment e.g. Mini-CEX, DOPS, CBD
- Educational supervisor's reports on observed performance (in the workplace)
- Annual Audit
- Medical Council Guide to Professional Conduct and Ethics

## Dealing with & Managing Acutely Ill Patients in Appropriate Specialties

**Objectives:** To be able to assess and initiate management of patients presenting as emergencies, and to appropriately communicate the diagnosis and prognosis. Trainees should be able to recognise the critically ill and immediately assess and resuscitate if necessary, formulate a differential diagnosis, treat and/or refer as appropriate, elect relevant investigations and accurately interpret reports.

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care, Clinical Skills.

### KNOWLEDGE

#### Management of acutely ill patients with medical problems

- Presentation of potentially life-threatening problems
- Indications for urgent intervention, the additional information necessary to support action (e.g. results of investigations) and treatment protocols
- When to seek help, refer/transfer to another specialty
- ACLS protocols
- Ethical and legal principles relevant to resuscitation and DNAR in line with National Consent Policy
- How to manage acute medical intake, receive and refer patients appropriately, interact efficiently and effectively with other members of the medical team, accept/undertake responsibility appropriately
- Management of overdose
- How to anticipate / recognise, assess and manage life-threatening emergencies, recognise significantly abnormal physiology e.g. dysrhythmia and provide the means to correct e.g. defibrillation
- How to convey essential information quickly to relevant personnel: maintaining legible up-to-date records documenting results of investigations, making lists of problems dealt with or remaining, identifying areas of uncertainty; ensuring safe handover

#### Managing the deteriorating patient

- How to categorise a patients' severity of illness using Early Warning Scores (EWS) guidelines
- How to perform an early detection of patient deterioration
- How to use a structured communication tool (ISBAR)
- How to promote an early medical review, prompted by specific trigger points
- How to use a definitive escalation plan

#### Discharge planning

- Knowledge of patient pathways
- How to distinguish between illness and disease, disability and dependency
- Understanding the potential impact of illness and impairment on activities of daily living, family relationships, status, independence, awareness of quality of life issues
- Role and skills of other members of the healthcare team, how to devise and deliver a care package
- The support available from other agencies e.g. specialist nurses, social workers, community care
- Principles of shared care with the general practitioner service
- Awareness of the pressures/dynamics within a family, the economic factors delaying discharge but recognise the limit to benefit derived from in-patient care

**SKILLS**

- BLS/ACLS (or APLS for Paediatrics)
- Dealing with common medical emergencies
- Interpreting blood results, ECG/Rhythm strips, chest X-Ray, CT brain
- Giving clear instructions to both medical and hospital staff
- Ordering relevant follow up investigations
- Discharge planning, including complex discharge
- Knowledge of HIPE (Hospital In-Patient Enquiry)
- Multidisciplinary team working
- Communication skills
- Delivering early, regular and on-going consultation with family members (with the patient's permission) and primary care physicians
- Remaining calm, delegating appropriately, ensuring good communication
- Attempting to meet patients'/ relatives' needs and concerns, respecting their views and right to be informed in accordance with Medical Council Guidelines
- Establishing liaison with family and community care, primary care, communicate / report to agencies involved
- Demonstrating awareness of the wide ranging effects of illness and the need to bridge the gap between hospital and home
- Categorising a patients' severity of illness
- Performing an early detection of patient deterioration
- Use of structured communication tools (e.g. ISBAR)

**ASSESSMENT & LEARNING METHODS**

- ACLS course
- Record of on call experience
- Mini-CEX (acute setting)
- Case Based Discussion (CBD)
- Consultant feedback

## Therapeutics and Safe Prescribing

**Objective:** To progressively develop ability to prescribe, review and monitor appropriate therapeutic interventions relevant to clinical practice in specific specialities including non-pharmacological therapies and preventative care.

**Medical Council Domains of Good Professional Practice:** Patient Safety and Quality of Patient Care.

### KNOWLEDGE

- Pharmacology, therapeutics of treatments prescribed, choice of routes of administration, dosing schedules, compliance strategies; the objectives, risks and complications of treatment cost-effectiveness
- Indications, contraindications, side effects, drug interaction, dosage and route of administration of commonly used drugs
- Commonly prescribed medications
- Adverse drug reactions to commonly used drugs, including complementary medicines
- Identifying common prescribing hazards
- Identifying high risk medications
- Drugs requiring therapeutic drug monitoring and interpretation of results
- The effects of age, body size, organ dysfunction and concurrent illness or physiological state e.g. pregnancy on drug distribution and metabolism relevant to own practice
- Recognising the roles of regulatory agencies involved in drug use, monitoring and licensing e.g. IMB, and hospital formulary committees
- Procedure for monitoring, managing and reporting adverse drug reaction
- Effects of medications on patient activities including potential effects on a patient's fitness to drive
- The role of The National Medicines Information Centre (NMIC) in promoting safe and efficient use of medicine
- Differentiating drug allergy from drug side effects
- Know the difference between an early and late drug allergy, and drug side-effects
- Good Clinical Practice guidelines for seeing and managing patients who are on clinical research trials
- Best practice in the pharmacological management of cancer pain
- The management of constipation in adult patients receiving palliative care

### SKILLS

- Writing a prescription in line with guidelines
- Appropriately prescribing for the elderly, children and pregnant and breast feeding women
- Making appropriate dose adjustments following therapeutic drug monitoring, or physiological change (e.g. deteriorating renal function)
- Reviewing and revising patients' long term medications
- Anticipating and avoiding defined drug interactions, including complementary medicines
- Advising patients (and carers) about important interactions and adverse drug effects including effects on driving
- Providing comprehensible explanations to the patient, and carers when relevant, for the use of medicines
- Being open to advice and input from other health professionals on prescribing
- Participating in adverse drug event reporting
- Take and record an accurate drug allergy history and history of previous side effects



**ASSESSMENT & LEARNING METHODS**

- Consultant feedback
- Workplace based assessment e.g. Mini-CEX, DOPS, CBD
- Educational supervisor's reports on observed performance (in the workplace): prioritisation of patient safety in prescribing practice
- Guidance for health and social care providers - Principles of good practice in medication reconciliation (HIQA)

## **Specialty Section**

# **Core Modules for HST in Pharmaceutical Medicine**

*All trainees must complete the core modules*

## Medicines Regulation

**Objective:** To have a working knowledge of medicines regulation both at national and EU level, and to be able to apply this knowledge in drug development or its assessment; to have an understanding of, and ability to, perform one's duties within the legislative framework

### Knowledge

- Principles of medicines regulation at national and international level
- International Conference on Harmonisation (ICH), including Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP)
- Medicines regulation in ICH regions and rest of world
- Clinical Trials regulations in ICH regions
- Common Technical Document
- Licensing in EU – Marketing authorisation applications (MAA), and other major regions including US New Drug Applications (NDA), Japanese NDA: integrating pre- and post-marketing regulatory activities
- Product information – Summary of Product Characteristics (SmPC), Patient Information Leaflets (PIL), Technical leaflets, Package Labelling
- Regulations pertaining to Pharmacovigilance
- Regulatory processes for special areas: rare diseases, children, advanced therapies
- Medical device regulation
- Regulation of herbal medicines and traditional remedies
- Provisions for, and use of, unlicensed medicines
- Non-prescription drugs and reclassification of “Prescription Only” and “Pharmacy only” medicines
- Patents, legal issues, parallel imports
- Ethics and operations of Ethics Committees
- Product restriction: suspension / withdrawal procedures

### Skills

- Demonstrate a broad understanding of prevailing regulations that govern medicines in all the ICH regions and rest of world, and outline the differences amongst them.
- Apply knowledge of current EU and international regulations, GCP and ethics committee requirements and regulatory review procedures in developing and undertaking clinical trials.
- Explain all aspects of the EU regulatory approval procedures and contribute to the writing and/or appraisal of a clinical expert report
- Demonstrate knowledge of the structure and function of the EU commission and European Medicines Agency (EMA), and describe the differences between Regulations, Directives and Guidelines.
- Demonstrate an awareness of the EU CHMP guidelines, knowledge on their development and their impact on the drug development process
- Explain the role of ICH guidelines including the Common Technical Document
- Outline the regulatory requirements for product information: SmPC, PIL, Package labelling, Technical leaflets, Package Labelling.
- Demonstrate a working knowledge of post authorisation procedures, including management of drug safety issues and reporting requirements (e.g. periodic safety update reports, periodic benefit risk evaluation reports),
- Describe the role of risk management: RMP, inverted black triangle / black box
- Outline the activities of the PRAC
- Demonstrate awareness of legal requirements for legal classification and reclassification of medical products, as well as renewal of marketing authorisations as required.
- Describe the processes for supply of unlicensed medicines, e.g. compassionate use etc.
- Outline the procedures involved in removing a medicine from the marketplace due safety concerns or quality defect

## Assessment & Learning Methods

### Courses

- Ethics Foundation
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

### Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

### Assessments

- Develop a guidance document describing the European centralised, decentralised & mutual recognition procedures for Marketing Authorisation and the role of the CTD
- Create a risk management plan for a novel active ingredient product (real or hypothetical).
- Complete an amendment (variation) application to a marketing authorisation for Types IA, IB, II
- **Complete at least one reflective commentary of the module**

## Clinical Pharmacology

### Objective:

- To be able to exercise judgement on the clinical pharmacology of a medicine in all phases of its research and development (both non-clinical and clinical) in order to facilitate the stepwise process towards marketing authorisation approval
- To be able to implement all aspects of the conduct of early-phase drug trials, including regulatory and ethical aspects
- To be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs

### Knowledge

- Receptor based approaches: Agonist/Antagonist
- Enzyme Inhibitors
- Genomics, Proteomics and metabolomics
- Gene Therapy
- Translational Medicine
- Pre-clinical development to support human safety testing – acute, subacute toxicology, genotoxicology, reproductive toxicology, topical irritation and hypersensitivity, safety pharmacology, immunotoxicology
- Differences between animals and humans in ADME of medicines
- Differences in pre-clinical safety evaluation of small (chemical) molecules and biological agents
- Exploratory clinical development assessment of preclinical data
- Planning of studies in exploratory development
- Objectives of early phase drug studies in man: rationale, advantages and disadvantages of the use of healthy or patient volunteers; knowledge of when there is a requirement to include special populations (e.g. elderly, female) in such studies
- Pharmacokinetics; pharmacokinetic / pharmacodynamic models
- Clinical pharmacokinetics; application to dosage regimen and study design
- Dose-response: selecting dose range and increments relating to minimum effective and maximum tolerated doses
- Biological variations seen in normal populations
- Pharmacogenetics
- Population pharmacokinetics
- Adverse drug reactions
- Benefit / risk evaluation
- Special populations e.g. children, elderly, pregnant and breast feeding women, patients with renal or hepatic dysfunction
- Ethics: principles, peer review, informed consent, Declaration of Helsinki
- Clinical studies: objectives, design, conduct and analysis, choice of site
- Relevant regulations for clinical trials in Europe and ROW
- Interpretation of study design, analysis and results
- Literature review and critical appraisal
- Major drug classes
- Management of common acute and chronic diseases
- Identification of Unmet Clinical Needs
- Identification of New Targets
- In depth knowledge of at least one major organ / system-based disease area including benefits and shortcomings of current therapy
- Ongoing developments in pharmacogenomics

**Skills**

- Identify the evidence needed to determine an investigational product's potential to proceed to clinical development, including interpretation of the pharmacological concepts of preclinical toxicology tests, the role of preclinical data to generate clinical testing rationale, and the toxicological data required to support the initiation and progression of the clinical development plan
- Review and interpret the animal toxicology of an investigational product before first in man trial is initiated
- Define and review the clinical pharmacology of an investigational product before clinical trials in patients are initiated
- Contribute to or review the design of clinical pharmacology studies in order to fulfil their aims
- Anticipate possible disease-related variations in drug handling in patients compared with healthy volunteers
- Propose or review any dosing changes or limits for phase 2 and phase 3 studies
- Implement the regulatory requirements and Good Clinical Practice provisions in the design, conduct and analysis of clinical pharmacology studies.
- Interpret the basic ethical principles involved in clinical research in healthy and diseased individuals and demonstrate experience with the activities of ethics committees (either as a member or as an applicant who has completed the necessary documentation)
- Describe how clinical pharmacology studies fit into the overall clinical development plan Describe previous issues in the relevant clinical area that have caused regulatory problems previously
- Write or review informed consent documentation, Expert Reports, Clinical Overviews and Production Information in accordance with regulatory requirements
- Work with relevant experts to identify areas of unmet clinical need and possible new treatment options

**Assessment & Learning Methods****Courses**

- Ethics Foundation
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

**Assessment Tools**

- Project-based Discussion (PbD)  
Pharmaceutical Medicine Assessment Tool (PMAT)

**Assessments**

- Prepare a written report on the impact of differences of drug handling in two patient subgroups on drug development (e.g. children versus the elderly; normal versus reduced renal or hepatic function)
- Critically appraise an early phase drug trial
- Report on clinical pharmacology aspects unique to a specific therapeutic area
- Complete at least one reflective commentary of the module

## Statistics and Data Management

### Objectives:

- Understand the overview of key efficacy & safety questions for a Clinical Development Plan and related data requirements
- Develop an understanding of statistical concepts, and their usage in clinical research to analyse clinical data.
- Contribute to clinical input, enabling effective collaborative work with professional statistical and data management staff; thereby ensuring optimal study design, effective management, analysis and reporting of clinical trial data to meet scientific and regulatory standards.

### Knowledge

#### Statistical principles in clinical trial design

- The purpose and fundamentals of statistics. Statistical considerations of study design: hypothesis testing, choice of endpoints, type I and type II errors, P-values, summary statistics, confidence intervals, modelling in data analysis, sensitivity and specificity testing, avoidance of missing data
- The use of control, blinding, randomisation and other methods for the reduction of bias in clinical trials
- The principles of power and sample size, the reduction of variation and other methods for increasing precision in clinical studies
- Design rationale for: dose-ranging studies; equivalence and non-inferiority trials – choice of margin; adaptive designs – advantages, concerns, avoidance of bias
- Choice of endpoints, types and rationale for selection, data transformation
- Methods for the interim analysis of clinical trial data and the management of analyses for the evaluation of efficacy, harm and futility, working through an Independent Data Monitoring Committee

#### Data Management principles

- The key areas where data management contributes to the clinical trial process, and its role in ensuring efficient and robust data collection for analysis: measurement of data, monitoring of clinical trial, source documentation verification, query generation and resolution. Common issues with CRF completion
- Types of data and standardisation of measurements
- The impact of Case Report Form (CRF) design on the conduct of the clinical trial: e-CRF vs manual, creation and management of patient directly reported data (eg. Diaries)
- Understanding the principles of Electronic Data Capture (EDC) process: standardisation, maintenance and security of databases.
- Principles of data processing: coding, identification of protocol deviations/violations, data cleaning process, and physician review of the data validation plan & the clinical data

#### Statistical Analysis Plan

- Clinical rationale for the inclusion/exclusion of patients in statistical analysis plan
- The overall structure of a Statistical Analysis Plan

#### Methodology of Statistical Analyses

- Basic statistical testing methodologies: odds ratios, hazard ratios, Kaplan-Meier curves
- Evaluation of populations: testing for sub-groups and homogeneity, interaction testing
- Missing data management: imputation, LOCF

#### Interpretation of Clinical Study data

- The concepts of sensitivity and specificity in diagnosis
- The statistical principles of benefit / risk assessments
- The major pharmaco-epidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases

- Patient reported outcome measures: appropriate choice and validation of measures for evaluating subjective and objective Quality of Life measures
- The key statistical aspects of a clinical study that should be included in a publication or report
- Working knowledge of Meta-analyses and observational data presentations

### **Ethics in clinical research pertaining to Data management and statistical analyses**

- Ethical aspects in research questions and study designs, from First in Human to post-marketing and epidemiological studies, including scientific rationale, statistical robustness, appropriateness of patient populations, comparators and choice of endpoints. Ensuring clinical equipoise in comparator clinical studies and consideration of conflicts of interest
- Ethical aspects of trial samples for genomic and related analyses: scientific rationale, ethics and consequences of anonymisation; biobank management

### **Skills**

- To explain the statistical principles in the design of clinical studies, and recognise the importance of working with a statistician in the design of clinical studies.
- To select the most appropriate design structure: superiority; equivalence; non-inferiority; dose-response - in order to meet the needs of the drug development programme
- To provide clinical input into sample size calculations, the selection of primary and secondary endpoints, choice of comparator and methods of interim analysis
- To provide a clinical input into, and review of, a Statistical Analysis Plan, and recognises own role in the review of a Statistical Analysis Plan.
- To justify the reasons for the inclusion of patients in different samples for analysis
- To explain the commonly used statistical principles & methods, for the design, conduct, analysis, reporting and the presentation of data in clinical studies of clinical development, post-marketing and health economic studies, and recognises the importance of the use of appropriate statistical methodology for the correct interpretation of clinical studies.
- To interpret the results of a statistical analysis of data based on methods including: survival analysis; analysis of covariance; logistic regression; meta-analysis
- To interpret the results of a statistical analysis based on commonly used statistical procedures presented in a publication or report
- To understand the principles of Case Report Form design and clinical data management, including Electronic Data Capture and MedDRA, and to provide input to the review of clinical data.
- To list the key areas where data management contributes to the clinical trial process
- Contribution to reviews of CRF design, & to identify examples of good CRF design practice and examples of poor CRF design
- To identify common problem areas in CRF completion
- To describe the data cleaning process
- To ensure ethics of clinical research is understood throughout the research team; maintain and encourage best practice.

### **Assessment & Learning Methods**

#### **Courses**

- Introduction to Health Research (Year 1)
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

#### **Assessment Tools**

- Project-based Discussion (PbD)  
Pharmaceutical Medicine Assessment Tool (PMAT)

#### **Assessments**



- Perform a critique of the statistical aspects of an agreed specific protocol (annually for years 1-3)
- Complete a data review of a clinical study, to ensure a clinically correct database for analyses, including assessments of protocol deviations, violations & withdrawals, [or successfully complete a recognised statistics and data management course or workshop].
- Complete at least one reflective commentary of the module

## New Medicine Development

### Objectives:

- Develop a thorough working knowledge of all aspects of drug development. To acquire the competency to prepare a constructive overview of the disease area and demonstrate the relevance of developing a product in this area.
- To prepare or critique a clinical development plan to explore the safety and efficacy of a new pharmaceutical agent that will lead to its safe adoption into clinical practice after approval by national and international regulatory agencies.
- To oversee a programme of clinical trials that will demonstrate ethically and adequately the safety and efficacy of a new pharmaceutical agent in compliance with national and international laws, regulations and guidelines.

### Knowledge

- The philosophy behind Research & Development (R&D) and organisation of an R&D programme
- Discovery of new medicines; HIT to Lead, Lead Optimisation, Candidate Selection, Backups
- Planning and Organisation: Organisation and operation of project teams
- Drug Development Plan, Target Product Profile
- Objective and target setting
- Integrated project planning
- Budgeting and costs control
- Quality Management Planning
- Regulatory requirements for licensing of new medicines ICH –Good Clinical Practice
- Ethical requirements: principles, peer review, informed consent, Declaration of Helsinki
- Regulatory review
- Indemnity
- Ethics in clinical research (including IFAPP Ethics framework, Declaration of Helsinki, CIOMS)
- Confidentiality and Data Protection (GDPR, Declaration of Taipei)
- Basic toxicology and safety pharmacology required before first in man studies (in healthy volunteers); In vitro, in vivo, in silico
- Designs and dose escalation plans for first in man studies
- Screening of Healthy Volunteers, Restrictions in phase I studies, Informed consent in Phase I studies
- Clinical Trials Planning of Clinical Trial programme – use of preclinical and Phase I data
- Phase I/II interface: Proof of Concept; Go/No-Go decision points
- Phase II/III interface: FDA End of Phase II meetings
- 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
- Fraud and professional misconduct
- Adverse Events and Serious Adverse Events (SAEs) – 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
- 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
- Non clinical study of biological medicines, vaccines, gene therapy, cell therapy, tissue engineering

**Skills/Competencies**

- To prepare a thorough literature review of a specified disease area including the epidemiology and pathophysiology of the disease area, critique of therapies available and their mechanisms of action, a summary of products under development in this area and unmet medical / therapeutic needs in the area
- To suggest the basic design of a First in man trial with proposed initial dose and provisional dose escalation plan
- Interpret the requirements of preclinical and phase I data and their impact on later phase developments. To write a reasoned critique on whether there are appropriate safety data to proceed into clinical efficacy trials for a new drug (real or hypothetical). To evaluate the clinical pharmacology data for a new drug (real or hypothetical). To review, evaluate and discuss the safety and toxicology data for a new drug candidate (real or hypothetical) planned for a clinical trial programme, from the first-time-in-man (FTIM) studies onwards. To recommend, with reasons on the basis of non-clinical and Phase I data, a range of doses to be studied in Phase II
- Identify the study design that is most effective in answering the scientific principles in question, allowing for ethical evaluation of new therapeutic strategies. The trainee should be able to implement the principles of informed consent, in the construction of consent forms and patient information leaflets
- To contribute to the design and preparation of a study protocol for a new drug (real or hypothetical). To review constructively a number of outline protocols considering: how they achieve the aims of the Clinical Development Plan and how they comply with ethical requirements
- Collate information collected from clinical trials, and be able to summarise, discuss, and critique the entire research programme, to allow for a meaningful assessment of risk/benefit
- Demonstrate ability: To interpret and explain the results of clinical studies. To write clear, coherent and comprehensive reports of clinical research undertaken. To summarise the results of a programme of clinical research. To assess the design and conduct of studies for a product (real or hypothetical)
- To constructively review the results of clinical research publications to determine the clinical significance of the data
- To assess the risks and benefits of a potential new medicine
- To explain the principles of meta-analysis
- To write or contribute to a Clinical Development Plan for a new drug (real or hypothetical).
- Demonstrate ability: To predict and address the ethical issues arising from clinical studies & to draft or review constructively an informed consent form that includes all the ICH-required elements, written in appropriate, patient-friendly language( write or review)
- To evaluate adverse events for severity and causality
- To categorise and 'report' some hypothetical examples of adverse events based on patient case histories. To be vigilant for identifying adverse events that are not necessarily drug-related but have been associated historically with adverse reactions for other drugs, and are therefore worthy of heightened pharmacovigilance e.g. hepatotoxicity, Stevens Johnson Syndrome

**Assessment & Learning Methods****Courses**

- Ethics Foundation
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

**Assessment Tools**

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

**Assessments**

- Critically review a clinical development plan for a new medicine (using published or internal data)
- Complete a Protocol Development workshop (Recognised interactive training programme on protocol development)
- Ability to list required sections of an informed consent form and to have written a complete pre-consent patient information document
- Describe procedures for obtaining informed consent in line with legal requirements
- Critical appraisal of an original clinical research publication
- Critically appraise a European Public Assessment report (for a new active substance)
- Write at least one reflective commentary of the module

## Drug Safety and Pharmacovigilance

**Objectives:** To acquire and demonstrate knowledge of and competency in the surveillance of the safety of medicines during all stages of development and clinical use, with particular emphasis on the choice, application and analysis of appropriate surveillance methods, on the principles of international regulatory reporting requirements, on the timely revisions of product information and practical methods for managing risk to patients and clinical trial subjects

### Knowledge

#### Regulatory requirements

- The pharmacovigilance legal and regulatory procedures at national level, EU level and rest of world
- Marketing authorisation (MAH) requirements and processes for safety reporting to regulatory authorities at national and International level
- The role of investigators, clinicians, study monitors, sponsors and manufacturers in the pre- and post-marketing phases to detect, assess and report suspected adverse events; regulatory reporting requirements in the pre- and post-marketing phases; medical literature reports.
- The requirements for informing prescribers, investigators, ethics committees and regulatory agencies of important safety concerns.
- ICH / CHMP guidelines and The CIOMS Working Groups and Reports on safety surveillance.
- Types of data and standardisation of measurements

#### Medical assessments of the individual patient (case report) and aggregate report

- The regulations relating to the collection and reporting of suspected Adverse Drug Reactions (ADR) in the jurisdiction where the Pharmaceutical Physician works.
- The content of aggregate reports required by local regulatory authorities e.g. PSURs.
- The contents of safety sections of Patient Information Leaflets (PIL) and package information.
- Processes to collect analyse and report product quality complaints (PQCs) and any associated adverse events.
- Patient related outcome events

#### Spontaneous reporting and signal detection methodologies

- The characteristics that make an ADR reportable according to international guidelines.
- Reportable events: medication error, off label, overdose and misuse and abuse, experience during pregnancy
- Main sources of pharmacoepidemiological safety information
- The major pharmacoepidemiological methods for approaching drug safety issues and the characteristics of the most commonly used databases.
- Signal detection, interpretation and management
- The major methods of post-marketing surveillance: post-marketing spontaneous reporting
- The application of the requirements for post-authorization safety studies (PASS) in the EU.
- The mechanisms of drug interactions.
- The principles of causality assessment and causality algorithms to classify events as to their likely causal attribution to a particular medicine; common causal mechanisms for ADRs.

#### Methods of evaluation of risk and benefit of clinical trial subjects

- The principles and methods for risk/benefit evaluation and related decisions during pre-marketing development.
- The principles and process for development of safety specifications documents.
- The CIOMS VI report in respect of safety in clinical trials,
- Measurement of data, monitoring of clinical trial, source documentation: Principles of Coding, common issues with CRF completion,

- The impact of the Case Report Form (CRF) design on the conduct of the clinical trial: e-CRF, creation, maintenance, and security of databases.
- Common issues with CRF completion at site level, and the importance of training.
- Understanding the principles of role of data management in Electronic Data Capture (EDC) process.

**Regulatory actions to address concerns about patient safety**

- The key regulatory actions including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension and withdrawal.

**Risk Communication**

- The requirements regarding presentation of safety aspects of a medicine in the Summary of Product Characteristics (SmPC) and Patient Information leaflet (PIL)
- Assessment of urgent safety issues, including product recall and the generation of appropriate communications to regulatory bodies, healthcare professionals and patients.
- The availability of urgent communication tools to relevant stakeholders in a timely fashion: the opportunities and pitfalls of their use.

**Crisis management**

- The organisation and conduct of a crisis management team.
  - Identifying the key individuals to be included in a crisis management team.
  - Identifying the main steps involved in assessing and reacting to a potential crisis situation.

**Skills**

- Communicate and discuss knowledge of the regulations with colleagues.
- Support the QPPV in the undertaking of pharmacovigilance activities and implement all safety measures as appropriate.
- Implement the pharmacovigilance legislation as laid down in the Good Vigilance Practice documents.
- Perform regular medical reviews of safety case reports in the literature and from clinical studies.
- Evaluate all new relevant information about the benefit-risk including other suspected ADRs and transfer the relevant information to the report formats for submission to relevant regulatory agencies according to required reporting timelines
- Demonstrate adherence to appropriate guidelines when carrying out post-marketing surveillance studies
- Evaluate all serious adverse events (SAEs) from clinical trials and determine their causal relationship to the study drug and expectedness
- Evaluate existing PSURs. Write the overall safety evaluation section of a PSUR (real or simulated)
  
- Write and/or constructively review the safety section of a PIL and package information
- Evaluate the impact on patient safety and the relationship with patients, healthcare professionals and regulators of inadequately assessed and managed Product Quality Complaints (PQCs)
- Classify new safety data using the standard definitions of adverse event, serious adverse event unexpected/unlabelled adverse event, suspected adverse drug reaction and clinically significant abnormal laboratory test value; and discuss the differences between them.
- 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
- To formulate appropriate follow-up questions to reporting healthcare professionals and consumers as well as specifying the data that are important in the assessment of adverse event/reaction reports
- Assess potential signals by using appropriate methods to assess adverse event frequencies in an external adverse event database e.g. FDA AERS/WHO Uppsala
- To constructively review the relevant documents e.g. protocol, PIL, safety specifications, risk management plan for appropriate risk and benefit statements
- Identify risks to patients, potential risks and missing information and propose appropriate risk mitigation activities in order to develop effective risk management plans by identifying risks to patients, potential risks and missing information and proposing appropriate risk mitigation activities
- Identify sources of information on medication errors and the regulatory reporting requirements of identified cases
- Ensure the SmPCs of company products cover all safety issues appropriately particularly in relation to clarity and completeness.
- Evaluate and discuss urgent safety issues including patient communications.
- Establish a crisis management team for a real or hypothetical issue
- Describe the appropriate response to various simulated drug safety issues

**Assessment & Learning Methods****Assessment Tools**

- Project-based Discussion (PbD)  
Pharmaceutical Medicine Assessment Tool (PMAT)

**Assessments**

- Describe the requirements and processes for reporting of safety information to the HPRA (in Ireland) and to the EMA
- Assess the serious adverse events (SAEs) from a Phase III clinical trial and determine their causal relationship to the study drug and their expectedness
- Evaluate a PSUR (Risk / Benefit Analysis)
- Review case reports (5 per training year on a specific product) commenting on seriousness, relatedness, reportability
- Perform a critique of the safety section of an SmPC and a PIL
- Write at least one reflective commentary of the module



## Healthcare Marketplace

**Objective:** To be able to keep the welfare of patients and clinical trial participants at the forefront of decision-making in the promotion of medicines and design of clinical trials; To acquire knowledge of the healthcare environment in which pharmaceutical marketing takes place; To be able to apply this knowledge & Good Medical Practice to the role of the Pharmaceutical Physician and to ensure that marketing activities in the healthcare environment are and remain appropriate, ethical and legal.

### Knowledge

- Relevant laws and regulations to the commercial healthcare environment.
- Familiarity with relevant legislation (European and national) for advertising and industry self-regulation.
- EU Advertising Directive (2001/83/EC).
- The Code of Practice for the Pharmaceutical Industry (IPHA Code of Practice).
- EFPIA European Code of Practice for the promotion of prescription only medicines to, and interactions with Healthcare Professionals.
- WHO ethical criteria for medicinal promotion; the role of the HPRA and other regulatory bodies.
- Medical Council Guide to Professional Conduct and Ethics.
- Awareness of product life-cycle management including impact of clinical studies.
- The key stakeholders and the main healthcare organisations (public & private) within the relevant healthcare environment e.g. HSE, Department of Health and Children, NCPE, HPRA.
- The contribution and decision-making processes within the healthcare environment e.g. HIQA, IQWiG / Transparency Code.
- The contribution and decision-making processes, in relation to prescribing, within the healthcare environment: NCPE, Medicines Management Programme, PCRS, value assessment of pharmaceuticals, Drugs and therapeutic committees, Treatment Guidelines, Reference Works: BNF, Martindale, MIMs.

### Understand the key elements in development of compliant medical-marketing communications

- Process involved in the preparation and production of legally compliant documentation to support medical-marketing activities.
- Targeting materials to appropriate audiences, e.g. journals, congresses and ensuring consistency with the commercial message.
- Product information: legislation and guidance (SI 541 and IPHA Code of Practice)
- The breadth of medical-marketing materials and activities, how to determine if they are promotional and how they should be assessed.
- Implementation of regulations surrounding the advertising and promotion of medicines

### Describe the information required and how to analyse and apply it in order to undertake a commercial analysis of potential for a pharmaceutical product within the industry business environment.

- Knowledge of the elements involved in the commercial assessment of a medicinal product.
- Profiling and positioning, clinical data, pricing, products and services, Intellectual Property, Health economics, costs of promotion, reimbursement, formulary listing, cost of goods, Break even and Net Present Value, co-marketing, co-promotion, co-development, patent expiry, generic medicines.
- The components required for the evaluation of an in-licensing /collaboration option.
- Identifying candidates, portfolio fit and management, due diligence, product safety and efficacy, Intellectual Property, exclusivity, patent etc. Commercial assessment.

### Understand the competitive commercial environment when evaluating the opportunity for a new product during development, or a currently marketed product

- The key components of a competitive commercial product analysis for a marketed product, pipeline product, therapy area, competitor product.
- Assessing products in development and probability of success.

**Understand 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**

- Knowledge of the identity of the industry's key stakeholders in the external environment and how the industry's activities impact on them, including the general public.
- Knowledge of the ethical issues which arise and approaches considered in reaching a judgement in:
  - The investigation and fraud and misconduct e.g. In clinical research
  - Unlicensed use of medicines e.g. compassionate use
  - Phase IV studies
  - Post marketing Surveillance studies
  - Open-label clinical trial extensions
  - Investigator initiated research
  - Charging for named-patient supplies
  - Giving a balanced clinical/scientific view
  - Policy on medical information to patients
  - Developing a data-on-file statement
  - Corporate communication and reputation

**Understand the Principles underlying the Economics of Healthcare and the basic principles underlying pharmaco-economic evaluation and evidence-based medicine.**

- Principles of healthcare economics; principles of justice and equity in healthcare economics, principles of pharmaco-economics, evidence-based medicine and outcomes research.
- Quality of Life, concept and measurement instruments.
- Measurement of healthcare efficiency, governmental policy and third-party reimbursement.
- Health Technology Assessment including meta-analysis and systematic review; health economics evaluation studies
- IFAPP [international ethics framework 2018](http://ifapp.org/ethics-practice/): <http://ifapp.org/ethics-practice/>

### Skills

- Analysing of the roles, importance, relative contribution and interactions of different components in supporting the legal and regulatory framework within which pharmaceutical medicine operates
- Evaluation of the major interactions between key stakeholders in the healthcare marketplace.
- Interpreting the interactions between the different groups and processes and how they can affect prescribing practices.
- Preparation of medical marketing materials e.g. briefing documents, presentations and publications, therapeutic training to medical representatives or other staff
- Evaluation of medical marketing material for scientific accuracy, legal and regulatory compliance, and comprehension of the reader
- Analysing selected materials and activities e.g. Media communications, professional and public relations, pre-launch activities with regard to scientific, educational and promotional content
- Ensuring a balanced perspective (safety and efficacy) is evident in medicine promotion and communication
- Ability to create alternative texts for advertising and promotion
- Leading colleagues to a legally compliant and ethical position on "grey area" promotional decisions
- Evaluation of the commercial potential for a pharmaceutical product, real or hypothetical.
- Evaluation of the commercial potential for an in-licensing opportunity for a pharmaceutical product real or hypothetical
- Performing a competitive product analysis for a product, real or hypothetical, at two different

stages of its development.

- Evaluating the promotional platform of a competitor product
- Construction of objection-handling statements.
- Contributing to a HTA and/or to the development of a guideline.
- Appraising health economic models produced for the assessment of a product for NCPE.
- Performing an industry key stakeholder analysis.
- Analyse the key relationships and interactions between the key stakeholders.
- Discuss how ethical judgements are made and relevant decisions guidelines applied in different healthcare marketplace scenarios

### **Assessment & Learning Method**

#### **Assessment Tools**

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

#### **Assessments**

- Design a promotional campaign for a new medicine focusing on the medical and legal aspects
- Perform a competitive product analysis for a product
- Perform a critical analysis of a complaint regarding promotional material or activities
- Write at least one reflective commentary on the module

## **SPECIALTY MODULES**

*All trainees are required to complete all core modules and one specialty module*

## Medicines Regulation II

**Objective:** To have a working knowledge of medicines regulation both at EU and outside the EU, and to be able to apply this knowledge in drug development; to be aware of product defects, counterfeit products, and other miscellaneous pharmaceutical procedures & requirements. To have a good knowledge of Pharmacovigilance requirements in the EU and in the US specifically relating to risk management (Risk Management Plans) and to Periodic Safety Update Reports

### Knowledge

- Differences between the EU and US Regulations
  - US FDA procedures
  - Appeal and arbitration procedures
  - US Investigational New Drug (IND) procedures
  - Risk management and PSURs
- European requirements for medicines development in the context of the ICH guidelines and their implementation
- The registration of pharmaceutical products in International markets
- Dealing with product defects.
- The investigation of product defects.
- Dealing with counterfeit medicines.
- The impact of product defects and counterfeit medicines on public health and safety.
- The maintenance of a manufacturer's/wholesaler's licence and the role and remit of inspection.
- The application for and maintenance of import and parallel import licences.
- Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).
- The regulation of other non-medicinal products e.g. certain foods, herbals, cosmetics, homeopathic preparations, medical devices.

### Skills

- Demonstrate a broad understanding and knowledge of prevailing regulations that govern medicines in the US, and awareness of differences between EU and US
- Demonstrate a knowledge of requirements for drug development in the US.
- Have a working knowledge and awareness of the procedures around product defects.
- Have a working knowledge and awareness of the procedures around counterfeit medicines.
- Demonstrate awareness of the requirements for import and parallel import licences.
- Demonstrate an awareness of the requirements for regulation of herbals, cosmetics, certain foods, homeopathic preparations, and medical devices.
- Have a working knowledge of the requirements to distinguish between medicines and medical devices.
- To have a good working knowledge of differences in EU and US risk management (Risk Management Plans) and Periodic Safety Update Reports

### Assessment & Learning Methods

#### Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

#### Assessments

- Complete an application for a generic drug
- Complete a workshop on regulatory submission and regulation
- Complete an application for a parallel import authorisation
- Write at least one reflective commentary on the module

## Clinical Pharmacology II

**Objective:** To be able to implement all aspects of the conduct of early-phase drug trials, including regulatory and ethical aspects

### Knowledge

Demonstrate knowledge of:

- Pharmacokinetic analyses and modelling
- Relevant statistical methods and analyses for clinical pharmacology studies

### Skills

- Ability to plan and undertake / contribute to proposed investigations of a new theoretical agent by applying key pharmacology principles

### Assessment & Learning Methods

#### Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

#### Assessments

- Develop an investigational plan of a new theoretical agent by applying key pharmacology principles
- Develop a clinical pharmacology plan of a new theoretical agent in a specific therapeutic area
- Complete at least one reflective commentary of the module

## New Medicine Development II

### Objectives:

- To appraise constructively and report on the evidence of safety and efficacy of a new pharmaceutical agent and assess its benefits, risks and place in the practice of clinical medicine.
- To acquire deeper understanding of statistical analysis and data management methodologies and techniques; and implement them in secondary research.

### Knowledge

- The role of meta-analysis in the analysis and presentation of results from a series of clinical studies.
- Case-control and cohort studies.
- Statistical methods, such as the analysis of covariance and the choice of statistical test, for maximising precision when analysing data.
- The methods of statistical analysis for investigating the homogeneity of the treatment effect.
- The methods of statistical analysis for the detection of fraud and misconduct.
- Describe the expectations of incidence when differentiating the pharmacologically identified event from the unexplained event.
- Definition of appropriate parameters for database searches.
- The typical contents of a Data Validation Plan.
- Understanding the principles of -
  - Internationally recognised databases such as CDISC
  - MedDRA structure and uses; how coding is performed, and its use in product labelling

### Skills

- Undertake research as part of on-going new drug development programme into a specific therapeutic area, define current practice, identify unmet medical needs, new therapies in development, and potential new therapeutic strategies, in order to integrate these into a meaningful discussion within the construction of a clinical R&D plan.
- To recommend, with reasons, appropriate imaging, laboratory methods and surrogate markers for a study protocol (real or hypothetical).
- Define the logistics of the entire clinical trial process, including set up, implementation, and appropriate controls on safety data acquisition.
- To contribute to the development of a project management plan for the clinical development of a new product (real or hypothetical), including key milestones.
- To describe how to arrange appropriate legal and ethical clearance for clinical trial supplies, Case Report Forms (CRFs) and other relevant materials.
- To explain the commonly used statistical principles & methods, for the design, conduct, analysis, reporting and the presentation of data in post-marketing and health economic studies.
- To interpret and critique the results of a statistical analysis of data based on methods including survival analysis & meta-analysis.
- To compile critical data to be included in the integrated report of efficacy & safety for a Clinical Development Plan for regulatory submissions.
- To identify justify the criteria for the inclusion of trials in a meta-analysis to answer specific questions and present the results of such an analysis.
- To develop secondary research parameters out of primary dataset/s.
- To develop methodologies for enhancing data collection efficiency and accuracy.

**Assessment & Learning Methods****Assessment Tools**

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

**Assessments**

- To have worked at least 50% FTE for at least 1 year in an R&D team
- Develop a clinical plan for a new clinical product
- Design and apply a statistical plan for 2 real studies: an early exploratory study and a late phase pivotal registration study within programme duration
- Critically analyse a dataset in early exploratory development to inform probability of technical success; 2 case studies within programme duration
- Critically analyse 2 datasets utilising 2 different statistical analysis methodologies within programme duration
- Complete at least one reflective commentary of the module



## Drug Safety and Pharmacovigilance II

**Objective:** To acquire a deeper understanding of drug safety and pharmacovigilance, historical context, international components and implication of required when safety issues arise.

### Knowledge

- The major past 'landmark' safety issues with major individual products e.g. thalidomide, COX-2 inhibitors, and drug classes e.g. oral contraceptives, inhaled anti-asthma products, their investigations and outcomes.
- The evolution of drug surveillance methods, and pharmacovigilance regulations worldwide, their harmonisation, and inter- and intra-company reporting systems for assembling and reporting suspected adverse reactions.
- The organisation and conduct of a crisis management team.
- The requirements regarding safety aspects of the Summary of Product Characteristics (SmPC) and PIL.
- Assessment of urgent safety issues, including product recall and the generation of appropriate communications to regulatory bodies, healthcare professionals and patients.
- The availability of urgent communication tools, the opportunities and pitfalls of their use.
- The key regulatory actions including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension and withdrawal.
- The European procedures for reassessment of risk: benefit (Articles 31 & 36 of Directive 201/83/EEC).
- The risk for a medical error occurring with a specific product and for including the identified risk in the risk management documentation, risk mitigation plans and labelling.
- The structure, roles and responsibilities of data safety monitoring committees.
- Methods of evaluation of risk and benefit of clinical trial subjects: principles and methods for risk/benefit evaluation and related decisions during pre-marketing development.
- The principles and process for development of safety specifications documents.
- The CIOMS working group report in respect of safety in clinical practice.
- Measurement of data, monitoring of clinical trial, source documentation: Principles of Coding, common issues with CRF completion,
- The impact of the Case Report Form (CRF) design on the conduct of the clinical trial: e-CRF, creation, maintenance, and security of databases.
- Common issues with CRF completion at site level, and the importance of training.
- Understanding the principles of role of data management in Electronic Data Capture (EDC) process.
- The principles of risk and benefit assessment based on CIOMS Working Group IV report.
- The principles and methods of post-marketing risk management plans (based on ICH E2E).
- The options and mechanisms for optimising safety in relation to benefit.

### Skills

- To identify sources of information on medication errors and the regulatory reporting requirements of identified cases.
- To establish a crisis management for a real or hypothetical issue.
- To describe the appropriate response to various simulated drug safety issues.
- To write the overall safety evaluation section of a PSUR (real or simulated).
- To write and constructively review the safety section of a PIL and package information.
- To 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.
- To formulate appropriate follow-up questions to reporting healthcare professionals and consumers as well as specifying the data that are important in the assessment of adverse event/reaction reports.
- To evaluate constructively some published research data.

- To assess medically the post-marketing suspected ADR reports and determine seriousness, causal relationship to suspect drug and expectedness.
- To assess potential signals by using appropriate methods to assess adverse event frequencies in an external adverse event database e.g. FDA AERS/WHO Uppsala.
- To review the SmPC of company products to ensure all safety issues are covered appropriately particularly in relation to clarity and completeness.
- To evaluate and discuss urgent safety issues including patient communications and be able to write a Dear Healthcare professional letter for a real or hypothetical issue.

**Assessment & Learning Methods****Assessment Tools**

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

**Assessments**

- Design a PASS study (real or fictional)
- Critical analysis of a published article to analyse potential safety signal
- Critical analyse 3 EPAR reports and comment on post- authorisation safety requirements
- Write at least one reflective commentary on the module

## Healthcare Marketplace II

**Objectives:** To understand and demonstrate the requisite skills of a pharmaceutical physician in the complex milieu of a Pharmaceutical Company. To be familiar with all the elements associated with reimbursement including the elements required in Health Technology assessment, to understand the requirements of a quality management system in a company and to fully understand the complex relationship with other stakeholders.

### Knowledge

- The role of the PCRS, the Corporate Pharmaceutical Unit.
- Distribution channels for medicines including parallel trade.
- Understanding the principles underlying marketing research and profiling in the context of regulations with regard to competition in the healthcare market, segmentation of customers and markets, customer targeting and methods of promotion.
- Understanding the underlying principles of activities of public and professional relations companies.
- Understand the structure and processes of the pharmaceutical industry internal environment.
- Structure and functions of Pharmaceutical companies.
- Essential documents/ SOPs required of a Company/ Medical organisation.
- Nature of organisational relations of Medical department with other parts of the organisation
- Portfolio management and return on investment.
- The clinical, regulatory and commercial aspects of a product reclassification.
- Prescription only to pharmacy, pharmacy to general sale.
- Knowledge of the roles and relationships between the relevant trade and professional organisations, including IPHA, IMO, RCPI, RCSI, other specialty training bodies.
- Product assessment by NCPE including QALY, HR-QALY, HTA, Guidelines, other forms of health economic evaluation (cost effectiveness, cost minimisation, cost utility, cost benefit analyses).

### Skills

- Evaluation of the requirements for product reimbursement including clinical evidence, outcomes research, health economic evaluation and HTA.
- Understanding how to create a questionnaire for market research to provide data to facilitate informed decision making.
- Comprehensive understanding of the requirements for the components and operation of a company quality management system.
- Familiarity with the makeup, role and relationships of key professional and trade bodies.

### Assessment & Learning Methods

#### Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

#### Assessments

- Perform a health economic evaluation
- Conduct a critical assessment of a Health Technology Assessment
- Create a local SOP covering a GXP function
- Write at least one reflective commentary on the module

## Documentation of Minimum Requirements for Training

- These are the minimum number of cases you are asked to document as part of your training. It is recommended you seek opportunities to attain a higher level of exposure as part of your self-directed learning and development of expertise.
- You should expect the demands of your post to exceed the minimum required number of cases documented for training.
- If you are having difficulty meeting a particular requirement, please contact your specialty coordinator

Curriculum Requirement	Required/ Desirable	Minimum Requirement	Reporting Period	Form Name
<b>Section 1 - Training Plan</b>				
<b>Personal Goals Plan</b> (Copy of agreed Training Plan for your current training year signed by both Trainee & Trainer)	Required	1	Twice per year	Personal Goal
<b>Section 2 - Training Activities</b>				
<b>Management Experience</b>	Required	1	Training Programme	Management Experience
<b>Core Modules</b>				Clinical Activities
<b>Medicines Regulation Core</b>				
Development of a guidance document describing the European centralised, decentralised & mutual recognition procedures for Marketing Authorisation and the role of the CTD	Required	1	Training Programme	
Completion of an amendment to marketing authorisation	Required	1	Training Programme	
Creation of a risk management plan (Real or hypothetical)	Required	1	Training Programme	
Medicines Regulation Reflective Commentary (Core)	Required	1	Training Programme	
<b>Clinical Pharmacology Core</b>				
The impact of differences in drug handling in 2 patient sub-groups (e.g. children versus the elderly) on drug development	Required	1	Training Programme	
Critically appraise an early phase drug trial	Required	1	Training Programme	
Clinical pharmacology aspects unique to a specific therapeutic area	Required	1	Training Programme	
	Required	1	Training Year	
Clinical Pharmacology Reflective Commentary (Core)	Required	1	Training Programme	
<b>Statistics and Data Management Core</b>				
Critique of the statistical aspects of an agreed specific protocol (annually for years 1-3) (stats and data mgmt.)	Required	3	Training Programme	

Curriculum Requirement	Required/ Desirable	Minimum Requirement	Reporting Period	Form Name
Complete data review of a clinical study	Required	1	Training Programme	
Statistics and Data Management Reflective Commentary (Core)	Required	1	Training Programme	
<b>New Medicines Development Core</b>				
Critically review a clinical development plan for a new medicine (using published or internal data) - one per training programme	Required	1	Training Programme	
Critically appraise a European Public Assessment report (for a new active substance) – one per training programme	Required	1	Training Programme	
Write a complete pre-consent patient information leaflet for a new clinical entity	Required	1	Training Programme	
New Medicines Development Reflective Commentary (Core)	Required	1	Training Programme	
Critical appraisal of an original clinical research publication	Required	1	Year of Training	
<b>Drug Safety and Pharmacovigilance Core</b>				
Evaluate a real or fictional PSUR	Required	1	Training Programme	
Assess medically the serious adverse events (SAE dataset) from a clinical trial and determine the causal relationship to the study <b>expectedness and reportability</b>	Required	5	Year of Training	
Perform a critique of the safety section of an SmPC and a PIL	Required	1	Training Programme	
Drug Safety and Pharmacovigilance Reflective Commentary (Core)	Required	1	Training Programme	
<b>Healthcare Marketplace Core</b>				
Design a promotional campaign for a new medicine focusing on the medical and legal aspects	Required	1	Training Programme	
Perform a competitive product analysis for a product	Required	1	Training Programme	
Perform a critical analysis of a complaint regarding promotional material or activities	Required	1	Training Programme	
Healthcare Marketplace Reflective Commentary (Core)	Required	1	Training Programme	
<b>Specialty Module (one from the list below)</b>	<b>Required</b>	<b>1</b>	Training Programme	
<b>Medicine regulations specialty</b>				Clinical Activities
• Complete an application for a generic drug	Required	1	Training Programme	
• Complete an application for a parallel import authorisation	Required	1	Training Programme	

Curriculum Requirement	Required/ Desirable	Minimum Requirement	Reporting Period	Form Name
<ul style="list-style-type: none"> <li>Medicine Regulations Reflective Commentary (Specialty)</li> </ul>	Required	1	Training Programme	
<b>Clinical pharmacology specialty</b>				Clinical Activities
<ul style="list-style-type: none"> <li>Develop an investigational plan of a new theoretical agent by applying key pharmacology principles</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Develop a clinical pharmacology plan of a new theoretical agent in a specific therapeutic area</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Clinical Pharmacology Reflective Commentary (Specialty)</li> </ul>	Required	1	Training Programme	
<b>New medicine development specialty</b>				Clinical Activities
<ul style="list-style-type: none"> <li>Design and apply a statistical plan for real studies (one of each): <ul style="list-style-type: none"> <li>an early exploratory study</li> <li>a late phase pivotal registration study</li> </ul> </li> </ul>	Required	2	Training Programme	
<ul style="list-style-type: none"> <li>Critically analyse a dataset in early exploratory development to inform probability of technical success</li> </ul>	Required	2	Training Programme	
<ul style="list-style-type: none"> <li>Critically analyse datasets utilising different statistical analysis methodologies</li> </ul>	Required	2	Training Programme	
<ul style="list-style-type: none"> <li>Develop a clinical plan for a new clinical product</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Work at least 50% FTE for 1 year in an R&amp;D team</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>New Medicines Development Reflective Commentary (Specialty)</li> </ul>	Required	1	Training Programme	
<b>Drug safety and pharmacovigilance specialty</b>			Training Programme	Clinical Activities
<ul style="list-style-type: none"> <li>Design a PASS study (real or fictional)</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Critical analysis of a published article to analyse potential safety signal</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Critical analyse EPAR reports and comment on post- authorisation safety requirements</li> </ul>	Required	3	Training Programme	
<ul style="list-style-type: none"> <li>Drug Safety and Pharmacovigilance Reflective Commentary (Specialty)</li> </ul>	Required	1	Training Programme	
<b>Healthcare marketplace specialty</b>				Clinical Activities
<ul style="list-style-type: none"> <li>Perform a health economic evaluation</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Conduct a critical assessment of a Health Technology Assessment</li> </ul>	Required	1	Training Programme	
<ul style="list-style-type: none"> <li>Create a local SOP covering a GXP function</li> </ul>	Required	1	Training Programme	

Curriculum Requirement	Required/ Desirable	Minimum Requirement	Reporting Period	Form Name
• Healthcare Marketplace Reflective Commentary (Specialty)	Required	1		
<b>Section 3 - Educational Activities</b>				
<b>Mandatory Courses</b>				Course Attendance
Ethics Foundation	Required	1	Training Programme	
Ethics for General Medicine	Required	1	Training Programme	
An Introduction to Health Research Methods (By end of Year 2)	Required	1	Training Programme	
HST Leadership in Clinical Practice (3rd year upwards)	Required	1	Training Programme	
Mastering Communication (By end of Year 2)	Required	1	Training Programme	
Performing Audit (By end of Year 2)	Required	1	Training Programme	
Pharmaceutical Medicine course (by end of year 3) Postgraduate diploma or M.Sc. (This is funded by trainees' employer, or self-funded)	Required	1	Training Programme	
Wellness Matters	Required	1	Training Programme	
<b>Non – Mandatory Courses</b>	Desirable	1	Training Programme	Course Attendance
<b>Study days (such as GCP, protocol development and regulatory submission and regulation)</b>	Required	2	Training Programme	Study Day Attendance
<b>Delivery of Teaching</b>				Delivery of Teaching
Lecture	Required	4	Year of Training	
Tutorial	Required	4	Training Programme	
<b>Research</b>	Desirable	1	Training Programme	Research Activities
<b>Audit activities and Reporting</b> (one per year either to start or complete, Quality Improvement (QI) projects can be uploaded against audit)	Required	1	Year of Training	Audit & QI
<b>Publications</b>	Desirable	1	Year of Training	Additional Professional Experience
<b>Presentations</b>	Desirable	1	Year of Training	Additional Professional Experience
<b>National/International meetings (attendance)</b>	Desirable	1	Year of Training	Additional Professional Experience
<b>Additional Qualifications</b>	Desirable	1	Training Programme	Additional Professional Experience



Curriculum Requirement	Required/ Desirable	Minimum Requirement	Reporting Period	Form Name
Committee Attendance	Desirable	1	Training Programme	Additional Professional Experience
<b>Section 4 - Assessments</b>				
PMAT	Required	4	Year of Training	Pharmaceutical Medicine Assessments
PbD	Required	4	Year of Training	Pharmaceutical Medicine Assessments
Quarterly Assessments/End-of-Post Assessments	Required	4	Year of Training	Quarterly Assessments/End-of-Post Assessments
End of Year Evaluation	Required	1	Year of Training	End of Year Evaluation