Pharmaceutical Medicine Modules at Kings' College London

What will I learn in each of the taught modules?

Preclinical Science

- You will gain an understanding of the choice and predictive value of the non-clinical (animal) testing and experimental programme as part of the overall drug development plan for potential new medicines.
- You will appreciate the importance of non-clinical safety testing (toxicology) in regulation and development of new medicines.
- You will learn about the important pharmaceutical formulation considerations that are needed to develop a final medicinal product from a chemical or biological substance.

Advanced Clinical Pharmacology

- You will learn how to interpret both pharmacodynamic and pharmacokinetic data.
- You will appreciate the value, and ethical issues, of using non-patient volunteers in clinical studies.
- Be able to discuss how data from a clinical pharmacology study can inform the future development and therapeutic use of a medicine.

Clinical Drug Development

- You will learn how to apply the principles of clinical development strategies to a wide variety of scenarios including Biological Therapies, New Chemical Entities and other products entering the commercial phase of drug development.
- You will learn how to create the product development plans, operational plans, statistical plans, publication plans and registration plans and associated documents to facilitate successful clinical development.
- You will appreciate the preclinical, manufacturing and other supporting developments to enable and determine clinical development strategies.

Statistics and Data Management

- You will learn how to use statistical techniques to produce a robust design for a clinical trial, including decisions on type 1 and type 2 errors and a power calculation.
- You will gain an understanding of the pros and cons of various study designs.
- You will review a data set and participate in the designing of an analysis plan.

Biologics and Advanced Therapies

- You will gain an understanding of the breadth of advanced therapies that are available and in development, including gene therapy, stem cell therapy, CAR T cells and other cell therapies.
- You will appreciate the new technologies that are now available (eg recombinant DNA) and those in development.
- You will learn about the range of monoclonal antibodies available and those in development and discuss the potential long term safety issues.
- You will understand the global need for new and improved vaccines and the barriers to their development.

Theory and Practice of Pharmacokinetics (PK)

- You will gain a full understanding of factors affecting the absorption, bioavailability, distribution, metabolism, clearance and excretion of drugs and be able to carry out the procedures and calculations required to determine the key PK parameters.
- You will learn about the individual, specific, pharmacokinetic studies that are required to characterise the PK of a new medicine.
- You will learn how to interpret PK data obtained from a single dose escalation study, including dose proportionality, linearity and non-linearity and understand how single dose data can be used to model the PK of repeated dosing and the importance of fluctuation at steady state and the effects of changes in clearance and dose.

Practical Clinical Pharmacology (this module is based around a one week placement in a Clinical Pharmacology Unit)

- You will observe and critically appraise staff, facilities and practical aspects of the conduct of clinical pharmacology studies in healthy and patient volunteers.
- You will understand the procedures and issues relating to ethics review of a clinical pharmacology study protocol, obtaining informed consent and reporting adverse events.
- You will critically appraise the procedures for routine safety monitoring of study subjects including vital signs, electrocardiograms and parameters measured in blood and urine samples.

Exploratory Development

- You will appreciate the toxicological and pharmacological data to aid dose selection in Phase 1 clinical trials.
- You will learn how to design a First-in-Human clinical study.
- You will understand the key safety, ethical and regulatory issues involved in a Phase I trial and how these can be assessed
- You will be able to interpret pharmacokinetic, pharmacodynamic and safety data generated during a Phase I trial

Drug Development Pharmacology

- You will evaluate the major stages in the drug development process where pharmacology can add value and apply this knowledge to gain an in-depth appreciation of pharmaceutical development.
- You will learn the key pharmacology terms and basic principles of pharmacology to address complex problems in specific therapeutic areas.
- You will critically appraise the role of *in vitro* methods in the development of new therapeutic agents.

Drug Safety and Ethics

- You will learn how to create multi-national clinical development programmes that protect study participants despite the many differences in the standards of ethics practised worldwide.
- You will gain and an appreciation of the value of non-clinical safety data and understand how to analyse and report adverse event data from clinical trials.
- Learn how to create a risk management plan, and a consent process that protects the clinical trial participants.

Drug Regulatory Affairs

- You will understand the guidelines and legislations applicable to specific regulatory tasks associated with the medicine lifecycle e.g. the EU authorisation procedures.
- You will recognise the responsibilities of sponsors and regulators arising from the regulations and to be able to enact in-house solutions to meet these responsibilities
- You will learn how to apply a fundamental knowledge of the regulation of medicines to create and/or review key documents e.g. the clinical trial application, the marketing authorisation application, the patient information leaflet; plans for quality assurance activities and plans for widening and restricting access to medicines through licence changes.

Healthcare Marketplace

- You will understand the commercial healthcare environment, the regulations that govern the healthcare market, and implement solutions in response to that market e.g. perform marketing activities that are both commercially justified and legally compliant and that also comply with the ethical separation of the influences of R&D on one hand and Sales and Marketing on the other.
- You will learn how to analyse healthcare marketplace healthcare data in order to analyse the commercial viability of a pharmaceutical product e.g. evaluate the sales and marketing potential for in-licensing a medicine.
- You will gain knowledge of how the pharmaceutical industry is structured and functions, stakeholders and commercial drivers that influence decisions take an active role within a multidisciplinary team to help evaluate and implement appropriate marketing strategies for a licensed medicine.

Health Technology Assessment & Pharmacoeconomics

- You will learn how to develop pharmacoeconomic and health technology assessments that are able to inform pharmaceutical and medical technology pricing and reimbursement strategies in major global financial markets.
- You will be able to evaluate the data required to construct economic arguments.
- You will gain knowledge of how to create the needed dossiers and publications to support pricing and reimbursement strategies and applications .

Principles of Medical Affairs

- You will gain a working knowledge of commercialisation and marketing of medicines.
- You will understand the regulation of marketed medicines, including – product advertising, funding bodies, and drug supply.
- You will understand the roles and responsibilities within the pharmaceutical industry Medical Affairs function.
- You will appreciate the importance of stakeholder communication and 'patient focus' for marketed medicines and be able to critically discuss how data from a Phase 4 clinical trial can inform the continuing value and use of a marketed medicine.

Practical Medical Affairs (this module is based around a one week placement in a pharmaceutical company Medical Affairs department)

- You will observe the practical, real world, knowledge of, role and responsibilities of the Medical Affairs and Pharmacovigilance Departments within the pharmaceutical industry, and of the UK regulator (MHRA), for licensed medicines.
- You will understand the processes and procedures for reporting of adverse events of marketed medicines.
- You will gain practical experience in preparing a report and delivering an oral presentation.

Ethics and Professionalism

- You will gain a broad knowledge of ethics and professionalism as it impacts upon healthcare and the pharmaceutical industry, including clinical trials and the role of Ethics Committees.
- You will understand the role and responsibilities of healthcare professional bodies, such as GMC, ABPI, RCN, GPhC and their codes of practice.
- You will appreciate the importance of sustainability and Corporate Social Responsibility (including indices such as the GRI and FTSE4Good) for the pharmaceutical industry.
- You will learn about the potential for fraud and misconduct, and how this can be prevented and detected to appreciate the opportunity and the regulation of drug supply for Compassionate Use.

Pharmacoepidemiology & Global Affairs

- You will gain a working knowledge of the global bodies (egs WHO, WMA) that impact upon healthcare provision, especially the sale and marketing of medicines.
- You will understand the methodology used to provide pharmacoepidemiologic evidence.
- You will understand the challenges with being able to deliver the highest standards of healthcare throughout the world and effective advocacy strategies for influencing government policy.
- You will learn of the range of national and international standards and regulations that cover the collection and reporting of safety data (Good Pharmacovigilance Practice).