SYLLABUS
MODULE ONE

Legal basis of EU pharmaceutical regulation

- Identify European Regulatory Institutions
- European legislation - where are we now?
- Analyse the development and scope of Regulations, Directives, and guidelines
- Identify sources of useful information to allow you to prepare a successful submission
- Assess the influence of ICH

Working effectively with the EMA

- Identify the structure and function of the EMA
- Understand EMA operating procedures
- Clarify the role of the EMA committees and working parties
- Analyse communication with the pharmaceutical industry
- Review communication with the public, including EPARs

SYLLABUS
MODULE TWO

Understand and select the most appropriate European registration procedure for your Marketing Authorisations Applications (MAAs)

- The Centralised Procedure (CP)
- The DeCentralised Procedure (DCP)
- The Mutual Recognition Procedure (MRP)
- The National Procedure

The Centralised Procedure

- Criteria for selecting the CP
- Principal aspects of this procedure
- Timing of the various procedural stages
- Advantages and disadvantages of the CP
- Examining experience to date

The Decentralised Procedure and Mutual Recognition Procedure

- What are the principle aspects of these procedures
- Timing of the various procedural stages
- Advantages and disadvantages of these procedures
- Examining experience to date

Making the DCP or MRP work for you

Participants will be able to:

- Select the best products for submission through the DCP or MRP
- Analyse decision criteria for selecting the DCP or MRP procedure
- Identify realistic time-frames and monitor the progress of their application
- Apply best-practice dossier preparation to help gain speedy regulatory approval

Understand Clinical Trials applications in the EU

- Review the implementation of the Clinical Trials Directive
- Data requirements for clinical trials
- Role of ethics committees and their influence on the approval of the trial
- Clinical trials supplies
- Future changes in clinical trial application procedures in the EU

Summary session

Time has been reserved in the day to allow participants to summarise the main points learned in the morning session. The following points will be covered:

- Discuss common formats and develop an understanding of the CTD structure
- Data requirements for different types of application

SYLLABUS
MODULE THREE

Compile a drug registration dossier: An overview of what information is needed and how to present it

A review and analysis of each part of the registration dossier. Participants
will take part in interactive exercises and discussions during the day that will give
them the tools and techniques to understand how to successfully compile the drug
registration dossier.

Format and content of the dossier: CTD

- Identify administrative data required to be presented in Module 1
- Understand the key importance of the Summary of Product Characteristics (SmPCs)
- Proposals for packaging, labelling and package inserts
- Requirements for Overviews and Summaries

Chemical, pharmaceutical and biological documentation

- The function of the Quality Overall Summary (QOS)
- Data requirements
- Using an ASMF or COS
- Understand the need for GMP inspections

Non-clinical or toxico-pharmacologial documentation

- Function of the Non-clinical Overview and Summaries
- Identify relevant guidelines
- Review of the data requirements and literature data for constructing CTD

Clinical documentation

- Function of the Clinical Overview and Summaries
- Understanding the terms used in clinical trials
- Identify the relevant guidelines
- Review of the data requirements

Summary session

- Discuss common formats and develop an understanding of the CTD structure
- Data requirements for different types of application

SYLLABUS
MODULE FOUR

Mastering specific regulatory areas: Post-approval obligations, lifecycle management, variations, and renewals

The specific regulatory areas you need to master in order to successfully perform in both your short and long-term regulatory affairs strategy.

Understanding abridged applications

- Understand the legal basis for abridged applications
- Identify various types of application and the corresponding data requirements
- Determine essential similarity
- Consider data exclusivity
- Look at SmPCs: Identifying guidelines and pinpointing obstacles to achieving a harmonised SmPC

Clarify the post-approval obligations of the marketing authorisation
holder and the competent authority

Successfully filing variations

- Understand the variations legislation
- Identify the types of variations
- Criteria that define each type of variation
- Pinpoint what documentation/data is required for each type of variation
- Identify the procedural steps and time-lines for filing the variations
- Variations vs Extensions (New Marketing Authorisations)

Determine obligations for renewals

- Understand renewal legislation
- Analyse data requirements for renewal
- Understand the 'Sunset Clause' and implications for not marketing a product

Pharmacovigilance obligations

- Continuous pharmacovigilance requirements
- Periodic Safety Reports
- Risk management plans

Examine the importance of intra-company interactions for regulatory affairs

- Making good use of project team for increased efficiency in the regulatory team
- Co-ordinating information collection processes
- The importance of manufacturing/analytical interface

SYLLABUS
MODULE FIVE

Proposing a registration strategy for a product

Participants will develop a strategy for effective product registration and learn best practice dossier preparation to gain speedy regulatory approval. Participants will have the opportunity to summarise and apply what they learned throughout the course and raise any outstanding questions.