SYLLABUS
DAY ONE

Reviewing the organisation of the US Food and Drug Administration (FDA) and how this may impact future regulation

- The FDA today
- The impact of the FDA's reorganisation: CBER products moving to CDER
- Considering FDA liaisons: Roles & responsibilities, interactions

Participants

Course Leader: Figen KABADAS OGE, Msc & MBA - Head of Regulatory Affairs, Delpharm

Examining drug development regulations in the US and implications for the industry

- Drug development process - Drug Approval—Bringing a New Drug to the Market
- Preclinical testing requirements
- Clinical testing requirements
- Identifying phases of clinical development as they relate to regulatory restrictions
- Engagement with the FDA during drug development

Evaluation of review options and obtaining information from the FDA

- Understanding the FDA review process and designations:
  - Fast track
  - Breakthrough status
  - Accelerated review
  - Priority review
- Consider eligibility requirements
- Obtaining information from the FDA
  - Access the Federal Register
  - The Freedom of Information Act (FOIA)
  - Optimising the use of the FDA home page
  - Exploring useful URL's
  - How to understand FDA's, SOP's and use them to your advantage

Analysing the Investigational New Drug Application (IND) and defining the regulatory requirements

- Introduction to INDs
- What are the types of IND's?
- Pre-IND Consultation, Guidance Documents, Law and Legislation
- Organisation of the IND
- Requirements for submitting an IND (CMC, Preclinical and clinical requirements)
- Understand the FDA review process for INDs
- Identifying and understanding FDA actions on INDs

Maintaining active INDs successfully

- Clarifying the obligations of the Sponsor
- Explaining the procedures for reporting Adverse Events (AEs)
- Defining other IND amendments
- Preparing Annual Reports

Identifying recent changes and other IND/NDA topics

- Examining accelerated development options
- Reviewing Pediatric use requirements: Pediatric rule & exclusivity
- Understanding financial disclosure requirements
- Requirements for listing clinical trials with the clinical trials database
- Understanding patent extensions and marketing exclusivities

SYLLABUS
DAY TWO

Identifying the various categories of NDAs

- Defining full NDAs
- Explaining abbreviated NDAs and 505 (b) (2)
- Understanding 'paper' NDAs and the impact of the Hatch-Waxman Act
- Understanding NDA's in the CTD Format
- FDA's approach to the CTD
- Defining differences in Agency review approaches
- The US Regional requirements

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How does the FDA review an NDA?

- Clarifying the procedure from the receipt to the filing of the NDA
- Assessing when there will be a refusal to file
- Reviewing the timelines
- Clarifying FDA - Sponsor meeting requirements
- Sponsor - reviewer interactions
- Preparing for pre-approval inspections
- Examining refusal to file

Generic Submissions

- Examine the legislative history
- Key regulations for ANDAs
- Patent and exclusivity
- Refuse-to-Receive Standards

Generic Drug User Fee Amendments (GDUFAs)

- GDUFA update
- Quality of ANDA submissions
- Opportunities for improvement and challenges

Maintaining NDAs successfully and post-approval activities

- When and how to do NDA amendments
- Scale-up and post approval changes (SUPAC, BACPAC, PACPAC)
- Clarifying what Annual Reportable changes (AR), Changes Being Effected (CBE) and Prior Approval Supplements means in practice: Looking at CMC and labelling
- NDA annual reports