Regulatory Affairs: The IND, NDA, and Post-Marketing

DIA Learning

Virtual Training Agenda

Introduction to Regulation of Drugs and Biologics in the United States: Pre-Course Part One

Introduction to Regulation of Drugs and Biologics in the United States: Pre-Course Part Two

***Pre-course work can be done through the DIA Learning Center.**

Regulatory Affairs: Part 1: The IND – Investigational New Drug Application

9:00 – 9:30 AM Welcome and Introduction

9:30 – 9:45 AM Drug Development: Pre-Course Work Review*

- Introduction to Drug Development
- Regulation Highlights
- Key Definitions
- Drug Development Highlights
- Regulatory Strategy

9:45 – 10:00 AM Session 1: The IND – A General Introduction

- What is an IND
- When is an IND Required/Not Required
- Types of INDs

10:00 – 10:45 AM Session 2: The IND in Detail – Modules 1, 2, and 5

- IND Item 1: Form FDA 1571
- IND Item 2: Table of Contents
- IND Item 3: Introductory Statement
- IND Item 4: General Investigational Plan
- IND Item 5: Investigator's Brochure
- IND Item 6: Protocols

10:45 – 11:00 AM Break

11:00 – 11:45 AM Session 3: IND in Detail – Modules 3 and 1

- IND Item 7: Chemistry, Manufacturing, and Controls

11:45 AM – 12:45 PM Session 4: The IND in Detail – Modules 4, 5 and 2

- IND Item 8: Nonclinical Pharmacology and Toxicology
- IND Item 9: Previous Human Experience
- IND Item 10: Additional Information

12:45 – 1:30 PM Break

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Regulatory Affairs: Part 2: IND Amendments

1:30 – 2:30 PM — Session 5: INDs for Biologics and Submission / FDA Review

- Additional Requirements for Biologics and Biotechnology-Derived Products
- Submission of an Initial IND
- FDA's Review of an IND
- Clinical Holds: Basis for Imposition and Process for Removal

2:30 – 2:45 PM — Break

2:45 – 4:00 PM — Session 6: IND Amendments and Maintenance

- Amendments to the IND
  - IND Protocol Amendments
  - Information Amendments
  - Further studies with the same molecular entity - same or new IND
- Annual Reports/DSUR
- Noncommercial INDs
  - Exploratory INDs, Sponsor-Investigator INDs, Expanded Access
- IND Administrative Actions and Sponsor Activities

4:00 – 5:15 PM — Session 7: IND Amendments Workshop

- In this workshop, learners will break into teams to determine the type and content of IND amendments needed to support changes to a protocol and associated development activities in their hypothetical company

5:15 – 5:30 PM — Questions and Answers

Regulatory Affairs: Part 3: Special Topics

9:00 – 9:15 AM — Welcome and Review of Day 1

9:15 – 10:45 AM — Session 8: Special Topics for Clinical Research

- Adequate and Well-Controlled Trials
- Diversity Plans in Clinical Trials
- Adaptive Study Designs
- Real World Data (RWD) and Real World Evidence (RWE)
- Patient Focused Drug Development
- Patient Reported Outcomes
- Surrogate Endpoints
- Qualification of Drug Development Tool
- Foreign Clinical Trials
- Changes to the Investigational Drug
- Financial Disclosure by Clinical Investigators
- Special Protocol Assessment

10:45 – 11:00 AM Break

11:00 AM – 12:30 PM Session 9: Special Regulatory Considerations for Development

- Expedited Programs for Serious Conditions
- Background and Subpart E
- Concepts for Expedited Programs
  - Serious Conditions/Available Therapy/Unmet Medical Need
- Expedited Programs
  - Fast Track
  - Breakthrough Therapy (BTD)
  - Regenerative Medicine Advanced Therapy (RMAT)
  - Qualified Infectious Disease Product (QIDP)
  - Accelerated Approval
  - Priority Review
- Other Programs
  - The Animal Rule
  - Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)
  - Orphan Products
  - Priority Review Vouchers
  - Emergency Use Authorization (EUA)
- Overview of Special Development Programs

12:30 – 1:15 PM Break

Regulatory Affairs: Part 4: Adverse Events and Quality Assurance

1:15 – 2:15 PM Session 10: Reporting Adverse Events (AEs) During Clinical Trials

- Definitions of Terms
- IND Safety Reports
- IND Annual Reports - Safety Information
- Discontinuation of Studies for Safety Reasons

2:15 – 2:20 PM Break

2:20 – 4:05 PM Session 11: Adverse Event (AE) Reporting Workshop

- In this workshop, learners will break into teams to discuss IND Safety Reporting based on safety information received from clinical trials and other sources in their hypothetical company

4:05 – 4:15 PM Break

4:15 – 4:45 PM Session 12: Quality Assurance in Drug Development (GxPs)

- Good Clinical Practices
  - Sponsor Responsibilities
  - Investigator Responsibilities
  - Institutional Review Boards
  - Informed Consent
- Good Laboratory Practices
- Good Manufacturing Practices

4:45 – 5:00 PM Question & Answer

Regulatory Affairs: Part 5: The NDA – New Drug Application

9:00 – 9:15 AM Welcome and Review of Day 2

9:15 – 10:30 AM Session 13: The NDA: Planning, Content, Types of NDAs/BLAs, and Exclusivity

- Getting from the IND to the NDA
- NDA Data Sources and Specific Populations
- Types of NDAs
- BLAs: Biologics and Biosimilars
- Combination Products and OTC Drugs
- Patent Term Restoration and Exclusivity

10:30 – 10:45 AM Break

10:45 AM– 12:00 PM Session 14: The NDA in CTD Format: Modules 1-5

- The Common Technical Document (CTD) Format – Overview
- Module 1
- Module 3
- Module 4
- Module 5
- Module 2
- Safety Update Reports (CTD Module 5)

12:00 – 12:45 PM Break

Regulatory Affairs: Part 6: Interactions with FDA

12:45 – 1:45 PM Session 15: NDA Submission, FDA Review and Action on Applications

- Electronic Submissions
- FDA Review of Applications and Actions on Applications
- Amendments to an Unapproved Application
- Reasons Applications are not Approved
- Prescription Drug User Fee Act (PDUFA)

1:45 – 2:15 PM — Session 16: The FDA and Risk Management
- The Foundation of Risk Management
- Pre-Marketing Risk Assessment
- Post-Marketing Risk Assessment
- Risk Evaluation and Mitigation Strategies (REMS)

2:15 – 2:35 PM — Break

2:35 – 3:50 PM — Session 17: Interactions with FDA – Part 1
- Communications with FDA
- Formal Meetings with FDA
- Time Course of Events in Requesting and Preparing for a Meeting
- Objectives and Conduct of Specific Meetings

3:50 – 3:55 PM — Stretch Break

3:55 – 5:15 PM — Session 18: Interactions with FDA – Part 2
- Principles for Communicating with FDA
- Meeting Etiquette
- Resolving Issues or Disputes with FDA
- Summary on Interacting with FDA
- Advisory Committee Meetings
- Advisory Committee Meeting Video

5:15 – 5:30 PM — Questions and Answers / Preparation for Mock FDA Meeting

Regulatory Affairs: Part 7: Mock FDA Meeting

9:00 – 9:15 AM — Welcome and Review of Day 3

9:15 AM – 12:15 PM — Session 19: Mock FDA Meeting
(There will be a 15-minute break during this session)
Learners will break into FDA or company teams and conduct a pre-NDA meeting.

12:15 – 1:00 PM — Break

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Regulatory Affairs: Part 8: Post-NDA

1:00 – 2:30 PM — Session 20: Regulatory Compliance and FDA Inspections: What to Expect After Submitting the NDA

- GLP Inspections
- GCP Inspections
- Inspection Outcomes: Additional Considerations in GCP Inspections
- GMP Inspections
- Inspection Outcomes (GLPs, GCPs, GMPs)
- FDA Enforcement Actions
- Application Integrity Policy (AIP)
- FDA Inspection Video

2:30 – 2:45 PM — Break

2:45 – 4:00 PM — Session 21: Post-NDA Approval Regulatory Requirements

- Post-NDA Approval Obligations
- Post-Marketing Requirements and Commitments
- Supplements and Other Changes to an Approved Application
- Post-Marketing Safety Reporting
- Drug Supply Chain Security Act
- NDA Annual Reports
- Other Post-Marketing Reports

4:00 – 4:15 PM — Questions and Answers

Regulatory Affairs: Part 9: Labeling, Promotion and Regulatory Intelligence

9:00 – 9:15 AM — Welcome and Review of Day 4

9:15 – 10:30 AM — Session 22: Requirements for Prescription Drug Labeling

- Definitions
- Labeling Requirements of Immediate Containers and Cartons
- Content and Format of Prescribing Information (PI)
    - Physician's Labeling Rule
- Patient Labeling
- Structured Product Labeling (SPL)

10:30 – 10:45 AM — Break

10:45 – 11:30 AM — Session 23: Requirements for Prescription Drug Advertising and Promotional Labeling

- Definitions
- Statutory Basis for Promotional Regulations
- Required Elements for Advertisements and Promotional Labeling
    - Product information
    - Brief Summary
    - Fair Balance / Not False or Misleading

- Consistency with the Labeling; Dissemination of Information to Payors
- Reminder Advertisements
- Direct-to-Consumer (DTC) Advertising
- Social Media
- Submission of Promotional Materials
- Disease Awareness/Help-Seeking Ads
- Pre-Approval Promotion and Dissemination of Off-Label Information
- FDA Enforcement Actions
- Summary of Principles for Promotion

11:30 AM – 12:45 PM **Session 24: Post-Approval Workshop**

- In this workshop, learners will break into teams to review planned changes to a hypothetical approved product and determine the type and content of FDA submissions needed to implement these changes.

12:45 – 1:30 PM **Break**

1:30 – 2:15 PM **Session 25: Review of Resources for Regulatory Intelligence**

- FDA and the Freedom of Information Act (FOIA)
  - Applicability of FOIA
  - What information is available?
  - What information is not available?
  - Submitting an FOI request
- FDA website and other useful websites

2:15 – 3:15 PM **Session 26: Regulatory Intelligence Workshop**

- In this workshop, learners will break into teams and use publicly available resources to address potential development, lifecycle management and general regulatory questions in their hypothetical company.

3:15 – 3:30 PM **Course Wrap-Up**