

Regulatory Affairs: The IND, NDA, and Post-marketing Agenda

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

*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* <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Form FDA 1571• Introductory Statement• General Investigational Plan• Investigator's Brochure• Protocols
10:45 – 11:00 AM	Break
11:00 – 11:45 AM	Session 3: IND in Detail – Modules 3 and 1 <ul style="list-style-type: none">• Chemistry, Manufacturing, and Controls
11:45 AM – 12:45 PM	Session 4: The IND in Detail – Modules 4, 5 and 2 <ul style="list-style-type: none">• Nonclinical Pharmacology and Toxicology• Previous Human Experience• Additional Information
12:45 – 1:30 PM	Break

Regulatory Affairs: Part 2: IND Amendments

1:30 – 2:30 PM

Session 5: Submission and FDA Review of the IND

- Submission of an Initial IND
- FDA's Review of an IND
- Clinical Holds: Basis for Imposition and Process for Removal

2:30 – 4:00 PM

Session 6: IND Amendments and Maintenance *(There will be a 15-minute break during this session)*

- 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 and Adverse Event Reporting in Clinical Research

9:00 – 9:15 AM

Welcome and Review of Day 1

9:15 – 10:55 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

10:55 – 11:10 AM Break

11:10 AM – 12:05 PM Session 9: Reporting Adverse Events (AEs) During Clinical Trials

- Definitions of Terms
- IND Safety Reports
- IND Annual Reports - Safety Information
- Discontinuation of Studies for Safety Reasons
- Introduction to Adverse Event Reporting Workshop

12:05 – 12:50 PM Break

Regulatory Affairs: Part 4: Special Regulatory Programs and Quality Assurance in Drug Development

12:50 – 2:35 PM Session 10: 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.

2:35 – 2:45 PM Break

2:45 – 4:20 PM Session 11: 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

4:20 – 4:30 PM Stretch Break

4:30 – 5:00 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

5:00 – 5:15 PM **Questions & Answers**

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 Intellectual Property Protection**

- 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: 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)
- Electronic submissions

12:00 – 12:45 PM **Break**

Regulatory Affairs: Part 6: Interactions with FDA

- 12:45 – 1:45 PM **Session 15: FDA Review and Action on Applications**
- 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 – 2:30 PM **Break**
- 2:30 – 3:45 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
- 3:45 – 3:50 PM **Stretch Break**
- 3:50 – 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

Regulatory Affairs: Part 8: Post-NDA Submission and Approval

- 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 – 10:15 AM **Session 22: 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.

10:15 – 11:30 AM

Session 23: 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)

11:30 – 11:45 AM

Break

11:45 AM – 12:30 PM

Session 24: 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

12:30 – 1:15 PM

Break

1:15 – 2:00 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

2:00 – 3:15 PM

Session 26: Labeling, Promotion and Regulatory Intelligence Workshop

- In this workshop, learners will break into teams and define requirements for labeling updates and promotion for their hypothetical approved product. They will also 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