Regulatory Submissions - IND, NDA, BLA, MAA Documentation Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In today?ÇÖs highly regulated pharmaceutical and biotechnology industries, regulatory submissions are critical to the success of any drug development process. Our Regulatory Submissions Training Course focuses on providing in-depth knowledge and practical experience in preparing and managing essential regulatory documents such as IND (Investigational New Drug), NDA (New Drug Application), BLA (Biologics License Application), and MAA (Marketing Authorization Application). With the increasing complexity of global regulatory requirements, professionals involved in drug development must be equipped with the right tools, strategies, and compliance protocols to ensure timely and successful product approval. This course offers a comprehensive understanding of the documentation processes, submission strategies, and regulatory guidelines across key international markets.

Regulatory Submissions - IND, NDA, BLA, MAA Documentation Training Course is designed to help participants navigate through the intricate submission processes, offering insights into regulatory requirements from agencies like the FDA (Food and Drug Administration), EMA (European Medicines Agency), and PMDA (Pharmaceuticals and Medical Devices Agency). By addressing key regulatory submission components, such as clinical trials, safety monitoring, and quality assurance, this training will enhance participants' capabilities in submitting robust, high-quality documents that meet global standards. Designed for pharmaceutical, biotech, and regulatory affairs professionals, this course incorporates the latest trends and best practices in regulatory affairs, making it essential for anyone looking to advance their expertise in this high-demand field

Programme Curriculum

Regulatory Submissions- IND, NDA, BLA, MAA Documentation Training Course

Introduction

The global biopharmaceutical industry is undergoing a paradigm shift, driven by rapid scientific innovation and increasing regulatory scrutiny. The journey from a novel molecule to a marketed drug requires a robust and meticulous approach to regulatory submissions. Regulatory Submissions- IND, NDA, BLA, MAA Documentation Training Course is designed to equip professionals with the critical knowledge and practical skills needed to navigate the complex landscape of regulatory documentation for Investigational New Drug (IND), New Drug Application (NDA), Biologics License Application (BLA), and Marketing Authorization Application (MAA) submissions. By focusing on compliance, data integrity, and strategic planning, this program empowers participants to streamline processes, mitigate risks, and accelerate product timelines, ensuring successful outcomes in a highly competitive and dynamic market.

A deep understanding of regulatory requirements, evolving guidelines, and digital submission platforms is no longer a luxury but a necessity for career advancement. Our curriculum is tailored to address the latest trends in global regulatory affairs, including the use of electronic Common Technical Document (eCTD) and Regulatory Information Management (RIM) systems. We emphasize a hands-on, case-study-driven approach that goes beyond theoretical knowledge, providing a real-world context for applying GxP (Good Practices), clinical data management, and quality control principles. This course is an investment in professional development, offering a comprehensive toolkit for building and submitting high-quality, compliant dossiers that meet the stringent standards of regulatory bodies like the FDA and EMA.

Course Duration

10 days

Course Objectives

1. Learn to compile, publish, and maintain electronic Common Technical Document (eCTD) dossiers for global submissions.
2. Develop a comprehensive understanding of diverse regulatory pathways, including IND, NDA, BLA, and MAA procedures.
3. Implement Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Laboratory Practice (GLP) principles throughout the documentation lifecycle.
4. **Optimize Regulatory Information Management (RIM):** Utilize trending RIM software to manage and track regulatory data and submissions efficiently.
5. **Accelerate Time-to-Market:** Identify and apply expedited regulatory pathways like Fast Track, Breakthrough Therapy, and Priority Review to shorten development timelines.
6. Proactively monitor and interpret new FDA and EMA guidance documents and legislative changes.
7. Implement robust quality assurance (QA) and quality control (QC) measures for all submission components.
8. Learn to effectively communicate with health authorities through pre-submission meetings and deficiency responses.
9. Understand the critical role of data analytics in shaping the content and strategy of regulatory dossiers.
10. Develop skills to handle post-marketing commitments, variations, and safety updates.
11. Facilitate effective communication and data exchange between R&D, clinical, manufacturing, and marketing teams.
12. Conduct risk assessments to anticipate and address potential regulatory hurdles and inspection findings.
13. Learn the modular structure of the CTD and its application to different submission types and regions.

Target Audience

1. Regulatory Affairs Professionals (Entry to Mid-Level)
2. Clinical Operations and Clinical Research Associates
3. Quality Assurance and Quality Control Specialists
4. Medical Writers and Technical Documentation Managers
5. Project Managers in Biopharmaceutical Development
6. R&D Scientists and Researchers
7. Pharmacovigilance and Drug Safety Specialists
8. Legal and Compliance Officers in the Life Sciences Sector

Course Modules

Module 1: Foundations of Regulatory Affairs and the CTD

- Introduction to the global regulatory landscape and key health authorities
- Understanding the Drug and Biologics development lifecycle.
- Overview of the Common Technical Document (CTD) and its modular structure.
- The critical role of regulatory affairs in accelerating product development.
- Ethical and legal considerations in regulatory documentation.
- **Case Study:** A small biotech firm needs to prepare its first IND

Module 2: Investigational New Drug (IND) Applications

- Purpose and content of an IND: Modules 1, 2, and 3.
- Pre-IND meeting preparation and strategies for effective communication.
- CMC (Chemistry, Manufacturing, and Controls) requirements for INDs.
- The 30-day review period and common reasons for clinical holds.
- Managing IND amendments, annual reports, and safety reporting.
- **Case Study:** A company receives a clinical hold letter from the FDA.

Module 3: New Drug Application (NDA) Documentation

- Transitioning from IND to NDA: The pivotal role of Phase 3 clinical data.
- Detailed breakdown of NDA Modules 4 (Nonclinical) and 5 (Clinical).
- Understanding the Clinical Overview and Clinical Summary documents.
- Submitting the NDA and navigating the FDA review process (Standard vs. Priority Review).
- Preparing for a potential Advisory Committee meeting.
- **Case Study:** A company has positive Phase 3 data for a small molecule drug.

Module 4: Biologics License Application (BLA) Documentation

- Differences between NDA and BLA submissions (PHS Act vs. FD&C Act).
- Specific requirements for biologics CMC, including manufacturing process and characterization.
- Strategies for handling immunogenicity and comparability data.
- Post-approval changes and manufacturing supplements for biologics.
- The role of CBER (Center for Biologics Evaluation and Research).
- **Case Study:** A company is developing a gene therapy.

Module 5: Marketing Authorization Application (MAA) for the EU

- Navigating the European Medicines Agency (EMA) and the centralized procedure.
- Understanding the EU CTD format and regional differences in documentation.
- The role of the Committee for Medicinal Products for Human Use (CHMP).

- Preparing the Non-Clinical and Clinical Overviews for the EU.
- Managing the MAA review process and addressing questions from rapporteurs.
- **Case Study:** A drug approved in the US needs to be submitted in the EU..

Module 6: Electronic Submissions and eCTD

- Introduction to electronic submission formats and the eCTD structure.
- Best practices for document preparation and publishing in eCTD.
- Using submission software and RIM systems for lifecycle management.
- The importance of metadata and document linking for a cohesive dossier.
- Hands-on workshop for creating and validating an eCTD submission package.
- **Case Study:** A company's internal documents are not eCTD-compliant.

Module 7: GxP and Data Integrity in Submissions

- Connecting Good Clinical Practice (GCP) to clinical trial data integrity.
- Ensuring GMP compliance for manufacturing data (Module 3).
- The role of Good Laboratory Practice (GLP) in preclinical studies.
- Audits, inspections, and how to prepare for them.
- Best practices for data collection, validation, and archiving.
- **Case Study:** An FDA inspection uncovers data integrity issues in a clinical site.

Module 8: Regulatory Intelligence and Strategy

- Methods for monitoring and interpreting global regulatory changes.
- Building a robust regulatory intelligence database.
- Developing a strategic roadmap for multi-regional submissions.
- Using regulatory intelligence to inform a product's target claims and labeling.
- The impact of global harmonization efforts (ICH guidelines).
- **Case Study:** A new FDA guidance on real-world evidence (RWE) is released.

Module 9: Dossier Management and Lifecycle

- Managing the full lifecycle of a submission: from IND to post-approval.
- Handling amendments, supplements, and variations.
- The importance of version control and document archiving.
- Strategies for managing large and complex dossiers.
- Using RIM systems for seamless lifecycle management.
- **Case Study:** An approved drug is undergoing a change in manufacturing location.

Module 10: Pre-Approval and Post-Marketing Inspections

- Types of regulatory inspections (pre-approval, for-cause, routine).
- How to prepare a cross-functional team for an inspection.
- Responding to inspectional observations and Form 483s.
- Best practices for host-role and back-room support during an inspection.
- The role of regulatory documentation in demonstrating compliance.
- **Case Study:** The FDA is conducting a pre-approval inspection of a manufacturing site.

Module 11: Special Regulatory Designations

- Understanding and applying for Fast Track, Breakthrough Therapy, and Priority Review.

- Strategies for obtaining Orphan Drug Designation.
- Expedited pathways for regenerative medicine and advanced therapies.
- The benefits and obligations associated with these designations.
- Compiling the necessary data and justification for a designation request.
- **Case Study:** A company has a promising oncology drug.

Module 12: Interacting with Health Authorities

- Types of meetings with the FDA (Type A, B, C) and EMA.
- Best practices for drafting meeting requests and briefing packages.
- Effective communication during and after meetings.
- Responding to deficiency letters and Information Requests (IRs).
- Negotiating with regulators on key submission issues.
- **Case Study:** A company receives a complete response letter (CRL) from the FDA.

Module 13: Clinical and Non-Clinical Summary Writing

- Techniques for writing clear, concise, and compelling summaries.
- The importance of storytelling and a clear narrative in regulatory documents.
- Practical tips for distilling complex data into digestible information.
- Reviewing and editing summaries for accuracy and consistency.
- Avoiding common pitfalls in summary writing.
- **Case Study:** Participants are given a mock clinical study report (CSR).

Module 14: Post-Approval and Post-Marketing Activities

- Handling post-marketing commitments and studies.
- Managing changes to labeling and packaging inserts.
- The role of pharmacovigilance and preparing Development Safety Update Reports (DSURs).
- Submitting variations and supplements for manufacturing and product changes.
- Understanding the nuances of marketing promotion and advertising regulations.
- **Case Study:** A post-marketing study reveals a new safety signal.

Module 15: Emerging Trends in Regulatory Submissions

- The use of AI and machine learning in regulatory documentation.
- Preparing for submissions involving real-world evidence (RWE) and digital health.
- Global regulatory harmonization initiatives.
- Regulatory challenges for biosimilars and cell and gene therapies.
- Future outlook for regulatory affairs.
- **Case Study:** A company is developing a digital therapeutic.

Training Methodology

This course utilizes a blended learning approach to maximize participant engagement and knowledge retention.

1. Interactive Lectures.
2. Hands-on Workshops.
3. Real-World Case Studies.
4. Role-Playing and Simulations.
5. Group Discussions and Peer Review.
6. Q&A with Industry Experts.

7. Resource Library.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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