Advanced Electronic Submission Management (eCTD) 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

The global pharmaceutical and biotechnology industries are undergoing a rapid digital transformation of their regulatory affairs processes, making expertise in the electronic Common Technical Document (eCTD) format non-negotiable. Advanced Electronic Submission Management (eCTD) Training Course is specifically engineered to bridge the gap between foundational eCTD knowledge and complex, multi-regional submission strategies. Participants will master the intricacies of the eCTD lifecycle management (LCM), moving beyond mere technical publishing to focus on strategic regulatory operations (RegOps), data integrity, and the critical shift to the new eCTD v4.0 standard. We emphasize hands-on application using industry-standard software and real-world case studies like managing a complex BLA/NDA submission across the FDA, EMA, and Health Canada to ensure immediate on-the-job competency and global compliance.

This intensive training delves into the operational excellence required for streamlining submission workflows and achieving a faster time-to-market for critical therapies. It tackles key challenges such as validation failure mitigation, regional specificity (Module 1), and integrating eCTD publishing with modern Regulatory Information Management (RIM) systems. By focusing on advanced topics like cross-functional team alignment, the course aims to cultivate Regulatory Intelligence experts capable of leading digital compliance initiatives. Mastering these advanced electronic submission techniques is essential for minimizing regulatory risk, accelerating agency review cycles, and positioning regulatory teams as strategic assets within the Life Sciences enterprise.

Programme Curriculum

Advanced Electronic Submission Management (eCTD) Training Course

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Course Duration

10 days

Course Objectives

Upon completion, participants will be able to:

1. Proficiently manage sequences, replacements, deletions, and appendices for all post-approval activities.
2. Analyze the transition from v3.2.2 to the eCTD 4.0 standard and its impact on data integrity and metadata.
3. Design and implement streamlined workflows that enhance submission efficiency and audit trails.
4. Tailor the Module 1 content to meet the specific requirements of the FDA, EMA, PMDA, and Health Canada.
5. Identify and resolve common technical and content-related eCTD validation errors
6. Leverage Regulatory Information Management (RIM) tools to automate eCTD publishing and tracking.
7. Formulate cohesive multi-regional filing strategies for simultaneous drug applications
8. Apply best practices for PDF publishing, hyperlinking, bookmarking, and creating navigational aids.
9. Handle the unique complexities of submissions for drug-device combination products and Advanced Therapy Medicinal Products
10. Strategically manage variations, renewals, and labeling updates throughout the product's life.
11. Perform comprehensive Technical Quality Control (TQC) checks and content reviews for final submission readiness.
12. Utilize the FDA Electronic Submissions Gateway (ESG) and similar regional portals for efficient dossier transfer.
13. Incorporate the latest ICH guidelines and regional regulatory updates into submission planning.

Target Audience

1. Regulatory Affairs (RA) Associates and Managers.
2. eCTD Publishers.

3. Regulatory Operations (RegOps) Specialists.
4. Quality Assurance (QA) and Compliance Professionals.
5. CMC (Chemistry, Manufacturing, and Controls) Experts.
6. IT/System Administrators.
7. Medical Writers
8. Project Managers.

Course Modules

Module 1: Foundational Review and ICH Global Framework

- Advanced eCTD Structure (M1-M5) and Document Hierarchy.
- Deep Dive into ICH Guidelines and their evolution.
- Understanding the role of metadata and XML Backbone in eCTD processing.
- Review of Region-Specific Module 1 requirements (US, EU, CA, JP).
- Establishing a Submission Ready document environment and template.
- Case Study: Analyzing the complete folder structure of a successful Phase III clinical trial report (M5) to ensure cross-module linking feasibility.

Module 2: Mastering eCTD Lifecycle Management (LCM)

- Principles of Cumulative Sequences and Full/Partial/Supersede submission types.
- Advanced LCM Operations.
- Strategic management of Product Lifecycle from IND/CTA to Post-Approval.
- Handling of administrative updates and annual reports efficiently.
- Maintaining the Historical Audit Trail and compliance throughout all submission versions.
- Case Study: Executing a multi-document Replace and Delete sequence to update the drug?ÇÖs labeling and a CMC report in a single submission.

Module 3: Transitioning to eCTD v4.0

- Understanding the structural and technical differences of the new eCTD 4.0 standard.
- Focus on Regulated Product Submission and the move toward message-based submissions.
- Implications of eCTD 4.0 on RIM System integration and data exchange.
- Strategies for planning a seamless internal and external v4.0 transition.
- Review of the latest FDA and EMA guidance documents on v4.0 implementation.
- Case Study: Developing a phased implementation plan for a large pharmaceutical company's switch from v3.2.2 to v4.0 across three major therapeutic areas.

Module 4: Regulatory Information Management (RIM) Systems & eCTD

- The critical role of a RIM System in RegOps.
- Integrating document management, tracking, and publishing capabilities.
- Automating the eCTD build process directly from the RIM environment.
- Ensuring data governance and system validation within the RIM.
- Leveraging RIM analytics for submission timeline forecasting and compliance reporting.
- Case Study: Mapping a new drug's Target Product Profile (TPP) through a RIM system to automatically generate the necessary eCTD document placeholders and workflows.

Module 5: Technical Quality Control (TQC) and Validation

- Advanced use of Validation Tools to preemptively identify errors.

- Common Technical Validation Failures and resolution.
- Content-related errors and their impact.
- Creating a robust, standardized internal TQC checklist for all submission types.
- Understanding Health Authority specific validation rules
- Case Study: Troubleshooting a simulated Validation Failure Report with 15 critical errors and correcting the source files and XML backbone.

Module 6: Document Authoring and PDF Publishing Best Practices

- Creating eCTD-compliant PDF documents
- Mastering hyperlinking strategies within and across eCTD modules
- Implementing mandatory bookmarks and navigational aids for reviewer ease.
- Best practices for document naming conventions and version control in the source system.
- Tips for efficient document finalization and electronic signatures.
- Case Study: Converting a 400-page Clinical Study Report (CSR) into a fully compliant, hyperlinked, and bookmarked eCTD PDF ready for submission.

Module 7: US FDA eCTD Submission Strategy

- Specific Module 1 requirements for FDA
- Utilizing the FDA Electronic Submissions Gateway (ESG) for secure transmission.
- Submitting Original NDAs/BLAs and managing ANDA submissions.
- Responding to Information Requests and Complete Response Letters via eCTD.
- Navigating the PDUFA timelines and submission deadlines.
- Case Study: Preparing the final version of a New Drug Application (NDA), including the administrative forms and **eCTD sequence 0000** for initial submission via the ESG.

Module 8: EU EMA eCTD Submission Strategy

- Specific Module 1 requirements for the European Medicines Agency (EMA).
- Handling submissions for Centralised Procedure (CP) and Mutual Recognition Procedure.
- Understanding the eSubmission Gateway/Web Client and related technical specifications.
- Managing the eCTD for Variations and Renewals in the EU.
- Best practices for Product Information (PI) and SmPC documentation.
- Case Study: Compiling an initial Marketing Authorisation Application (MAA) submission dossier, ensuring the correct EU regional administrative and legal documents are included in M1.

Module 9: Multi-Regional and Global Harmonization Strategy

- Developing a Core Dossier Strategy to maximize content reuse across regions.
- Addressing regional differences in Module 1 while maintaining a harmonized M2-M5.
- Strategies for simultaneous global filings and phased submissions.
- Managing localization and its impact on the eCTD structure.
- Coordination of a global submission team across different time zones.
- Case Study: Planning the submission timelines and content adaptations for a Phase III product targeting initial approval in the US and EU within a 6-month window.

Module 10: Advanced Post-Approval Submissions

- Classification and management of Type IA, IB, and Type II Variations (EU).
- Handling major and minor Supplements and Changes Being Effected (CBEs) (US).

- Managing the eCTD sequence for Labeling Updates and Safety Variations
- Strategies for Renewals and License Transfers in the eCTD format.
- Best practices for submitting Commitment Tracking and Post-Marketing data.
- Case Study: Processing a major CMC change and preparing the corresponding Type II Variation (EU) and PAS (US) eCTD sequences.

Module 11: CMC (Module 3) & Nonclinical (Module 4) Submission Focus

- Structuring complex Module 3 sections
- Ensuring correct placement and hyperlinking for Drug Substance and Drug Product data.
- Technical requirements for nonclinical data (M4) Study Tagging Files (STF) and reports.
- Managing cross-referencing and letter of authorization (LOA) documents effectively.
- Common Module 3 validation issues and how to prevent them.
- Case Study: Building the M3 and M4 sections for a new generic drug (ANDA) submission, focusing on bioequivalence and Quality overall summary (QOS) linkage.

Module 12: Clinical (Module 5) Data Submission and Management

- Organizing the complex structure of Module 5.
- Handling Individual Patient Data (IPD), ISS, and ISE documentation.
- Technical specifications for Clinical Trial Applications .
- Effective use of the Study Tagging File (STF) for large clinical datasets.
- Managing the continuous update of DSUR and PSUR/PBRER documents.
- Case Study: Submitting an Investigational New Drug (IND) application, focusing on the proper inclusion and sequencing of the clinical protocol, IB, and Investigator forms.

Module 13: Submitting to Other Key Regions

- Health Canada eCTD requirements and gateway.
- PMDA (Japan) eCTD specifications
- TGA (Australia) and other common regional eCTD deviations and compliance.
- Understanding the regional review processes and dossier expectation differences.
- Managing language-specific documents and translations within the eCTD.
- Case Study: Preparing the regional Module 1 content for a final submission in both the US and Health Canada, highlighting the necessary form and administrative document variations.

Module 14: Submissions for Combination Products and ATMPs

- Regulatory pathways and unique eCTD filing requirements for Drug-Device Combination Products.
- Structuring the dossier to address both drug and device components
- Specific eCTD considerations for Advanced Therapy Medicinal Products
- Coordinating regulatory submissions with Quality System and Device File documentation.
- Handling the complexity of different lead health authorities.
- Case Study: Analyzing the eCTD structure for an auto-injector pen (drug-device), ensuring cross-referencing between the drug (M3) and device (M1/M2) aspects.

Module 15: Future Trends and Regulatory Intelligence

- The impact of AI and Automation on future eCTD publishing and RegOps.
- Implementing a formal Regulatory Intelligence program for proactive compliance.
- Anticipating future ICH guidelines and global convergence efforts.

- Developing Standard Operating Procedures (SOPs) for continuous eCTD compliance.
- Career pathways and skill evolution for the Advanced Regulatory Professional.
- Case Study: Benchmarking a company's current submission workflow against industry best-in-class performance metrics to identify and plan for AI-driven workflow efficiencies.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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