Advanced Regulatory Harmonization (ICH Guidelines) 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 biopharmaceutical landscape demands regulatory agility and compliance excellence. The International Council for Harmonisation (ICH) Guidelines are the definitive, globally accepted standard for ensuring the quality (Q), safety (S), and efficacy (E) of medicinal products. Advanced Regulatory Harmonization (ICH Guidelines) Training Course is specifically designed for seasoned regulatory professionals and R&D leaders who must move beyond fundamental knowledge to master the strategic application and current developments of the ICH framework, especially navigating the rapidly evolving areas of Quality by Design (QbD), Good Clinical Practice (GCP), Real-World Data (RWD), and electronic submissions (eCTD). This is not a beginner's overview; it's a deep-dive into complex implementation challenges, risk-based approaches (ICH Q9), and lifecycle management (ICH Q12) to accelerate global market access and ensure regulatory submission integrity.

This intensive program offers a practical, case study driven curriculum focusing on the latest ICH updates, including the revolutionary ICH E6(R3) on GCP modernization and emerging M-series guidelines. By achieving advanced mastery of these principles, participants will gain the critical skills needed to develop robust global regulatory strategies, optimize pharmaceutical quality systems (PQS), minimize compliance risk, and streamline product development across major markets. The outcome is a highly competent professional capable of translating harmonized standards into actionable, business-critical processes that drive efficiency and maintain the highest level of patient safety and product quality worldwide, positioning your organization at the forefront of international regulatory compliance.

Programme Curriculum

Advanced Regulatory Harmonization (ICH Guidelines) Training Course

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Course Duration

10 days

Course Objectives

1. Master the ICH E6(R3) Modernization and implement the new principles of Quality by Design (QbD) in clinical trials.
2. Strategically Apply the ICH Q12 Guideline to establish robust Product Lifecycle Management (PLCM) and post-approval change control.
3. Optimize Quality Risk Management (QRM) processes using the principles of ICH Q9(R1) to enhance decision-making in manufacturing and development.
4. Evaluate and apply the requirements for managing and reporting data from Real-World Studies for safety assessment and regulatory submissions.
5. Develop an Advanced eCTD Submission Strategy for simultaneous filing across multiple ICH regions in line with ICH M8.
6. Interpret and comply with the ICH M7 guideline regarding the control of DNA Reactive Impurities in drug products.
7. Integrate the ICH Q10 Pharmaceutical Quality System (PQS) with current Good Manufacturing Practices for holistic quality management.
8. Analyze the Non-Clinical Safety Testing requirements, focusing on the latest updates in ICH S-series guidelines for novel therapeutics.
9. Formulate a cohesive Global Regulatory Strategy that leverages ICH harmonization to achieve expedited market authorization.
10. Assess the impact of emerging ICH Topics on current pharmaceutical operations and future strategy.
11. Conduct effective Regulatory Intelligence to anticipate and incorporate new and revised ICH guidelines into organizational SOPs.

12. Implement data integrity and traceability standards for clinical data management in compliance with ICH E-series digital requirements.
13. Drive organizational change by translating ICH Harmonization principles into operational excellence across R&D, Clinical, and Manufacturing.

Target Audience

1. Senior Regulatory Affairs Managers/Directors
2. Heads of Quality Assurance (QA) and Quality Control (QC)
3. Clinical Operations and Clinical Trial Managers
4. Pharmaceutical R&D and Drug Development Scientists
5. Pharmacovigilance (PV) and Drug Safety Professionals
6. CMC (Chemistry, Manufacturing, and Controls) Specialists
7. Auditors and Compliance Officers
8. Senior Consultants in the Pharmaceutical/Biotech Industry

Course Modules

1. Foundational Strategy & ICH Framework

- ICH's Role in Global Regulatory Landscape.
- Structure and Interplay of Q, S, E, M Guidelines.
- ICH Process and how to track implementation timelines.
- Translating ICH into Regional Regulatory Requirements
- Case Study: Analyzing the impact of a recent ICH Step 4 implementation on a multi-regional filing strategy.

2. Advanced ICH Q9: Quality Risk Management (QRM)

- Detailed review of ICH Q9(R1) principles and Annexes.
- Risk Assessment Tools for PQS.
- Developing a Risk-Based Approach for process validation and cleaning validation.
- Integrating QRM into Deviation Management and CAPA.
- Case Study: Applying QRM to justify a reduced stability testing program for a low-risk product.

3. ICH Q12: Product Lifecycle Management (PLCM)

- Scope and Benefits of the ICH Q12 Guideline and its connection to Q8, Q9, and Q10.
- Implementing Established Conditions and their regulatory impact.
- Developing and using a Post-Approval Change Management Protocol
- The concept of the Product Knowledge Management System.
- Case Study: Scenario planning for a major manufacturing site transfer using Q12 PACMPs for minimal regulatory burden.

4. ICH Q8 & Q11: Pharmaceutical Development & Drug Substance

- Moving from traditional development to Quality by Design principles.
- Defining the Design Space and its regulatory implications.
- Advanced strategies for Process Validation (Q11) for API manufacturing.
- Use of Real-Time Release Testing
- Case Study: Designing a successful regulatory strategy based on a QbD-derived Design Space for a complex parenteral product.

5. Emerging Quality Guidelines

- ICH Q13 on Continuous Manufacturing (CM) principles and regulatory expectations.
- ICH Q14 on Analytical Procedure Development and lifecycle management.
- The convergence of CM with Process Analytical Technology (PAT).
- Regulatory challenges and opportunities of implementing Q13 in an existing facility.
- Case Study: Developing a Q13 submission pathway for transitioning a batch process to a continuous manufacturing line.

6. ICH E6(R3): Good Clinical Practice (GCP) Modernization

- Core principles and key changes from E6 to the latest E6 revision.
- Implementing Quality by Design (QbD) into clinical trial design.
- Advanced concepts of Risk-Based Quality Management (RBQM).
- Oversight responsibilities for sponsors in decentralized and complex trials.
- Case Study: Structuring a clinical trial protocol with embedded RBQM to justify reduced source data verification.

7. ICH E-Series: Clinical Efficacy and Trial Design

- Advanced application of ICH E8 on general considerations for clinical trials.
- Principles of ICH E11A for conducting Pediatric Extrapolation Studies.
- Standardization of Clinical Study Reports
- Statistical principles and Estimands in complex designs.
- Case Study: Justifying a pediatric dose using extrapolation based on adult data in an E11A compliant manner.

8. ICH E2-Series: Pharmacovigilance and Safety Reporting

- In-depth understanding of Individual Case Safety Reports (ICSRs).
- Advanced use of ICH E2B(R3) for electronic reporting standards.
- Global expedited safety reporting requirements (ICH E2A).
- Management of safety data from Real-World Data (RWD) studies (ICH E20).
- Case Study: Resolving data inconsistencies and bottlenecks in cross-regional E2B(R3) electronic safety data exchange.

9. ICH S-Series: Non-Clinical Safety Strategy

- Applying ICH S9 for the non-clinical evaluation of Anticancer Pharmaceuticals.
- Revised safety testing for Biologics (ICH S6(R1)) and Gene Therapies (ICH S12).
- Strategic planning for Carcinogenicity and Genotoxicity testing programs
- Toxicokinetics and the role of Non-Clinical PK/PD in first-in-human studies.
- Case Study: Designing an efficient S9 non-clinical battery for a novel oncology small molecule to support an IND/CTA filing.

10. ICH M7: Mutagenic Impurities

- Defining and classifying DNA Reactive Impurities (CMR).
- Establishing Acceptable Intake (AI) limits
- Developing and justifying a Risk-Based Control Strategy for impurities.
- Addressing M7 expectations for both New and Existing Products.

- Case Study: Developing a justified analytical control strategy for a process impurity with potential mutagenic concern.

11. ICH M4 & M8: The Common Technical Document (CTD) and eCTD

- Mastering the CTD Structure for Quality, Safety, and Efficacy documents.
- Advanced eCTD Implementation and lifecycle management.
- Regulatory requirements for eSubmission across FDA, EMA, and other regions.
- Planning and compiling an original Marketing Authorisation Application (MAA) or NDA/BLA.
- Case Study: Auditing and remediating a legacy paper dossier for full conversion and submission as a compliant eCTD.

12. ICH M1: MedDRA Terminology

- Advanced application of the Medical Dictionary for Regulatory Activities
- Principles of proper MedDRA coding for adverse events and product indications.
- Impact of MedDRA version changes on safety databases and reports.
- Using MedDRA for Aggregate Safety Report generation
- Case Study: Conducting a system audit to ensure consistent and accurate MedDRA coding across a global pharmacovigilance database.

13. Regulatory Intelligence and Future ICH Topics

- Techniques for proactive Regulatory Intelligence monitoring.
- Analyzing potential impact of Draft (Step 2) and Concept Papers on R&D pipeline.
- Exploring the role of Artificial Intelligence (AI) in R&D and regulatory processes.
- Best practices for influencing or responding to draft ICH guidelines.
- Case Study: Preparing a gap analysis and implementation plan for a forthcoming ICH guideline based on Step 2 documentation.

14. Global Submission Strategy and Expedited Pathways

- Strategies for simultaneous global submissions
- Leveraging ICH to access Expedited Programs
- Addressing major Regulatory Deficiencies across ICH regions.
- Understanding the role of Regulatory Communication with agencies
- Case Study: Developing a response strategy for a major quality deficiency received from a lead regulatory authority post-submission.

15. Auditing, Compliance, and Data Integrity

- Designing an ICH-Compliant Internal Audit Program
- Best practices for Regulatory Agency Inspection Readiness.
- The crucial role of Data Integrity in all ICH submission documents.
- Auditing Suppliers and CROs for ICH compliance.
- Case Study: Simulating an internal audit of a clinical study site focusing on E6(R3) compliance and data integrity principles.

Training Methodology

This Advanced Regulatory Harmonization course employs a blended, high-impact methodology to ensure immediate and practical knowledge transfer:

- Interactive Workshops & Deep Dives.
- Real-World Case Studies & Simulations.
- Practical Tools and Templates.
- Expert-Led Discussions.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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