Advanced Stability Protocols for Investigational Products 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

Advanced Stability Protocols for Investigational Products Training Course is designed to transition stability professionals from ICH-compliant stability testing to strategic, risk-based stability management for complex Investigational Products. The pharmaceutical landscape, especially in biologics, Advanced Therapy Medicinal Products, and combination products, demands more than just rote protocol execution. We emphasize Quality by Design principles, accelerated predictive modeling like Accelerated Stability Assessment Program, and rigorous cold chain management for clinical supply chain resilience. By mastering advanced statistical data analysis and stability-indicating methods validation, participants will gain the expertise required to design phase-appropriate stability programs that minimize clinical hold risk, justify extended shelf-life for global trials, and secure optimal regulatory submission outcomes. This training transforms stability science into a strategic asset for modern drug development.

The program directly addresses the critical industry need for expertise in handling novel modalities and navigating complex global regulations. Delegates will acquire actionable knowledge in Quality Risk Management to anticipate and mitigate stability challenges, such as Out-of-Specification investigations and temperature excursion management. From the design of forced degradation studies to the technical writing of the Chemistry, Manufacturing, and Controls stability section for IND/IMPD filings, this course provides a comprehensive toolkit. Ultimately, successful completion ensures a profound understanding of how to establish a robust, compliant, and cost-efficient stability program that accelerates Time-to-Market while safeguarding patient safety and product quality throughout the entire product lifecycle.

Programme Curriculum

Advanced Stability Protocols for Investigational Products Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Design and execute ICH Q1/Q5C-compliant, phase-appropriate stability protocols for novel small molecules and biologics.
2. Implement Quality by Design (QbD) and Quality Risk Management (QRM) principles in stability program development.
3. Master Accelerated Stability Assessment Program (ASAP) techniques for rapid shelf-life estimation and justification.
4. Develop risk-based bracketing and matrixing designs to minimize analytical testing and reduce costs.
5. Utilize predictive stability modeling and statistical data analysis for robust shelf-life determination.
6. Strategically manage Cold Chain logistics and assess the impact of temperature excursions (TE) on IP quality.
7. Design and conduct comprehensive forced degradation studies to elucidate degradation pathways and stress profiles.
8. Identify, develop, and validate stability-indicating analytical methods, including impurity profiling.
9. Navigate the unique stability and container-closure integrity challenges of Advanced Therapy Medicinal Products
10. Effectively conduct and document stability OOS (Out-of-Specification) and OOT (Out-of-Trend) investigations.
11. Prepare the CMC Stability Section of IND/IMPD/NDA for optimal regulatory review and approval.
12. Establish robust in-use stability and post-reconstitution protocols for clinical administration.
13. Integrate data integrity and Pharma 4.0 principles into stability data management systems.

Target Audience

1. Stability Scientists and Analysts (Pharmaceutical/Biotech)
2. Quality Assurance (QA) and Quality Control (QC) Professionals
3. Regulatory Affairs Specialists (Focusing on CMC/Module 3)
4. Clinical Supply Chain/Logistics Managers
5. Formulation Development Scientists
6. R&D Management seeking strategic stability oversight
7. Analytical Development Scientists involved in method validation
8. Project/Program Managers overseeing Investigational Product development

Course Modules

Module 1: The Regulatory & Strategic IP Stability Framework

- ICH Q1A-F, Q5C, Q8, Q9, Q10 for IPs and Biologics.
- Phase-appropriate stability.
- Linking stability to IND/IMPD and Clinical Trial Application requirements.
- Global regulatory variations in early-phase stability programs.
- Case Study: Analyzing an FDA Clinical Hold resulting from insufficient pre-IND stability data.

Module 2: Quality by Design (QbD) in Stability Program Design

- Defining the Quality Target Product Profile and Critical Quality Attributes
- Risk assessment for stability-critical parameters.
- Establishing the Design Space for optimal formulation and process.
- Utilizing Design of Experiments to optimize stability studies.
- Case Study: Designing a stability program for a lyophilized IP using a QbD-driven approach to justify a matrixing study.

Module 3: Accelerated Stability Assessment Program (ASAP)

- Principles of Arrhenius Kinetics and rapid stability assessment.
- Designing and interpreting isothermal and non-isothermal stress studies.
- Establishing a Provisional Shelf-Life for early clinical trials.
- Statistical criteria for ASAP compliance and extrapolation.
- Case Study: Using ASAP data to reduce a 24-month long-term study to a 6-month commitment for a new dosage form.

Module 4: Advanced Protocol Design: Bracketing & Matrixing

- Principles and regulatory justification for bracketing and matrixing.
- Selecting appropriate design variables.
- Statistical power and regulatory risks associated with reduced designs.
- Documentation requirements for regulatory submission of reduced protocols.
- Case Study: Developing a justified matrixing plan for five IP strengths and two container sizes to reduce analytical workload by 50%.

Module 5: Cold Chain & Temperature Excursion (TE) Management

- Defining, mapping, and qualifying controlled cold chain environments.
- Developing Temperature Excursion SOPs and risk assessment tools.
- Science-based justification for continued use of temperature-excursioned product.
- Conducting shipping studies and transport simulation testing.

- Case Study: Investigating a major TE during global shipment of a refrigerated biologic and successfully establishing a science-based justification for use.

Module 6: Stability for Biologics & ATMPs

- Unique degradation pathways in proteins, peptides, and viral vectors.
- Developing stability protocols for cell and gene therapies.
- Monitoring viral titer, aggregation, and particle formation.
- Ultra-low temperature storage and specialized container systems.
- Case Study: Developing an ultra-low temperature stability program for a viral vector-based gene therapy product.

Module 7: Forced Degradation Studies & Degradation Pathways

- Design and execution of studies under stress conditions
- Elucidating the chemical structure of degradants and degradation pathways.
- Establishing toxicological qualification thresholds for impurities.
- Mass balance, peak purity, and the need for LC-MS analysis.
- Case Study: Tracing a critical oxidation degradant back to a specific excipient in the drug product formulation.

Module 8: Stability-Indicating Analytical Methods (SIAM) Validation

- Criteria for a method to be deemed "stability-indicating".
- ICH Q2(R1) validation requirements for SIAMs
- Focus on low-level impurity detection and quantitation.
- The role of UPLC/HPLC and specialized analytical techniques.
- Case Study: Validation of a novel UPLC method to separate a critical, low-level degradation product in a complex peptide IP**.**

Module 9: Statistical Analysis of Stability Data

- Regression analysis for linear and non-linear degradation kinetics.
- Determining the retest period for APIs and the shelf-life/expiration dating for IPs.
- Pooling data from multiple batches and establishing statistical justification.
- Defining and statistically evaluating a "significant change" event.
- Case Study: Using ANCOVA to justify pooling stability data from three pivotal clinical batches for shelf-life extrapolation.

Module 10: Out-of-Specification (OOS) & Out-of-Trend (OOT) Investigations

- Defining OOS and OOT in the context of stability time points.
- The three-phase OOS investigation process
- Handling confirmed OOS results and their impact on IP release and use.
- Implementing effective CAPAs from stability failures.
- Case Study: Conducting an OOS investigation that reveals a packaging component failure rather than formulation instability.

Module 11: Container-Closure System (CCS) and Stability

- Selecting appropriate primary and secondary packaging for IP stability.
- Designing and interpreting Container-Closure Integrity (CCI) testing.

- Assessing the impact of leachables and extractables on product quality.
- Stability considerations for drug-device combination products.
- Case Study: Evaluating a high-density polyethylene bottle system for moisture ingress against a blister pack for a moisture-sensitive oral IP.

Module 12: In-Use and Post-Reconstitution Stability

- Developing protocols to mimic clinical administration.
- Establishing appropriate "in-use" period and storage conditions for clinical sites.
- Stability of products after reconstitution
- Labeling requirements for patient and clinician handling.
- Case Study: Designing an in-use stability protocol for an injectable IP that is diluted and stored for up to 24 hours prior to patient infusion.

Module 13: The CMC Stability Section for Regulatory Filings

- Structure and content of the Stability Section for IND/IMPD.
- Common deficiencies cited by regulatory reviewers in stability submissions.
- Presenting and summarizing large volumes of stability data clearly.
- Justifying tentative shelf-life and stability commitments.
- Case Study: Reviewing a mock Module 3.2.P.8 submission and identifying critical stability data gaps.

Module 14: Data Integrity and Digital Stability Management

- ALCOA+ principles applied to stability data generation and review.
- Validating Laboratory Information Management Systems for stability data.
- Electronic data capture, audit trails, and data governance.
- Integrating stability with Pharma 4.0 and digital transformation.
- Case Study: Performing an Audit Trail Review on stability data to identify potential data manipulation or non-compliance.

Module 15: Ongoing & Post-Approval Stability Programs

- Designing and managing the on-going stability program
- Stability commitments for major changes
- Role of stability in post-market surveillance and reporting.
- Stability requirements for comparability studies.
- Case Study: Establishing the required post-approval stability commitment following a major change in API supplier and manufacturing site.

Training Methodology

The course employs a highly interactive, adult learning methodology focused on practical application and critical decision-making.

- Expert-Led Lectures.
- Interactive Workshops.
- In-Depth Case Studies.
- Group Discussions.
- Regulatory Document Review.

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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