CONCEPT

Pharmaceutical Stability Testing: ICH Study Design, Shelf-Life Statistics and OOT Control

8 – 12 November 2027
Paris - Right Bank business hotel



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Ref: 382_13414 **Date:** 8 – 12 November 2027 **Location:** Paris - Right Bank business hotel **Fees:** 23500 SAR

Introduction:

Pharmaceutical stability testing decides how long a medicine keeps its quality, yet many programmes run with protocols that miss storage conditions for target markets, analytical methods that cannot separate degradation products and shelf-life claims that rest on unpooled or over-extrapolated data. This Core Concept course trains QC, QA, regulatory affairs and R&D staff to design, run and evaluate stability studies against ICH Q1AR2, Q1B, Q1D and Q1E and the WHO stability guidelines. Participants build a Stability Protocol and Shelf-Life Evaluation Pack for a product from their own portfolio.

Course Objectives:

- Define the purpose and scope of a stability programme for drug substances and drug products across development, registration and commercial supply
- Design long-term, intermediate, accelerated, forced degradation and photostability studies with storage conditions matched to the climatic zones of intended markets
- Write stability protocols with batch selection, container closure, test attributes, acceptance criteria and pull schedules, applying bracketing and matrixing where justified
- Evaluate whether an analytical procedure is stability-indicating using forced degradation results, peak purity and mass balance
- Estimate retest period and shelf life with regression, poolability testing and limited extrapolation as described in ICH Q1E
- Handle out-of-specification and out-of-trend stability results, chamber excursions and dossier stability sections with defensible records

Target Audience:

- QC analysts who run stability pulls, test samples and record results against protocol
- QA staff who review stability protocols, investigations and chamber records before release decisions
- Regulatory affairs specialists who compile stability data for registration dossiers and variations
- R&D formulation scientists who select packaging and define storage conditions for new products
- Analytical development staff who build and transfer stability-indicating methods
- Stability coordinators who schedule studies and maintain chamber capacity and sample inventories

Course Outline:

Day 1: Stability Programme Purpose, Degradation Science and Programme Review

- Stability Programme Scope: Development, Registration, Commitment and Annual Ongoing Batches
- Retest Period Versus Shelf Life Versus Expiry Date: Definitions and Label Storage Statements
- Chemical, Physical and Microbiological Degradation Pathways in Solid, Liquid and Sterile Dosage Forms
- Temperature, Humidity and Light Effects and the Arrhenius Equation as a Kinetic Model
- Stability Programme Gap Review Checklist Against Current Site Practice

Day 2: ICH Q1 Guidance Family, WHO Stability Guidelines and Study Types

- ICH Q1AR2 Stability Data Package for New Drug Substances and Drug Products
- WHO Guidelines on Stability Testing of APIs and FPPs as a Comparative Reference
- Climatic Zone Classification and Selection of Long-Term and Intermediate Storage Conditions
- ICH Q1B Photostability Testing: Confirmatory and Forced Exposure Design
- ICH Q1C Requirements for New Dosage Forms and Line Extensions

Day 3: Stability Protocol Design, Sampling and Stability-Indicating Methods

- Stability Protocol Template: Batch Selection, Container Closure, Test Attributes and Acceptance Criteria
- Pull Schedule and Sample Quantity Calculation With Retain and Retest Allowances
- ICH Q1D Bracketing and Matrixing Design Justification for Strengths and Pack Sizes
- Forced Degradation Study Plan: Acid, Base, Oxidative, Thermal and Photolytic Stress
- Stability-Indicating HPLC Method Evidence: Peak Purity, Resolution and Mass Balance

Day 4: Shelf-Life Statistics, OOS and OOT Investigation and Chamber Control

- ICH Q1E Linear Regression and One-Sided Confidence Limit for Shelf-Life Estimation
- Batch Poolability Testing of Slopes and Intercepts and Limits on Extrapolation
- Out-of-Trend Detection Using Regression Control Charts and Prediction Intervals
- Out-of-Specification Stability Result Investigation: Phase I Laboratory and Phase II Full Review
- Stability Chamber Qualification: Temperature and Humidity Mapping, Alarms and Excursion Impact Assessment

Day 5: Stability Case Work, Dossier Presentation and Evaluation Pack

- Case: Tablet Product Protocol Review With Bracketing and Matrixing Challenge
- Case: Shelf-Life Regression Workbook Build From Three Registration Batches
- Registration Dossier Stability Section Structure and Post-Approval Stability Commitments Overview
- Case: Out-of-Trend Degradant Result and Chamber Excursion Decision Record
- Stability Protocol and Shelf-Life Evaluation Pack Presentation and Peer Critique

Skills You Will Gain:

- Stability Study Design
- Climatic Zone Storage Selection
- Stability Protocol Authoring
- Forced Degradation Planning
- Shelf-Life Regression Analysis
- Stability Trend Monitoring
- Chamber Excursion Assessment
- Stability Dossier Compilation

Why Attend This Course:

- Leave with a Stability Protocol and Shelf-Life Evaluation Pack built on a product from your own portfolio
- Work through regression and poolability calculations on real-style batch data rather than reading about them
- Defend bracketing, matrixing and extrapolation choices to reviewers with clear written justification
- Compare stability practice with peers from innovator, generic, biotech and contract testing organisations

Conclusion:

A shelf-life claim is only as strong as the stability design, analytical methods and statistics behind it. The week moves from degradation science and programme scope, through ICH Q1AR2, Q1B, Q1C and the WHO stability guidelines, to protocol writing, pull schedules, bracketing, matrixing and forced degradation. It then covers ICH Q1E regression, poolability, out-of-trend and out-of-specification handling and chamber control, and closes with case work and a Stability Protocol and Shelf-Life Evaluation Pack for each participant.