# Pharmaceutical Stability Testing Training Course

19 – 23 April 2027
Kuala Lumpur

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**Ref:** 1537_213520 **Date:** 19 – 23 April 2027 **Location:** Kuala Lumpur **Fees:** 5200 Euro

## Overview

Pharmaceutical Stability Testing Training Course is a one-week foundation course for quality control, quality assurance, formulation, regulatory, laboratory, manufacturing-support, and technical personnel, who leave with a Pharmaceutical Stability Study Control Pack. The course addresses inconsistent pharmaceutical stability studies through protocol design, storage-condition planning, sampling schedules, stability-indicating methods, data integrity, stability data evaluation, OOS and OOT handling, shelf-life support, and lifecycle governance. Agile Leaders Training Center presents pharmaceutical stability testing as controlled evidence for product-quality decisions.

## Who Should Attend

- Teams responsible for stability testing, sample management, and laboratory records
- Functions responsible for quality assurance, data review, and investigation governance
- Personnel responsible for formulation, packaging, and product-development support
- Teams responsible for regulatory documentation and lifecycle submissions
- Managers responsible for study oversight, change control, and cross-functional decisions

The course assumes participants support pharmaceutical testing, quality, development, manufacturing, or regulatory work and leaves out independent approval decisions and advanced analytical method development.

## Departments and Industries

The course supports departments and organizations that generate, review, or rely on pharmaceutical stability evidence.

- Pharmaceutical and biopharmaceutical manufacturing
- Quality control and analytical laboratory services
- Quality assurance and data-integrity functions
- Formulation, packaging, and product-development departments
- Regulatory affairs, supply, and technical operations

## Learning Objectives

By the end of this course, participants will be able to:

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- Apply ICH Q1AR2 principles to a stability study protocol
- Use batch, storage, sampling, and test-selection criteria
- Build controlled sample, chamber, and documentation workflows
- Analyze stability trends, OOS results, and OOT signals
- Prioritize data-integrity, deviation, and change-control actions
- Evaluate evidence supporting retest periods, shelf life, and storage statements

## Course Agenda

## Day 1: Stability Study Foundations

- ICH Q1AR2 Stability Study Scope Map
- Drug Substance and Drug Product Evidence Matrix
- Long-Term, Accelerated, and Intermediate Study Decision Guide
- Retest Period and Shelf-Life Evidence Chain
- Stability Governance Responsibility Matrix

## Day 2: Protocol and Study Design

- Batch Selection and Commitment Strategy Checklist
- Storage Condition and Climatic-Zone Planning Table
- Sampling Interval and Pull Schedule Template
- Container-Closure Representation Assessment
- ICH Q1D Bracketing and Matrixing Decision Tool

## Day 3: Testing and Operational Control

- Stability-Indicating Method Suitability Review
- ICH Q1B Photostability Test Planning Guide
- Stability Chamber Monitoring and Excursion Record
- Sample Chain-of-Custody and Inventory Tracker
- Laboratory Data Integrity Control Checklist

## Day 4: Data Review and Lifecycle Decisions

- ICH Q1E Stability Data Evaluation Framework
- Trend Plot and OOT Signal Review Method
- OOS Investigation Evidence Map
- Deviation, CAPA, and Change-Control Interface
- Shelf-Life and Storage Statement Support File

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## Day 5: Stability Study Practice

- Suggested Exercise: Protocol Design Review
- Suggested Exercise: Pull Schedule and Storage Plan
- Suggested Exercise: Trend and OOT Assessment
- Suggested Exercise: OOS and Change-Control Case Review
- Capstone Exercise: Pharmaceutical Stability Study Control Pack

## Practical Exercises

The course uses suggested activities based on fictional pharmaceutical manufacturing, development, laboratory, and supply situations.

- Suggested activity: build a protocol summary linking batches, conditions, intervals, tests, and acceptance criteria.
- Suggested activity: examine chamber and sample records for traceability, excursion, and data-integrity gaps.
- Suggested activity: evaluate a stability trend and distinguish an OOT signal from an OOS result requiring investigation.
- Suggested activity: assemble a cross-functional evidence file supporting a shelf-life or storage decision.

## FAQs

### Who suits pharmaceutical stability testing training, and what does it assume?

Quality, laboratory, formulation, regulatory, manufacturing-support, and technical personnel suit the training; it assumes involvement in pharmaceutical evidence or oversight and excludes independent regulatory decisions and advanced method development.

### How does pharmaceutical stability testing differ from analytical method validation training?

Pharmaceutical stability testing focuses on study design, storage, sampling, testing over time, trends, investigations, and shelf-life support, while analytical method validation training focuses on demonstrating that a method performs suitably for its intended analytical purpose.

### What is the purpose of pharmaceutical stability testing?

Pharmaceutical stability testing provides evidence of how product quality changes over time under environmental influences and supports retest periods, shelf life, storage conditions, packaging choices, and lifecycle decisions.

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## How are OOS and OOT results handled in stability studies?

OOS results require a documented investigation against established specifications, while OOT signals require review of unexpected trends against historical or expected behavior; both need protected data, scientific assessment, defined responsibilities, and controlled follow-through.

## Why are stability-indicating methods important?

Stability-indicating methods help distinguish relevant product changes from normal analytical variation so teams can evaluate degradation, quality attributes, trends, and continued conformance using methods suitable for the stability study.

## Conclusion

Participants leave with a Pharmaceutical Stability Study Control Pack containing protocol, batch, condition, schedule, chamber, sample, trend, investigation, change-control, and decision-support tools. The pack makes study evidence and responsibilities traceable. It strengthens coordination among laboratory, quality, development, manufacturing, regulatory, and supply functions.