

# **Stability Testing: ICH/FDA Regulations and Industry Best Practices**

(Two-Day course )

## **Proposed Syllabus:**

1. Understanding cGMPs of Stability Testing Requirements
  - Overview of the Drug Development Process
  - Discuss the impact of GMPs on Stability
2. Understanding FDA guidance for Stability Testing
  - Review ICH process and Q1AR2
  - Incorporate protocol to satisfy global submission
  - Discuss requirements at different phases of development
3. Develop Stability SOPs
  - Understand structure of a standard procedure
  - Discuss stability related SOPs
  - Evaluate cGMPs requirement on training personnel
4. Design Bracketing and Matrixing Strategies for Stability Testing
  - Define bracketing and matrixing from Q1A
  - Benefits and drawbacks of bracketing and matrixing
  - Discuss matrixing strategies for submission
5. Ensure that your Stability Testing Lab meets Regulatory Requirements
  - Establish laboratory controls according to cGMPs requirements
  - Establish a metrology program to increase product quality
  - Discuss key factors of environmental chambers
6. Validation of Stability Test Methods
  - Review ICH Q2A and Q2B on Validation
  - How to develop stability-indicating test methods
  - Identify special studies to support stability
7. Implement a Stability Data Management Systems
  - Discuss GMPs requirements on records and reports
  - Develop spreadsheets to effectively manage data
  - Define benefits and drawbacks of worksheet system in R&D environment

#### 8. Ensure Stability Section comply with CMC Submission Requirements

- Discuss CMC requirement highlights
- Establish information necessitate Stability Data tables
- Establish related SOPs on how to report stability data

#### 9. Conduct Out-of-Spec investigation for Stability Results

- Review FDA draft guidance on OOS and FDA Guides to inspection
- Discuss analyst's and supervisor's roles in OOS investigation
- Discuss the benefits and drawbacks of outlier test

#### 10. Prepare for an FDA Inspection of Your Stability Labs

- Identify internal problems before the inspection
- Prepare employees to effectively communicate with FDA investigators
- Incorporate effective employee training on stability concerns

#### 11. Design stability strategies to expedite the drug development process

- Build the department infrastructure to ensure product quality
- Identify key factors to reduce development timelines
- Establish systems to cycle back learnings

#### *Suggested Interactive Exercises*

Exercise 1: Review case scenarios of stability deficiencies and discuss common pitfalls according to cGMPs

Exercise 2: Propose a sample matrix based on ICH Q1D

Exercise 3: Discuss matrixing strategies for stability submission

Exercise 4: Develop an FDA/ICH compliant protocol from sample drug product information

Exercise 5: Discuss submission strategies of a stability program

Exercise 6: Discuss example FDA warning letters related to Stability Operations