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- Review FDA draft guidance on OOS and FDA Guides to inspection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
Exercice 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