

Developing and Validating Stability-Indicating Methods

Proposed Agenda:

I. Regulatory Expectations for Stability Methods

- Discuss cGMP Requirements
- International Conference of Harmonization (ICH) Requirements
- Why do we need stability indicating methods
- Determine Method Requirements
- Evaluate Regulatory Impacts

II. On the Road of Method Development

- Discussion of laboratory practices
- Design meaningful stress conditions
- Conduct forced degradation studies
- Review of instrument capability
- Establish validation Protocol

III. Validating Stability Indicating Methods

- Discuss validation characteristics
- Establish validation protocol
- Harmonize science and regulations
- Quality perspectives

IV. Interactive Activity

Participants will generate several challenges in developing stability indicating methods, from minor to major changes, and develop a plan for a specific approach to effectively monitoring product stability profiles and minimizing risks.