

# STABILITY PROGRAM

## *Proposed Agenda:*

1. FDA/ICH Guidances regulating Product Stability Program
  - Overview of stability role in the drug development process
  - Review cGMP for stability testing requirements
  - Discuss stability requirements from ICH and FDA
2. Technical Aspects of Drug Stability
  - Develop stability indicating analytical methods
  - Design forced degradation studies for HPLC analyses
  - Identify special studies to support stability methods
  - Concepts of bracketing and matrixing
3. Regulatory Aspects of Stability Program
  - Review warning letters and citations
  - Prepare stability protocols according to regulations
  - Discuss stability reporting formats for regulatory and CMC
  - Discuss Stability related operation procedures
4. Interactive discussion and exercises will be developed based on group background.