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.