

INVESTIGATIONS OF OOS/OOT

Proposed Agenda:

Part 1: Understanding Regulatory Expectations on OOS/OOT

- Determine regulatory impact of OOS
- Review of warning letters relating to OOS/OOT
- Definition of OOS and OOT
- Outline a general OOS procedure

Part II: OOS Investigation Process

- Identifying and assessing OOS test results
- Phase I: Laboratory Investigation
- Phase II: Full Scale OOS Investigation
- Conclusions and Documentations

Part III: Understanding OOT and Documentation

- Recognize different types of OOT results
- Determine course of actions to process
- Understand cross-functional investigation
- Establish documentation and performance metrics

Part IV: Interactive discussion and exercises will be developed based on group background.