Out Of Specification Results (OOS)

This course summarizes the cGMP requirements for Out Of Specification results and prepares participants to investigate and document OOS results on their own. They will learn how to write Final Reports that will stand up to regulatory scrutiny and will be useful for future investigations.

Who Should Attend: Anyone who generates or reviews laboratory test data including, QA Personnel, Stability personnel, QC laboratory managers and technicians validation personnel; and operations managers and technicians who generate data for batch records

Class Length: one day

Maximum Class Size: 20

Course Prerequisites: Working knowledge of cGMP's

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The definition of Out Of Specification test results
- A review of the history of the Barr Laboratories Decision
- FDA requirements for Investigations- Guidelines and 21 CFR requirements
- Review of 483's associated with Failure Investigations
- Define who is responsible and accountable for the investigations and why
- A review of a GMP Standard Operating Procedure for OOS
- The scientific, statistical and regulatory issues and pitfalls for Investigations
    - Re-Testing
    - Re-Sampling
    - Averaging
    - Outliers
    - Interpreting the results
    - Validation
    - Out Of Trend
    - People
    - Microbial
- Training
- Root Cause Analysis- Final Conclusions
- laboratory deviations
- manufacturing deviations
- Corrective Actions
- Final Report
- Consequences of improper investigations
- Activity: A case study will be presented

VALIDATION & COMPLIANCE INSTITUTE
537 Fort Dearborn St.
Dearborn, MI 48124
734-274-4680