Investigating Out-of-Specification (OOS) Test Results in the Laboratory

Course Description

FDA regulations require that an investigation be conducted whenever an Out-of-Specification (OOS) test result is obtained. The purpose of the investigation is to determine the root cause of the OOS result. The source of the OOS result should be identified either as an aberration of the measurement process or an aberration of the manufacturing process. To be meaningful, the investigation should be thorough, timely, unbiased, well-documented, and scientifically sound. Investigation should be conducted in a phased approach and include an initial assessment of the accuracy of the Quality Control (QC) laboratory's data. If initial assessments show no meaningful errors were made in the analytical method used to arrive at the data, a full-scale OOS investigation should be conducted and may include evaluation of the manufacturing process as well. Although this approach sounds straight-forward, performance of in-depth investigations which identify and correct root causes are extremely challenging. This course will provide you with the necessary techniques and tools to allow you to perform meaningful investigations which identify the root or most probable cause, and design and implement sustainable corrective actions. In addition, the second day of the course will focus on student performance of laboratory investigations based on recent real-world scenarios. Tools and templates for use back in your own laboratory will be provided on DVD.

Target Audience

All Laboratory and Quality Assurance personnel involved in the execution and documentation of investigations related to Out-of-Specification (OOS) test results.

Course Outline

1. Overview of Laboratory and Manufacturing Investigations in a Pharmaceutical Production Environment
2. Standard Operating Procedures for Investigating Out-of-Specification (OOS) Test Results
3. Performing Out-of-Specification (OOS) Investigations
4. Supporting Documentation
5. Developing and Implementing Corrective and Preventive Actions (CAPAs)-An Overview
6. Tracking, Trending and Periodic Evaluation of CAPA Effectiveness
7. The Laboratory's Involvement with Manufacturing Investigations
8. Personnel Training, Qualification and Re-Qualification
9. Case Studies: Small Group Break-Out Sessions
10. Selected References and Resources
11. Student One-on-One Sessions (as scheduled)