COBBLESTONE

COURSE ID 2942

Handling OOS Test Results and Completing Robust Investigations

GMP Laboratory Control Professional Certification Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Root Cause Analysis Methods
- Testing Hypotheses
- Developing a CAPA Plan
- Proper Documentation and Write-ups

about the course

It was the Barr Decision in the early 1990s that first coined the term "Out-of-Specification (OOS)." Since that landmark case, pharmaceutical companies, both drug and biologicals have had to perform adequate investigations whenever an OOS result was obtained through laboratory testing. Since that time, FDA continues to cite companies for not performing an adequate investigation.

This 90-minute accredited course is designed to provide sound training on how to recognize and investigate atypical or out-of-specification results, using approaches that have been recommended by regulatory authorities, and performing appropriate investigations.

This training is one part of the 10-course series required for the GMP Laboratory Control Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course has been developed for professionals responsible for generating or evaluating test results in a regulated environment.

Lab Analysts, Supervisors, and Managers in Pharmaceutical or Biological Laboratories, including Quality Control and Quality Assurance will benefit greatly from this training.

learning objectives

Upon completion of this course, you will be able to:

- List the responsibilities of Analysts and Supervisors
- Explain what the FDA looks for in terms of Human Errors
- Describe when a Full Investigation should be triggered
- Describe the frequency for Re-testing and Re-sampling
- Implement the corrective and preventive action plans (CAPA)

course outline

Review of Learning Objectives
Module 1
Guidelines for Detecting an OOS or Atypical Result

- Definition Atypical or Out of Specification Result?
- Review of the FDA Guidance for Industry on Investigating OOS Test Results

- Phase I: Initial Laboratory Investigation
- Phase II: Full-Scale Investigation
  - Root Cause Analysis Methods
- 5 Whys
- Flow Charts
- Check Lists
- Fishbone Diagrams

Module 2
Testing the Hypotheses Regarding Potential Root Causes

- Retesting
- Considering Other Batches

Module 3
Developing a Proper CAPA Plan to Address Any Corrective Actions

- How to properly document findings
- Example of proper OOS investigation write up

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is currently the owner of ASA Training & Quality Consulting, LLC, an Independent Consultant Agency to the Biologics and Pharmaceutical Industries specializing in the areas of Quality Assurance and Quality Systems. Prior to this role, Danielle has been in the industry for 18 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices, and provided QA oversight of numerous filling and packaging operations.

Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters and consent decrees establish more robust quality systems so that the company can succeed.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.