COBBLESTONE

COURSE ID 2581

Out-of-Specification (OOS) Result Investigation

How to Perform a Compliant, Effective, and In-depth Out of Specification (OOS) Investigation

DIRECTED BY

Charity Ogunsanya —(Owner/CEO), Pharmabiodevice Consulting LLC

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Differentiate between a true OOS, a Known Lab Error (KLE), an Atypical Event (ATE), and a Laboratory Calibration Out-of-Tolerance
- Attributes of a Full-Scale OOS Test Result Investigation
- How to report and interpret test results

about the course

Some FDA (form 483's) and other regulatory bodies' inspectional findings, FDA warning letters, product recalls and plant shutdown (voluntary or involuntary) sometimes relate to incomplete, ineffective, and non-compliant OOS investigations that impact a manufactured product. Per the regulations, all Failures, Deviations, or OOS results investigations regardless of its product impact should be appropriately documented, investigated, and analyzed for the root cause(s), with a justifiable retest plan and an effective corrective action plan. Understanding how to identify a true OOS from other types of Laboratory investigations, Invalid Assays, Known Lab Error, Atypical Events, or Lab Calibration out of Tolerance as well as when to perform a retest based on the findings of the OOS investigation is critical to achieving compliance. It is also critical to know when and how to apply "averaging" versus an "outlier" to an original test and re-test data generated during an OOS result. This will allow a product manufacturer to achieve compliance relating to an OOS investigational process.

This 90-minute accredited training will benefit manufacturers of cGMP products in designing an effective, robust and compliant OOS investigation process.

who should attend

This webinar will provide a great resource to Pharmaceutical, Biotechnology, Biologics, Drugs, Medical Device, In-vitro Diagnostics Industry personnel within the following functions:

• Quality Control	• Quality Assurance
• Analysts	• Manufacturing
• Materials	• Engineering
• Chemist	• Microbiologist
• Facilities	• Validation
• Management	• Vendors/Supplies

However, if you are already familiar with how to perform an effective out-of-specification investigation and apply its requirements, you may recommend this webinar to anyone within your company that may require additional knowledge about this subject.

learning objectives

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

- Apply the regulatory guidance and differentiate between a true OOS, a Known Lab Error (KLE), an Atypical Event (ATE), and a Laboratory Calibration Out-of-Tolerances (LCOT investigations)
- List the Attributes of a Full-Scale OOS Test Result Investigation and the step-by-step process of how it is performed
- Describe when, how and the criteria to be applied when performing re-sampling and retest of a product including handling inadequate re-sampling Methodology
- Summarize how to report and interpret test results including the appropriate and inappropriate use of "Averaging of Test Data" or "Statistical Outlier Tests"
- Describe how to handle the interpretation and disposition of products for confirmed, unconfirmed or inconclusive OOS test result investigational findings
- Describe how to Process, conclude and approve an OOS Test Result Investigation including the Impacted Departments
- List the different ways of documenting an OOS investigation (Manual versus automated system) as well as the advantages and disadvantages of each documentation system

course outline

Review of Learning Objectives
Module 1

- Regulatory and FDA Guidelines for Investigating an Out of Specification Investigation (OOS) Result
- Types, definition, and purpose of an OOS Investigation
- Differentiating between an OOS, Known Laboratory Errors (KLE), Atypical Event (ATE), and a Laboratory Calibration Out-of-Tolerances (LCOT) investigation
- Types and Examples of Possible OOS Test Results Requiring Investigation Industry

Module 2

- Detailed steps in processing, evaluating, and documenting an OOS Test Result Investigation
- When and how to perform a Sample Retest, Re-sampling, and the Criteria for Performing a Sample Retest
- Handling Inadequate Re-sampling Methodology
- How to Report and Interpret Results including when to use Averaging of Test Data and Statistical Outlier Tests

Module 3

- Appropriate and Inappropriate Use of Averaging of Data and Statistical Outlier Test
- Concluding an OOS Test Result Investigation
- Handling an Unconfirmed, Conformed, and Inconclusive OOS Test Result Investigation
- Types, benefits, and challenges of various OOS Documentation Systems
- Interpreting, documenting, approving, and closing the full-scale OOS Test Result Investigation

Question and Answer Session

Assessment Opportunity

course instructor

Charity Ogunsanya has more than 31 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology, and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and a Master's degree from the Advanced Academic Master's Biotechnology Program at Johns Hopkins University with a concentration in Biotechnology/Biodefense. She is the CEO/ Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology, and Medical Device Industries.

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