TRAINING COURSE

Investigating Out of Specification (OOS) Results

[Total Learning time = 7 hours]

This course is designed to be an exploration of best practice for OOS investigations in a GMP environment.

The course is aimed at the investigation of all out of expectation (OOE) results, including out of specification (OOS), out of trend (OOT) and any atypical, aberrant or anomalous results. For convenience, the term OOS is used in the following information, but all OOE results will be covered in the course.

Course overview

The course explores the process for investigation of OOS results and the different phases of investigation, and also best practice investigation skills for effective and scientific OOS investigations. This includes:

- Following a scientific rationale,
- The expectations of regulatory authorities,
- Gathering available evidence,
- Generating potential hypotheses,
- Testing those hypotheses,
- Interpretation of hypotheses testing using appropriate statistical tools,
- Performing root cause analysis, using appropriate and effective tools and techniques.

Learning Objectives

1. Comprehend the significance of investigating OOS results effectively.

2. Understand the process for investigation of OOS results through the phases defined by regulatory authorities such as FDA and MHRA.
3. Formulate appropriate hypotheses regarding potential assignable causes for OOS results.
4. Conduct effective and scientific OOS investigations
5. Effectively evaluate the data resulting from OOS investigations using appropriate techniques and tools.
6. Perform root cause analysis for laboratory failures which lead to OOS results and design relevant CAPAs to prevent reoccurrence.

Attendees are invited to bring along any real life examples that they would like advice on during the training. These may be discussed during group exercises, or, where intellectual property is an issue, privately with the trainer.

Delivery options for this course

This course is available either as an open enrolment option, where anyone can book onto the course, or as an in-house option where the course is run for employees in a specific company.

The open enrolment option is delivered as a 2 day 'virtual' live online training event which is delivered over a 3 hours and 45 minutes period on each day, from 9am to 12:45pm, including a short break. The time zone is typically based on GMT (UTC) from November to March, and BST (UTC+1) from April to October.

The agenda is provided on (starting on page 4) and the full schedule of dates is available on the MTS website, click here.

The in-house option may be delivered either in the live online format or in a classroom based format at your site. An agenda for the classroom based option is provided (page 6), it is typically delivered from 9am to 5pm but the timings are based on customer preference.

In-house training may include customisation to meet specific requirements. For example, it may be beneficial to use real case studies of OOS investigations performed by your group, and/or to link the steps of the course to your standard operating procedure for OOS/OOT/atypical results investigations.

This course is suitable for

Anyone who is involved in an OOS (or similar) results investigation, including those who are responsible for leading the investigation. The focus of the

content is on the analytical aspects of the investigation, rather than manufacturing.

For example:

- Quality Control (QC) analytical chemists
- Quality Control (QC) managers/ supervisors
- Quality Assurance personnel

Included in the course fees

- Comprehensive course hand-outs - The training book is provided as an electronic copy (pdf) for both live online and classroom based options.
- Certificate of Attendance
- Optional post training assessment (accessed in e-MTS, our learning management system) which leads to a Certificate of Training.
- Access to training materials via e-MTS
- Post training support – Attendees can contact the trainer with questions that may occur when they apply their learning to real life situations.

Course Agenda & Outline
Live Online Training Option

Day 1

Timings (approximate)	Content
0900 to 1045	Introduction: • Why is the investigation of OOS results important? • Atypical results (OOS, OOT and OOE) and what they mean • The investigation process for atypical results as per regulatory guidance from FDA and MHRA Phase 1 - Laboratory investigations: • Overview • Obvious errors
1045 to 1100	*Refreshment break*
1100 to 1245	Phase 1 - Laboratory investigations continued: • Laboratory investigation checklist • Tools for investigation and generating hypotheses • Hypothesis testing • Case Studies

Day 2

Timings (approximate)	Content
0900 to 0915	Review of Day 1
0915 to 0945	Phase 1 - Laboratory investigations continued: • Case studies
0945 to 1045	Phase 2 - Manufacturing investigation/additional testing • Evaluation of results using appropriate statistical techniques • Case Studies
1045 to 1100	*Refreshment break*

Timings (approximate)	Content
1100 to 1245	Phase 2 - Manufacturing investigation/additional testing continued • Case studies Concluding OOS investigations • Root cause analysis (RCA) for OOS laboratory failures • CAPAs for OOS investigations • Case studies 5 Golden Rules for effective OOS investigations Review of key messages Q&A

Course Agenda & Outline

Classroom Based Training Option

Timings (approximate)	Content
0900 to 1030	Introduction: • Why is the investigation of OOS results important? • Atypical results (OOS, OOT and OOE) and what they mean • The investigation process for atypical results as per regulatory guidance from FDA and MHRA Phase 1 - Laboratory investigations: • Overview
1030 to 1045	*Refreshment break*
1045 to 1230	Phase 1 - Laboratory investigations continued: • Obvious errors • Laboratory investigation checklist • Tools for investigation and generating hypotheses • Hypothesis testing • Case Studies
1230 to 1315	*Lunch*
1315 to 1345	Phase 1 - Laboratory investigations continued: • Case studies
1345 to 1500	Phase 2 - Manufacturing investigation/additional testing • Evaluation of results using appropriate statistical techniques • Case Studies
1500 to 1515	*Refreshment break*
1515 to 1700	Phase 2 - Manufacturing investigation/additional testing continued • Case studies Concluding OOS investigations • Root cause analysis (RCA) for OOS laboratory failures • CAPAs for OOS investigations • Case studies 5 Golden Rules for effective OOS investigations Review of key messages Q&A