TRAINING COURSE

Out of Specification (OOS) Investigations

This one day course is designed to be a highly interactive 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 result. 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,
- Performing root cause analysis, using appropriate and effective techniques and tools.

Learning Objectives

The learner will be able to:

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 using appropriate techniques and tools.
5. Effectively evaluate data resulting from OOS investigations.
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. 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.

For both options the delivery may be by live online training, where the trainer delivers the course remotely using the internet, or in a classroom based setting, where the trainer and attendees are together in the same room.

The full schedule for open enrolment courses and more information on both these delivery options is available on the MTS website.

This course is suitable for:

Laboratory staff who are responsible for leading OOS investigations and everyone associated with analysis in the pharma laboratory who may be involved in an OOS investigation.

For example:

- Analysts
- Reviewers
- Supervisors
- Managers

Included in the course fees:

- Comprehensive course hand-outs - The training book is provided as a hard copy for both live online and classroom based options. For live online training, the book is posted to the attendee prior to the event.
- Certificate of Attendance
- Optional post training assessment (accessed in e-MTS) which leads to a Certificate of Training.
- Access to training materials via e-MTS – For live online training, all course materials are accessed through e-MTS. For classroom based courses, the post training assessment and useful resources are accessed 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.

- Lunch and refreshments (for classroom based open-enrolment courses only).

Course Agenda & Outline

The agendas for the delivery options for this course differ in that the classroom based training option is a 1 day course (typically running from 09:00 to 17:00) whereas the live online training option is spread over 2 shorter days.

The agenda for each option is provided. The time zone for the classroom based option is that of the location where the training is being held. The time zone for live online open enrolment courses is typically based on GMT (UTC) from November to March, and BST (UTC+1) from April to October. For in-house training it is based on customer preference.

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 • 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

Course Agenda & Outline – Live Online Training Option

Day 1

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

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 • Case Studies
1045 to 1100	*Refreshment break*
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