

# DEVIATIONS

How to investigate, resolve and document deviations and OOS results

**INDIVIDUAL TRAINING FOR PHARMACEUTICAL & HEALTHCARE INDUSTRIES**  
DELIGHTING THE TRAINEES AND THE EMPLOYER



**Somerset Maugham, British author, dramatist (1874-1965)**

'It's a funny thing about life; if you refuse to accept anything but the best, you very often get it.'

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*This course will develop an understanding of the GMP requirements*

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**Consistently one area of GMP attracts more citations than any other – that is the area of deviation investigations.**

**In an audit, deviations are one of the first parts of our Quality System inspected. Inspectors place great value on the standard of the investigations and reports presented.**

**Modern investigations should also include the requirements of ICH Q9 on Risk Analysis.**

**This course is designed for QA/QC personnel or anyone involved in conducting and documenting investigations into deviations or OOS results in a pharmaceutical or medical device facility.**

## Course Outline

The one day course includes the following topics:

- The GMP requirements for failure investigations, including the requirements of ICH Q9
- The initial recording of the investigation, including a look at Cognitive Dissonance and Hindsight Bias
- Practical Application of Root Cause Analysis Tools, including
  - Brainstorming
  - Ishigawa (Fishbone) root Cause Analysis
  - Process Mapping
  - 5 Whys
  - Barrier analysis
  - Force Field Analysis
  - Failure Mode Analysis
- Identifying appropriate Corrective & Preventative Actions
- Evaluation of CAPA
- Documenting Investigations, including Technical Writing Techniques
- Expectations for Failure investigations in Validation Activities.
- Presenting Deviation Reports at audit

## Who should attend?

This course is designed for QA/QC personnel or anyone with a role in investigating or documenting failure investigations in the pharmaceutical, medical device, API, or Biotech industries.

## Who are we?

**GMP Services** is a team of associates with extensive pharmaceutical management expertise and the belief that a quality culture is achievable within all pharmaceutical and healthcare organisations, including our own. We are experts in the areas of Compliance, GMP, Training, Auditing, and Validation

This course is delivered by **Valerie Mulholland**, a Senior Consultant with GMP Services and is an expert in the field of GMP compliance. Valerie is well known for her interactive and fun training sessions

*"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives."*

William A Foster, US Marine Corp, WW2

## Course Cost

This one day course is run in-house for up to 20 employees. The course cost is €1500.

For a quote on other delivery options, please contact GMP Services

All training materials will be provided.

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