

Root Cause Analysis

How to use in investigations

**WORKPLACE TRAINING IN THE PHARMACEUTICAL
& HEALTHCARE INDUSTRIES
DELIGHTING THE TRAINEES AND THE REGULATOR**



With the publication of ICH Q9 and the updating of chapter 1 of The Rules governing Medicinal Products, Volume 4 – it is clear that we should be using Root Cause Analysis Tools in our investigations. However, many of us are not familiar with these tools, are unclear how we might apply them, and do not understand which methods would suit our organization best.

This course is designed to give an overview of the tools available. Examples are used to apply the tools and trainees can see for themselves how they work!!!

**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.'

*This course will develop
an understanding of
the available RCA tools
and their application*

Course Outline

Exercises are used to expose the trainee to the following RCA Tools. The exercises are designed to show the application of the methods:

- Brainstorming
- Ishigawa (Fish-bone) Root Cause Analysis
- Process Mapping
- 5 whys
- Barrier Analysis
- Force Field Analysis
- Failure Mode and Effects Analysis

This is a half day in-house course. Because of the interactive nature of the material, class size is limited to 20.

Who should attend?

This course is designed for anyone involved in the investigation of complaints, deviations or out of specification results in the pharmaceutical or healthcare 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.

Course Cost

Each course costs €600 per session; up to 2 sessions can be run on a day.

The course can accommodate up to 20 trainees.

All training materials will be provided.

“Make a proper investigation first. Proper investigation is good for a well-known person like yourself.”

Hindu Prince Gautama Siddharta, the founder of Buddhism, 563-483 B.C.)

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