

Auditing Skills

How to perform GMP Audits

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



**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.'

*Because of the
interactive nature of the
material, class size is
limited to 12.*

Many companies offer courses on HOW to audit, but only GMP Services help you to understand WHAT to look for!

Our auditing course not only delivers the essential skills an auditor requires, but also includes all the regulations you will need, discussions on the risk based approach and how to assess what issues you need to uncover.

We take people through the skills required to prepare, conduct and report on Internal Inspections, so that the inspections are value added and help avoid regulatory issues for the company. We don't forget the opening or closing meetings and following up on the corrective actions either.

Course Outline

The 2 day course covers the following material:

- Knowing your stuff – the regulations & the regulator
- Risk Management – How to assess what your audit should cover
- Preparing for an audit, including the preparation of actual checklists
- Skills and role of a good auditor
- Audit Management – time / team / topics
- Opening & Closing Meetings
- LIVE AUDIT (Highly recommended)
- Issue Evaluation & classification
- Writing audit reports
- Identifying corrective actions, appropriate timelines & effectivity measures
- Q & A

Who should attend?

This 2 day course is designed for anyone required to perform Internal, Supplier, and Contractor Audits in the Pharmaceutical, API, and Medical Device industries. It is also useful for anyone who is frequently required to present information to auditors. The second day includes a LIVE AUDIT.

"The only stupid question is the one that is never asked"

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 pharma 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 €2400 for the 2 day course.

The course can accommodate up to 20 trainees.

All training materials will be provided.

This course includes a live audit, so some facilitation will be required

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