

GMP for Auditors

Objective:

Periodically auditing for GMP compliance is a regulatory requirement. This not only requires a thorough understanding of the regulations, but also an insight into how they are being applied.

Do you auditors know how to keep current with what is being found in regulatory inspections?

It is essential that auditors understand these requirements and the importance of the function that they perform. Many inexperienced auditors have difficulty establishing when an issue is an issue and the appropriate corrective action required.

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.

However, delivering the training in an effective and interesting way can be a challenge. Especially, if most employees have heard it all before!

At GMP Services, we don't just consider what we need to say, but also how we are going to say it. This way we ensure that our courses are interesting and interactive. And because we are willing to spend some time with you discussing your products and your process, it can be customised and specific.

Suitable for:

All employees involved in auditing or monitoring GMP compliance.

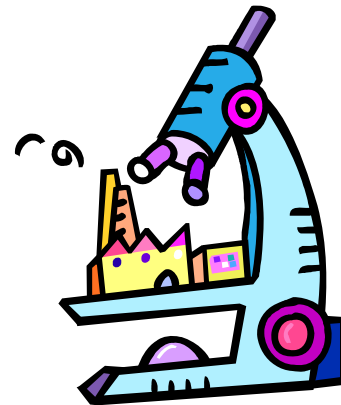
Course Details:

Basic Course (2 Days)

- Knowing your stuff - a review of regulators and regulations
- Risk Management - a role for the audit?
- Preparing for an audit



- Role of the auditor
- Skills of a good auditor
- Audit Management - checklists/ time / team
- Meetings - opening & closing
- LIVE AUDIT
- Identifying issues
- Writing audit reports
- Classification of issues
- Identifying appropriate actions & timelines
- Effectivity monitoring



A multiple-choice questionnaire will be used to evaluate the training. This is an Irish Medicine Board requirement.

On completion of training, we will provide the company with an 'Inspectors package', which will describe the course content, the tutors, the evaluation results, etc. This will allow for an easy, clear evaluation of the training by any external audit team.

Tutor:

Our GMP training courses are presented by Valerie Mulholland. Valerie is a Senior Consultant in GMP both IMB and FDA requirements. Valerie has over 15 years experience in both the medical device and finished pharmaceutical industries. Valerie has worked in the area of Quality Management for most of her career.

Valerie is a popular tutor and presents her courses in an entertaining manner.

Benefits:

On completion of this course, attendees will have a good understanding of the requirements of GMP and should be able to adopt a pro-active approach to GMP auditing.

Details:

Course cost is £2,400 for the 2 day course. This cost includes the provision of all training materials and course manuals. A session can accommodate up to 15 employees. The cost does not include tutors accommodation or travelling expenses. Travel expenses will be charged at 63c/ mile. Training facilities will be provided at the company's expense.

Further Information:

We would be delighted to make an appointment to discuss your particular training requirements.