

GMP for Managers & Supervisors

**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.'

*This course will develop
an understanding of
the GMP requirements
and their application
within a facility*

Compliance with regulations is an essential part of business in our sector. This represents some challenges for those in charge of an operation.

This one-day course sets a number of objectives. It aims to ensure that all managers and supervisors are familiar with the regulations and their requirements. It explores these requirements in the context of current issues and 'hot topics'. Forthcoming or proposed changes are also explored. Trainees should have a good understanding of their regulatory obligations at the end of this course.

But this course goes further, challenging those with a responsibility for managing a quality culture. We examine the role of quality in a busy operation and how to prioritise quality objectives. We look at Risk Management and issue resolution as key management responsibilities.

Course Outline

The course includes the following topics:

- Who are the regulatory authorities (FDA, IMB, EU, Japan, etc)
- What are the regulations (EU / US/ Japan)
- A review of the current 'Hot Topics' in the industry
- Recent and forthcoming legislation
- Risk Management – what is required
- An overview of Risk Management tools (as per ICH Q9)
- Understanding Human Error
- Resolving and Preventing Compliance Issues

This is a one day in-house course, but can be sectioned down and run in smaller sessions for specific audiences.

Because of the interactive nature of the material, recommended class size is limited 20.

Who should attend?

This course is designed for Managers and Supervisors in operations, projects or any area where regulatory compliance is a requirement. Suitable for anyone with a responsibility for ensuring compliance in an organisation through their own actions or through people that report to them.

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/chem 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

Each course costs €1500 per day session

(all materials and expenses are included)

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

The course can accommodate up to 20 trainees.

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