e: Enquiries@GxPpro.co.uk call: 07724865209/01304 362918

GxP and Quality Auditing Practices (2 days)

Overview

Audits are a fundamental part of implementing, maintaining and improving quality systems. If the audit process is deployed to the operational level of an organisation, it can serve to educate personnel and also as a means of conferring ownership for various aspects of the system.

Participants will develop skills in planning, conducting and reporting on internal quality audits. Techniques for preparing audit plans, performing the audit, verifying observations, reporting and corrective action will be studied and practiced in a syndicate environment.

Objectives

On completion, participants will be able to:

- Apply the basic principles of internal auditing
- Analyse their own quality systems in order to apply appropriate auditing activities
- Conduct internal audits to meet the requirements set out in the Codes of Good Manufacturing Practice and ISO Standards for Quality Systems
- Prepare audit check lists
- Initiate and confirm corrective actions

Contents

- Critical role of quality audit in GMP compliance & improvement.
- GMP audit schedule, managing regulatory audits in an effective manner, what to expect from GMP licensing audits.
- Documents, records & data for effective audits.
- Four fundamental steps of auditing explained in detail, tips on how to manage & facilitate audits in a constructive manner.
- Utilisation of risk management in relation to prioritising audits.

The program has a strong bias towards practice and review. On completion of this subject, students will be required to conduct a mock audit, assessing GxP risks and provide a written report on compliance status.

Format

Led by qualified presenters with many years' industry experience at senior level, the course consists of a lively mix of presentations, workshops, group exercises and discussions. Anecdotes and personal experiences will be shared to help delegates apply the knowledge in the workplace.

Attendees

This course is designed for operational personnel (key operators, supervisors and managers) who have a role in quality systems implementation.

Course Materials

Copies of all presentation slides, notes and handouts will be provided. On completion of the course, each delegate will be presented with a certificate of attendance.

Workplace Assignment

Participants are offered the opportunity to complete a GMP assignment following completion of the course. This will be facilitated and supported remotely by GxPpro's team of consultants, and successful completion will be rewarded with additional **competence** certification. There is no additional charge for this.