


Pharmaceutical Quality Management System

 **Delivery:** Classroom, Inhouse

 **Duration:** 3 days

 **Cost:** £2335 (+ VAT)

Course overview

Provides a comprehensive understanding of the key elements required for a successful Pharmaceutical Quality System (PQS) implementation and ongoing maintenance of quality standards, based on ICH Q10, EU / UK GMP and FDA guidelines. This highly interactive eLearning course provides a comprehensive and detailed guide to a Pharmaceutical Quality System, based on ICH Q10, EU / UK GMP and FDA guidelines.

Who should attend?

The course is relevant to anyone working in both quality and operational roles. In particular, this course is of direct relevance for those working in quality compliance or quality system roles.

Course programme

The course includes the following topics and reinforced using group exercises:

Day 1	Day 2	Day 3
<ul style="list-style-type: none"> Philosophy of quality management Introduction to PQS Issue management Complaints and recall Training 	<ul style="list-style-type: none"> Documentation Validation / qualification Audits and self-inspection Outsourcing Change management 	<ul style="list-style-type: none"> Product quality reviews Management review Influencing / leadership skills Soft skills Quality risk management Future of quality management

Learning outcomes

By the end of the course you will know and understand:

- The key role the PQS plays in ensuring quality and compliance
- The key elements of a PQS
- Monitoring and oversight of the PQS
- The current regulatory expectations for PQS and how these can be achieved
- The interpersonal skills associated with maintaining a robust PQS infrastructure
- Be able to produce a report that demonstrates the continuing suitability and certification of the API(s) in question
- Know how to obtain auditee cooperation and acceptance of findings

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