GxP Computerised Systems Validation & Compliance

Delivery: Online, Inhouse | **Duration:** 2 days | **Cost:** £1560 (+ VAT)

Course overview

This course covers the key concepts of GxP computerised systems validation and compliance, including the key regulatory requirements and effective industry good practice based on GAMP®5.

Computerised systems validation and compliance is a basic GxP regulatory requirement. Inadequate or inappropriate validation approaches can lead to serious compliance and quality problems. Compliant and validated computerized systems are a prerequisite for effective Data Integrity. This course describes a practical and efficient framework for computerised systems validation and compliance, following current industry good practice, and gives attendees an appreciation of how these ideas may be applied to their own systems and processes.

Who should attend?

Pharmaceutical validation professionals, IT, Engineering, Quality Assurance, Qualified Persons, Quality Control and Project Managers in the GxP and validation area. The course is also relevant for any IT or related service providers (including cloud providers), and providers of software products, or computerized systems and equipment to life science companies.

Course programme

The course covers the following topics:

- Regulatory environment and risk-based approaches
- Regulatory expectations for GxP computerised systems
- EU GMP Annex 11 requirements for computerised systems
- Overview of current industry good practice based on GAMP®5
- Computerised system lifecycle approach
- Validation planning and reporting
- Regulated company and supplier responsibilities
- Application to cloud computing and cloud service providers
- Quality Risk Management (QRM) approach
- Testing and operation of GxP systems
- Impact on data integrity
- Application of ideas and concepts to your systems

Learning outcomes

By the end of the course you will be able to:

- Understand the current regulatory expectations for GxP and EU GMP Annex 11 for computerised systems
- Gain awareness of the current industry good practice based on GAMP®5
- Understand the principles of a computerised system lifecycle approach
- Comprehend the responsibilities of your suppliers including Cloud Service Providers
- Have an understanding of the operation and testing of systems
- Be able to apply Quality Risk Management (QRM) principles
- Understand the impact of data integrity

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