

GMP FastTrack 3-day Training Course

Day 1 a.m.

Introduction to GMP and Compliance Management

- Overview of the history and development of regulatory control
- The major GMP regulators worldwide, including the roles of ICH, PICS and WHO
- Describe how MHRA and FDA regulate Products and Manufacturers – including a comparative review of the of the EU GMP and FDA cGMP rules, regulations and guidance documents
- Sources of information and guidance

Managing Quality

- Fundamental concepts of QA, GMP and QC – quality as an advantage, not a cost
- Critical QA and GMP systems:
 - Design control and change control
 - Non-conformance control
 - Corrective and preventative action
 - Annual product reviews – an EU and US requirement
- The importance of people in the management of quality

Day 1 p.m.

Risk Management

- Science-based risk management
 - FDA - Pharmaceutical cGMPs for the 21st Century: A Risk Based Approach
 - ICH - Q9 Quality Risk Management
 - WHO - Quality Assurance - Risk Analysis
- Process Analytical Technology (PAT)
- Risk management methodologies:
 - HACCP
 - FMEA
 - Etc.

Day 2 a.m.

Documentation and Records

- Types of GMP documents that are part of a quality management system
- Essential GMP requirements for documents and records
- Examples of the different types of GMP documents
- Requirements for document and record control
- Current GMP requirements for electronic records and signatures

Validation

- Reasons for validation and the development of validation and regulatory control
- Application of risk management methodologies to optimize validation activities
- The 'V' model life-cycle approach to validation documentation
- The difference between critical and non-critical items in terms of validation
- Regulatory and GMP validation guidance documents
- 21 CFR Part 11 and computer systems validation

Day 2 p.m.

Manufacturing and Packaging GMPs

- Critical GMP requirements for manufacturing control and packaging control
- Controlling pre-printed matter under GMP
- The importance of adulteration and misbranding
- Preparation and review of SOP's for control of packaging materials and line clearances
- The control of yield and reconciliation of all components that make up the final product
- Sources of information to address practical GMP compliance issues

Day 3

Contamination Control

- Understand "contamination" with respect to pharmaceutical products
- Investigate the main types of contamination and their sources
 - Cross-contamination
 - Microbial
 - Chemical
 - Foreign materials
- Using risk analysis techniques to evaluate and manage to reduce the risk of contamination

Process Control

- The use of basic SPC techniques to reinforce GMP and control of critical processes
 - Histograms
 - Process capability
 - Run charts
 - Introduction to PAT

Quality Audits

- The structure and mechanism of the auditing process
- Differences between systems and compliance audits
- Key steps in a GMP or quality audit
- Internal GMP audit programmes
- How to prepare, manage and respond to GMP regulatory audits