Good Manufacturing Practices (GMP) for Products & Hardware

Special Workshops
Orlando, Florida (USA)
25 Aug - 05 Sep 2025

Good Manufacturing Practices (GMP) for Products & Hardware

Ref: 32114_138641 **Date:** 25 Aug - 05 Sep 2025 **Location:** Orlando, Florida (USA) **Fees:** 9600 **Euro**

Course Description

This intensive 10-day course provides a comprehensive understanding of Good Manufacturing Practices GMP for products and hardware. Participants will learn essential principles, regulations, and best practices to ensure quality and compliance in manufacturing processes. The course covers key aspects of GMP implementation, quality control, and continuous improvement strategies.

Learning Objectives

- Understand GMP principles and their application in product and hardware manufacturing
- Interpret and implement relevant GMP regulations and guidelines
- Develop effective quality control and assurance systems
- Implement risk management strategies in manufacturing processes
- Apply GMP principles to facility design, equipment maintenance, and personnel management

Course Modules

Day 1: Introduction to GMP

- Overview of GMP principles and regulations
- Historical context and importance of GMP
- GMP in different industries: pharmaceuticals, medical devices, electronics
- Key regulatory bodies and their roles

Day 2: Quality Management Systems

- Fundamentals of quality management
- Developing a quality policy and objectives
- Documentation and record-keeping requirements
- Internal audits and management reviews

Day 3: Facility Design and Environmental Controls

- GMP requirements for facility layout and design
- Clean room classifications and environmental monitoring
- HVAC systems and air quality control
- Pest control and waste management

Day 4: Equipment and Maintenance

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- GMP requirements for manufacturing equipment
- Equipment qualification and validation
- Preventive maintenance programs
- Calibration and metrology

Day 5: Personnel and Training

- Personnel hygiene and health requirements
- GMP training programs and competency assessment
- Developing standard operating procedures SOPs
- Managing contractors and temporary staff

Day 6: Raw Materials and Supplier Management

- Supplier qualification and auditing
- Raw material specifications and testing
- Material handling, storage, and inventory control
- Traceability and chain of custody

Day 7: Production and Process Controls

- Process validation and verification
- In-process controls and monitoring
- Change control procedures
- Batch record review and product release

Day 8: Packaging and Labeling

- GMP requirements for packaging materials
- Packaging line clearance and setup
- Label control and reconciliation
- Stability testing and expiration dating

Day 9: Quality Control and Laboratory Practices

- GMP for quality control laboratories
- Analytical method validation
- Out-of-specification OOS investigations
- Laboratory information management systems LIMS

Day 10: Continuous Improvement and Risk Management

- CAPA Corrective and Preventive Action systems
- Risk assessment tools and methodologies
- Quality metrics and performance indicators
- Preparing for regulatory inspections

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Practical Wins for Participants

- Ability to implement and maintain GMP-compliant systems in their organizations
- Enhanced skills in quality management and risk assessment
- Improved capacity to prepare for and manage regulatory inspections
- Network with industry peers and share best practices in GMP implementation

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