Good Manufacturing Practices (GMP) for Products & Hardware

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Tunis (Tunisia)



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Why This Course

In today's highly regulated manufacturing environment, adherence to Good Manufacturing Practices GMP is essential to ensure product quality, safety, and compliance. Whether producing pharmaceuticals, medical devices, or high-tech hardware, organizations must establish robust systems that prevent errors, reduce risks, and maintain consumer trust.

Professionals responsible for manufacturing quality must understand how GMP principles apply across processes, facilities, equipment, materials, and personnel.

The GMP for Products & Hardware Program is an intensive 2-week course designed to build deep technical and practical expertise in GMP compliance. Through a combination of industry standards, hands-on applications, and real-world case studies, participants will learn how to implement, monitor, and continuously improve GMP systems within their organizations.

What You'll Learn and Practice

By completing this program, participants will be able to:

- Apply core GMP principles to ensure quality, consistency, and regulatory compliance
- Interpret and implement GMP regulations relevant to hardware and product manufacturing
- Develop and manage effective quality control and quality assurance systems
- Apply risk management tools to prevent failures and reduce manufacturing variability
- Implement GMP requirements across facility design, equipment management, materials control, and personnel practices

The Program Flow

Day 1 - Introduction to GMP

- Overview of GMP principles, regulations, and global expectations
- Historical evolution of GMP in product and hardware industries
- GMP applications in pharmaceuticals, medical devices, electronics, and high-tech manufacturing
- Roles of regulatory authorities FDA, EMA, ISO, WHO, etc.



Day 2 - Quality Management Systems

- Elements of a robust quality management system QMS
- Quality policy, objectives, and documentation structure
- Record-keeping requirements and document control best practices
- Conducting internal audits and management reviews

Day 3 - Facility Design & Environmental Controls

- GMP-compliant facility layout and workflow design
- Cleanroom classifications and environmental monitoring programs
- HVAC systems, filtration, and contamination control
- Waste disposal, pest control, and environmental hygiene standards

Day 4 - Equipment & Maintenance

- GMP requirements for equipment design, installation, and use
- Equipment qualification IQ/OQ/PQ and validation strategies
- Preventive and predictive maintenance programs
- Calibration, metrology, and traceability of measurement systems

Day 5 - Personnel & Training

- GMP personnel requirements: hygiene, gowning, and health practices
- Developing GMP training and competency assessment programs
- Writing and managing Standard Operating Procedures SOPs
- Managing contractors, temporary staff, and external personnel

Day 6 - Raw Materials & Supplier Management

- Supplier qualification, auditing, and approval processes
- Raw material specifications, sampling, and testing procedures
- Material storage, labeling, handling, and inventory control
- Traceability requirements and chain-of-custody systems

Day 7 - Production & Process Controls

- Process validation, verification, and continuous monitoring
- In-process controls, sampling, and real-time decision-making
- Change control procedures and deviation management
- Batch record review, approval workflows, and product release



Day 8 - Packaging & Labeling

- GMP requirements for packaging materials and components
- Line clearance, setup, and reconciliation procedures
- Label control systems and prevention of mislabeling
- Stability studies, shelf-life determination, and expiration dating

Day 9 - Quality Control & Laboratory Practices

- GMP expectations for QC laboratory operations
- Analytical method validation and equipment qualification
- Out-of-Specification OOS investigation best practices
- Laboratory Information Management Systems LIMS and data integrity

Day 10 - Continuous Improvement & Risk Management

- Implementing CAPA systems for systematic improvement
- Risk assessment methodologies: FMEA, HACCP, risk matrices
- Quality performance indicators and metrics
- Preparing for regulatory inspections and managing audit findings

Practical Wins for Participants

Participants will finish the program able to:

- Build and maintain a compliant GMP system tailored to their manufacturing environment
- Strengthen quality management and risk assessment capabilities
- Prepare confidently for regulatory inspections and external audits
- Apply industry best practices and share knowledge with a network of GMP professionals

Organizational Impact

Organizations benefit through:

- Improved product quality, safety, and reliability
- Stronger compliance posture and reduced regulatory risk
- More efficient processes, reduced waste, and increased operational consistency
- Enhanced culture of quality and continual improvement

Training Methodology

This program incorporates:



- GMP case studies and compliance scenarios
- Hands-on exercises in documentation, risk assessment, and process validation
- Group discussions and quality problem-solving activities
- Expert-led sessions aligned with international GMP standards

Beyond the Course

Participants return ready to:

- Lead GMP initiatives across departments
- Enhance manufacturing reliability and compliance
- Drive continuous improvement and quality excellence
- Support audit readiness and regulatory accountability

