Online GMP Training
GMP1 | Introduction to GMP

This module provides a solid introduction to control and management of manufacturing and quality of pharmaceutical products.

OBJECTIVES

- Explain why your company has implemented GMP
- State the purpose of GMP regulations
- State the four key product quality attributes
- State the requirements for personal hygiene
- Describe the correct way to complete records
- List the essential production and packaging controls

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CONTENT

Introduction
- What is GMP?
- Objectives
- Reviews and assessment
- Events that have shaped GMP
- Evolution of GMP
- Introduction to GMP codes
- GMP regulatory bodies (EMA, FDA, Health Canada, Medsafe, MHRA, PIC/S, TGA, WHO)
- Specific GMPs (FDA, EU, PIC/S)
- What is GxP?
- Why are GMPs important? Select all that apply.
- GMP stands for?
- Match the GMP regulatory body to the region

Quality
- What do you think?
- What do the GMP rules state?
- What is product quality?
- Purity
- Identity
- Effectiveness
- Safety
- Why does quality matter?
- Pharmaceutical Quality System (PQS)
- Select true or false for each statement
- Fill in the blanks

Scope of GMP rules
- What do you think?
- What do the GMP rules state?
- Scope by EU and PIC/S Guide to GMP chapters

Scope of GMP rules (continued)
- Comparing GMPs of the EU and PIC/S with the FDA
- Personnel and training
- Premises
- Equipment
- Manufacturing areas
- Manufacturing controls
- Self inspection / internal audit
- How much is true?
- What's the impact?
- Why are self inspections needed?

Cleaning, hygiene and gowning
- What do you think?
- What do the GMP rules state?
- Housekeeping
- Cleaning and sanitation
- Personal hygiene and gowning
- Topic review

Documentation
- What do you think?
- What do the GMP rules state?
- Proof of product quality
- Manufacturing records
- Rules for completing records
- Which correction is correct?
- Electronic data
- Data integrity
- True or false?
- Select all that apply

Conclusion
- Summary