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Creators of the GMP Ready-to-Use Training System™

Advanced GMP Training Programs

These six programs contain over 240 PowerPoint slides and 80 pages of participant handouts.

Module 101 - The Quality System

Module 102 - The Production System

Module 103 - The Materials System

Module 104 - The Equipment and Facility System

Module 105 - The Packaging and Labeling System

Module 106 - The Laboratory System

Module 101 - The Quality System

- A review of the US FDA System-based Inspection Approach and discuss the importance of the Quality System within the overall approach.
- A review of the specific elements covered under the Quality System.
- An overview of the ICH documents Q8, Q9, and Q10 which support and relate to Quality Systems.

Module 102 - The Production System

- A discussion of manufacturing production and process control activities and procedural and documentation requirements
- An examination of validation of processes
- A review of production personnel work responsibilities, including the legal requirement of training for production personnel

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Module 103 - The Material System

A review of the GMP general and specific requirements for:

- Starting materials
- Intermediate and bulk products
- Finished products
- Rejected and recovered materials
- Recalled products
- Returned goods
- Reagents and culture media
- Waste materials

Module 104 - Equipment and Facilities

The objective of this program is to discuss the following topics related to equipment and facilities. The program is divided into two major sections, first is equipment and the second section focuses on facility controls.

Equipment

- General Requirements and Equipment Design
- Equipment Cleaning
- Log Books
- Calibration and Maintenance
- Change Control
- Training
- Equipment Usage and Storage

Facilities

- general requirements regarding facilities
- design considerations and requirements
- areas like manufacturing, QC labs, warehouse, rest rooms, changing room and their facility requirements, design considerations and operational activities to protect the product

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Module 105 - Packaging and Labeling

- Discussion of packaging and labeling operations in general and their regulatory requirements, including before, during and after packaging and labeling of product.
- Examination of specific label and labeling requirements
- Examination of specific packaging requirements, distribution and shipping records

Module 106 - Laboratory Controls

Laboratory controls - Regulatory requirements: GMP Part 211

- Methods validation
- Out of specification results
- Stability testing
- Requirements for laboratory equipment

Pricing

GMP Advanced Six Pack for $3499.00 - savings of $1295.00

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