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GxP/GMP and its Consequences for Quality Management, Quality Audit, Documentation, and Information Technology Systems

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Organizer : GlobalCompliancePanel

Venue :

Location : Four Points by Sheraton Boston Logan Airport,
Revere, MA, US, ZIP: 02151

GxP/GMP and its Consequences for Quality Management, Quality Audit, Documentation, and Information Technology Systems

GxP/GMP regulations are required to be used in regulated industries such as food and beverages, pharmaceutical, medical devices, and cosmetics. GMP regulations describe required quality management system for production and testing of products in these regulated industries. The purpose of the GMP regulations is to ensure that a product is safe and meets its intended use.

Quality management system ensures that a product is safe and meets its intended use. Quality management system has four main components: quality planning, quality assurance, quality control, and quality improvement.

Quality audit is the process of systematic inspection of quality management system which is

carried out by an internal or external auditor or an audit team. It is an important part of organization's quality management system and is the major part of GxP/GMP regulations.

CAPA - Corrective and Preventive Action plan. It is required for FDA compliance in case of specification situations or other deviations.

Documentation is a critical tool for ensuring GxP/GMP compliance.

In the regulated environment which must be GxP/GMP compliant, document control is the cornerstone of the quality system. It is so important that if an external audit identifies deficiencies in the document control system, the entire organization can be shut down.

There are also GMP requirements for information technology. For a drug to be produced in a GxP/GMP compliant manner, some specific information technology practices must be followed. Computer systems involved in the development, manufacture, and sale of regulated product must meet certain requirements.

Change control within quality management systems (QMS) and information technology (IT) systems is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. In the regulated industries, manufactures are required to use a change control procedure.

In this seminar, you will learn the framework of GxP/GMP regulations, quality management system, quality audit, and CAPA.

You will also learn the connection between GxP/GMP and document control, details of document control procedures and the role of Quality Assurance in the documentation systems.

This seminar also includes very important GMP requirements for information technology and how computer systems including documentation management systems must meet GxP/GMP requirements. There is also a review of change control procedure and how it should be used in GxP/GMP environment.

GMP regulations require that all documentation be issued, managed, and controlled using a document management system. This seminar also includes information about few major document management systems.

Why you should attend:

GxP/GMP is about Quality Management System (QMS) where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.

There are few types of quality audits. One of them is GMP audit. GMP audit is very important and critical for an organization in a regulated industry. The preparations for the audit should be done properly before the audit. The primary objective of the audit is to demonstrate the compliance

with GxP/GMP regulations.

In the regulated environment which must be GxP/GMP compliant, document control is the cornerstone of the quality system. It is so important that if an external audit identifies deficiencies in the document control system, the entire organization can be shut down.

Documentation is the key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final product.

What is quality management system? Are you ready for the audit?

Learn about GxP/GMP regulations and how they affect quality management system and quality audit. Learn about different types of quality audits and how to properly prepare for them, what actions you need to take to ensure that your organization will pass an audit.

Do you know how to properly manage and control your documentation so that your organization can pass GMP audit? Are your IT systems GxP/GMP compliant?

Learn how to manage and control documents as well as IT systems in compliance with GxP/GMP requirements and be able to pass quality audit.

Who will benefit:

- Quality Assurance
- Documentation Managers
- Records Managers
- Document Control
- Compliance
- Medical Affairs
- IT

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