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Deviation management and CAPA (2 days)

Overview

Regulators continually cite one of the main reasons for GxP deficiencies in organisations as an inability to effectively manage their deviations through CAPA. Although organisations clearly identify deviations, rarely do they perform a well structured investigation which accurately defines the root cause.

Organisations should have a well defined policy relating to deviation management and a full understanding of the various tools and techniques available to ensure that the CAPA system is achieving the desired results. Many organisations view CAPA as simply a regulatory "tick in the box" but when applied properly it provides a tool for continually improving processes and avoiding future failures.

Objectives

On completion of the course, delegates will:

- Understand the regulatory requirements of a deviation and CAPA system
- Understand Human Error and error investigations
- Be able to relate the guidelines in ICH Q10 to deviation and CAPA
- Be able to classify deviations
- Be able to identify when to use CAPA
- Be able to carry out root cause analysis in relation to preventative and corrective action.
- Be able to identify an assess risk (RRF, FMEA)
- Be able to document and manage CAPA's efficiently
- Be able to improve operational and regulatory performance by effective deviation management

Content

The course covers the following topics:

- Presentation on ICH Q9 and Q10
- Deviation management
- Corrective and preventative action (CAPA)
- Classifying deviations - Major – Minor
- Root cause analysis – Five why's plus alternative approach to reviewing Human Error
- Principles of Risk management (identification, analysis, control)
- Introduction to Risk management tools (RRF, FMEA)
- Regulatory guidance for applying risk management to pharmaceuticals
- Understanding Human factors and error investigations
- Investigating Error "The Forensic Investigator"
- Case Studies
- Company specific CAPA review exercise

Format

The course consists of a mix of presentations, workshops, group case study exercises and discussion. Anecdotes and personal experiences will be shared to help delegates apply the knowledge to the workplace.

Attendees

The course is designed for a wide range of participants from specific disciplines within the pharmaceutical industry. Typically, participants will be manager or supervisors who have experience in GMP related environments.

Course Materials

Copies of all presentation slides, notes and handouts will be provided. Upon completion of the course, each delegate will be presented with a certificate.