e: Enquiries@GxPpro.co.uk call: 07724865209/01304 362918

Quality Risk Management (2 days)

Overview

Recent regulatory requirements means that organisations are now expected to integrate Quality Risk Management (QRM) into their current quality system. QRM can be used to either help with making decisions about events that have happened in the past (i.e. release of a product that hasn't met specification), or to evaluate change and come to a decision (i.e reducing the level of validation). In each case, the outcomes should be based on data and any other relevant information.

It is extremely important that QRM is properly integrated into your current quality system and not used in isolation. It is also important to understand when there is a need to use QRM and when not to use QRM.

Our 10 step process (based on ICH Q9) will ensure that a thorough evaluation process in place, which includes ensuring that the right people are involved throughout the process as well as effective documentation of your evaluation and outcome.

Objectives

On completion of the course, delegates will:

- Understand the regulatory requirements of Quality Risk Management (ICH Q9, part 3 of EU GMP Guide, chapter 1 EU GMP guide)
- Understand the relationship of QRM to existing quality systems
- Understand the GxPpro10 step process and how to use it within your organization
- Understand how QRM can be used as part of a continuous improvement strategy
- Be able to Identify the components and principles of QRM
- Be able to Identify where risk management is already being applied in your organization
- Be able to develop a strategy for implementation within your organisation
- Practically apply QRM to specific work related cases

Content

The course covers the following topics:

- Presentation on ICH Q9
- Appropriate use of QRM
- ICH Q9 model (Initiation, assessment, control, outcome/documentation, review, communication, tools)
- GxPpro10 step process
- QRM tools (RRF, FMEA, simple logic)
- Associated tools and techniques (Brainstorming, process mapping, fishbone diagram, 5 whys)
- 2 Principles of QRM
- Potential applications of QRM
- Documenting QRM
- Implementation of QRM in your organization
- Case studies
- Application of QRM to company specific topics

Format

The course consists of a mix of presentations, workshops, group case study exercises, company specific 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 managers, supervisors, QPs or technical experts 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.