Risk Management for Clinical Research

One day

Objectives

- Understand risk management tools and when and how the tools are used in clinical research projects
- How to plan risk based approaches, how to document this, and where to focus to meet regulatory requirements and expectations
- Develop and apply risk management principles and tools to your clinical research projects
- Identify and share best practices for implementing risk based tools and principles

Introduction

Risk management is becoming increasingly important to running clinical trials. There are now numerous pharmaceutical guidelines covering risk management including ICH Q9, the revised ICH GCP guideline, recently released EU Clinical Trial Regulation guideline on risk management and several other risk management clinical research standards and initiatives.

This essential one day course will explain the importance of using risk management techniques in Clinical Research to comply with the latest focus on GCP inspection in this area. You will learn how to identify, evaluate and also how to implement specific risk based techniques for risk management used in clinical trials.

This course will enable you to identify and share best practices for implementing risk management tools for clinical research.
Programme

Objectives

An overview of risk management

- Why risk management is important?
- Definitions of key risk management terminology
- Regulations and guidelines which cover risk management applied to clinical study-level risk management

Risk based QM system – what does this really mean? How does it look?

- The elements of QM system are and what a regulatory inspector would expect to be in place for clinical trials
- Participants share what they have in place in group discussions

Risk based process/tools and techniques

- Examples of Risk Management Process
- Risk based tools including
  - Root Cause analysis, 5 Whys, risk register, risk matrix, and examples of pharmaceutical risk tools for clinical trials including RACT (Risk Assessment Categorization Tool)

Risk based approach to the protocol

- e.g. Quality by design (QbD) applied to the protocol
- How this is being applied to the design of protocols

Risk based approach to monitoring / data handling

- Different approaches to risk based monitoring and examples of how this is carried out - eg of monitoring plans, and group discussion of what approaches and document participants use
- case study example

Brief review of risk based approaches to QC / QA (Auditing)

- Example of best practice guide RQA (Research Quality Association)

Summary and Close

Timings: start 9.30, 11.00 Break, Lunch 13.00 to 14.00, 15.15 Break, Close 17.00
COURSE LEADER

**Dr Laura Brown** is an independent Pharmaceutical QA and Training Consultant, and Course Director for the MSc in Clinical Research, School of Pharmacy at the University of Cardiff, UK. Laura has more than 20 years’ experience of Quality Assurance and managing international clinical trials including risk identification and management. She has worked for several companies including GSK, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has consulted with numerous pharmaceutical companies, suppliers to the pharmaceutical industry as well as academic institutions.

Dr Brown has an MBA with specialisation in project management including risk management. She was the external project management expert for a pharmaceutical e-learning MSc module in project management covering risk management, and the author of two books on project management including the leading book “Pharmaceutical Project Management” (Gower).