UNDERSTANDING RISK MANAGEMENT

Background

The ultimate responsibility for the performance of a pharmaceutical product during its lifetime; safety, quality, and efficacy, lies with the marketing authorisation holder (MAH). To achieve the quality objective, “there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice, Quality Control and Quality Risk Management.”

Updated to reflect the 2023 Revision 1 of ICH Q9, this workshop provides you with a thorough understanding of quality risk management as set out in ICH Q9. We will explore the full extent of the approach and practice, the most commonly used tools and techniques to improve your decision-making skills, and better protect your organisation and your patients by addressing both proactive and reactive risk management.

We will discuss on how to take a structured, risk-based approach to quality management to enable a science- and data-based approach toward the business, enabling a detailed process understanding to allow establishing control strategies. We explore the best practice approaches including risk perspectives and incorporating risk in the pharmaceutical quality system.

We will discuss facilitation methods and tools such as flowcharts, process mapping, and cause and effect diagrams (also called Ishikawa or fish bone diagrams). We then consider the statistical tools that enable effective data assessment, aid in determining the significance of the data set(s) and facilitate more reliable decision-making, including control charts to turn data into information. We will also introduce the less frequently used tools and their applicability, and explore real-life scenarios and case studies using the most commonly used techniques of failure mode effect analysis (FMEA) and Hazard Analysis and Critical Control Point (HACCP)

Learning Objectives

1. Understand how to apply ICH Q9 routinely and in times of crisis in the workplace
2. Learn how and when to use the supporting facilitation and statistical tools
3. Learn decision-making tools such as FMEA and HACCP

Target group

- Production or Manufacturing
- Research and Development
- Quality Control (QC)
- Quality Assurance
- Regulatory Affairs

Programme

The presentation will consist of a presentation emphasizing practical approaches of conducting effective investigations as per regulatory requirements; practical cases studies relating to production and analytical processes emphasizing the following:

- Risk-based decision-making – The theory
- Practical implementation and use of ICH Q9
- Good decision-making practices (reactive and proactive)
- FMEA and HACCP
- Fishbone diagrams and other techniques

Presenter

Mbonisi is a qualified pharmacist and formulation scientist with a great passion for the pharmaceutical industry with extensive research background and has served in well renowned organizations. His experience includes medicine systems consultancy; technical operations; operations management; pharmaceutical development; academia; regulatory affairs; strategic planning and execution.

Mbonisi holds a postgraduate degree and a vast number of courses from various institutes and thus he well versed with current techniques, skills and standards in the pharmaceutical industry and various business environments. He holds a Bachelor of Pharmacy (B.Pharm) degree, Master of Science (M.Sc) in Pharmaceutical Chemistry degree from Rhodes University in collaboration with University of Tiaret (Algeria). To date he has published three journal articles and co-authored one book chapter.