PharmaConsult (Pty) Ltd
Reg. No. 2018/030383/07
Cell: 082 457 1380
Email: rkietz2@gmail.com

Pharmaceutical Quality System Element - QUALITY RISK MANAGEMENT
Date: 28 Sept 2026, 09h00 – 12h15 via MS Teams

PRESENTER: Rosemary Kietzmann
Pharmaceutical Quality Consultant

Rosemary is the owner and Director of consulting company PharmaConsult (Pty) Ltd., which provides comprehensive quality management activities, training sessions, cGxP inspections & gap analysis audits, compilation and implementation of theoretical and practical PQS processes and compilation of SAHPRA Inspection deficiency responses, amongst other service offerings.

COURSE OUTLINE:

Quality Risk Management (QRM) principles should be applied across each product's life cycle. Failure to demonstrate an effective QRM program to facilitate compliance with cGxP is often reported as a deficiency by Health Authorities.

The focus is on your assessment of how your facility is implementing a comprehensive QRM procedure – is it being used proactively and is it adding value to your facility?

In this workshop, we will work through the theory and requirements of QRM with reference to the guidelines. We will discuss the QRM element in depth, review the terminology and review the templates suggested for both the QRM Report based on the FMECA model and the QRM Register and how to apply them in a practical and effective manner. A brief review of risk analysis tools is included. Thereafter we will review a practical compilation of the required documentation for various scenarios:

- A proactive FMECA QRM Report, including a pFMEA example, related to a Change Control record
- A concurrent FMECA QRM Report related to a temporary Change Control
- A reactive FMECA QRM Report related to a Deviation
- A QRM Register – multiple entries
- QRM Review requirements – requirements and application with a practical example.

Finally, we will assess the further applications of implementing QRM as part of integrated quality management and the relevance of QRM assessments with continuous improvement initiatives.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for either compiling or QRM Reports / Registers &/or conducting the review of these from contract acceptor sites.
- Responsible Pharmacists and/or Batch Release Pharmacists who are required to comply with the GMP requirements for Handling of Deviations, to assess the impact of the deviation and its associated risk category, wherever it occurred during the manufacturing and testing process of the batch, prior to making their batch disposition decision.
- Senior Management, whose leadership and active participation in the Quality Management System is essential, to make decisions regarding provision for appropriate resources such as personnel, financing and time to organise, plan and execute the QRM activities.