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COMPILING QUALITY INVESTIGATIONS using ROOT CAUSE ANALYSIS TOOLS, QUALITY RISK MANAGEMENT REGISTERS AND ANNUAL PRODUCT QUALITY REVIEW REPORTS – THEORY AND PRACTICAL APPLICATION

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Rosemary has spent more than 35 years working in the pharmaceutical industry, specifically in Quality Control, Quality Assurance, Regulatory Affairs and Technical Operations including Supply Chain, for local and international manufacturers of medicines and for Applicants of registered medicines. The products range from: biosimilars in medical device presentations; sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; homeopathic and herbal preparations; OTC products.

She has extensive knowledge of managing QC and QA departments and is passionate about ensuring quality is built into each product by applying an effective quality management system and following cGMP requirements. Her passion is training people who wish to fully understand how the QMS works and who want to contribute positively and make a difference in their organisations.

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

COURSE INTRODUCTION:

Pharmaceutical Companies who are the Holders of the Certificate of Registration (HCR) supplying medicinal products to patients in South Africa, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the PIC/S Guide to GMP for Medicinal Products and relevant international guidelines. Health Authorities inspect pharmaceutical HCRs to confirm this compliance and where Inspectors identify non-conformances, they issue their observations regarding the affected areas. Over the course of all drug product inspections performed by the FDA in 2022, the FDA rated the following observation as the second highest experienced: “Investigations of discrepancies, failures”. Similarly, the lack of “Thorough Investigations” was the second highest observation recorded

from all Biologic product's inspections in 2022. In addition, articles on non-conformance areas following inspections, and warning letters issued, include many that relate to non-compliance with cGMP, such as: Lack of effective utilisation of root cause analysis (RCA) tools; Failure to effectively perform investigations competently; Lack of application of QRM principles across the product life-cycle; Failure to demonstrate a systematic approach to QRM to facilitate compliance with GMP and other quality requirements.
Furthermore, the compilation of a comprehensive APQR Report, where the HCR is not the sole player in the sourcing of all data required, is frequently recorded as a non-conformance.

In this workshop, we will work through the theory and requirements of each of these three key areas of our QMS, with reference to the guidelines. We will discuss various RCA tools and how to apply them in an effective manner. Thereafter we will break up into small groups to perform a practical compilation of the required documentation for each parameter, based on various scenarios that will be provided. Each group will then present their compilations for further discussion.

As the HCR in SA, how do your QA / Regulatory / Compliance personnel address and effectively manage these requirements when subcontracting manufacturing and/or testing to third party contract-acceptor sites, either located locally or internationally? How do you plan these activities? How involved are you or should you be with these? Does your site, as the HCR, have relevant protocols and procedures in place that govern these activities?

This workshop, held by SAAPI as an in-person, one day session in Johannesburg, aims to provide to delegates, a forum in which to discuss three key QMS principles: RCA; QRM; APQR. The intention is to enable delegates to consider ways to proceed in a compliant manner as part of the requirement of continuous improvement initiatives in the pharmaceutical industry.

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 collating source data to produce the required QMS documentation for the three areas in scope of this workshop.

- Personnel who are required to demonstrate competence in both using RCA Tools effectively for inclusion in Investigation Reports and/or responsible for reviewing and assessing RCA Tools used by the Contract- Acceptor sites.
- Responsible Pharmacists and/or Batch Release Pharmacists who are required to comply with the GMP requirements for Handling of Unexpected Deviations, to assess the impact of the deviation, wherever it occurred during the manufacturing and testing process of the batch.
- 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 above-mentioned activities.

COURSE CONTENT:

- ✓ Regulatory Guidelines and references
- ✓ Relevant QMS terminology
- ✓ Personnel roles and responsibilities
- ✓ Quality Investigation requirements with explanation of several Root Cause Analysis Tools
- ✓ Practical small group sessions: Using various RCA Tools to compile Investigation Reports based on scenarios provided. Delegates present their Reports.
- ✓ Introduction to Quality Risk Management and examples on how to compile a QRM Schedule / Register.
- ✓ Practical small group sessions: Compiling QRM Registers based on scenarios provided. Delegates present their Registers.
- ✓ Introduction to Product Quality Reviews - Identification of Source documents required from both Sending Unit and Receiving Unit.
- ✓ Demonstration of various process flows to achieve a comprehensive APQR Report.

COURSE OUTCOMES:

At the end of this workshop Delegates should have a clear understanding of the following:

- ✓ Knowledge of the sections in various GMP Guidelines on the topics included in the workshop.

- ✓ How to compile and/or review an Investigation for a product or process, together with effectively using or assessing use of applicable RCA Tools, based on the quality risk level of the deviation / non-conformance / quality defect, to the product under review.
- ✓ Awareness of the requirements of Quality Risk Management as an integral part of product life cycle management.
- ✓ Compiling QRM entries into a comprehensive register that includes all areas within the site under scope.
- ✓ Awareness of the various roles and responsibilities across multiple sites, for collation of all source data required to compile a comprehensive APQR Report.
- ✓ How to interpret the APQR as a source of Continuous improvement initiatives.
- ✓ Networking with colleagues in the industry to facilitate knowledge sharing.