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QA FOR QC LABORATORY PERSONNEL WORKSHOP:
Quality Management System (QMS) requirements for compliance

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B. Sc (Chemistry & Biochemistry)

WHO SHOULD ATTEND THE WORKSHOP:

- Quality Control Managers / Heads, Supervisors / Team Leaders, QC Chemists / Analysts and QC Equipment / Facility / Analytical method technical specialists who are responsible for compiling, implementing, performing and / or monitoring the QMS elements within the laboratory. This includes personnel employed in Manufacturer's / Contract Manufacturer's (CMOs) QC laboratories and those in Contract Acceptor site laboratories.
- Quality Assurance Pharmacists, QA Personnel and Responsible Pharmacists working in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that an effective QMS is designed, developed and implemented in the QC Laboratory or are responsible for self-inspections of their company's QC laboratory or for auditing contract QC Laboratories.

Note: This workshop does not include any information pertaining to laboratory techniques or requirements for performing the testing. It is concentrated on ensuring that all areas required to operate within an effective quality management system are in compliance with the current requirements. It applies to laboratories for testing of the finished pharmaceutical product (FPP), intermediates, starting materials for the production of the FPP and in-process controls.

COURSE INTRODUCTION:

Pharmaceutical manufacturers, in the capacity of the Holder of the Certificate of Registration of a product (HCR) - either contracting with international manufacturing sites and importing medicines into South Africa for distribution, or contracting with local manufacturers or manufacturing themselves locally, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP and the PIC/S Guide to GMP (PE009). The role of the head of Quality Control (QC) is described as one of the key personnel with clear responsibilities listed for this person, together with shared responsibilities with the heads of Production and Quality Assurance (QA). They are required to participate in the management reviews of process performance, product quality and

the Quality Management System (QMS) with a view to advocating continual improvement. In addition, the head of QC is responsible to ensure that performance of analytical chemistry and microbiological testing on pharmaceutical products, are similarly required to comply with Good Laboratory Practice (GLP). This incorporates Quality Risk Management (QRM) as part of Laboratory Control. The South African Health Products Regulatory Authority (SAHPRA) requires a set of standard operating systems (SOPs) and master documentation to be implemented. The attainment of this quality objective is the responsibility of senior management and all laboratory staff and includes suppliers and service providers contracted with each laboratory. This forms a foundation for ensuring compliance that all registered medicines are handled accordingly to produce the required level of quality, safety and efficacy.

This comprehensive workshop is presented over two (2) consecutive mornings on 30 & 31 July 2025, from 08:30 to 12:30 each day. It is hosted by SAAPI and presented virtually via MS Teams.
It covers multiple QMS elements based on relevant pharmaceutical guidelines. Specific elements will be addressed in each module as described below, with provision of practical examples for many elements. This workshop provides either an introduction to the requirements of managing the QMS for a QC laboratory or provides a refresher course for reflection of the applicable QC areas within your company or provided by outsourced laboratories, to equip QC personnel as well as QA personnel and Responsible Pharmacists in their self-inspection activities, preparation for local health authority inspections or contract auditor roles.

COURSE CONTENTS:

- ✓ Regulatory Guidelines and references – WHO, PIC/S, USP and key master documentation requirements: SMF, Quality Manual, VMP, Quality Contracts
- ✓ Application of the QMS to QC Laboratories - including QRM, GMP, GLP, GDocP
- ✓ Personnel requirements
- ✓ Laboratory facility design – process flows for analytical chemistry and microbiology areas and environmental monitoring
- ✓ Laboratory equipment, computer systems & utilities – qualification, validation and calibration, preventative maintenance program, cleaning/sanitation

- ✓ Laboratory documentation requirements & controls – including data integrity principles and release of test results process
- ✓ Technology transfer – analytical method transfer requirements; method validation / verification and lifecycle management
- ✓ Laboratory Materials & Equipment management – Supplier qualification process & external audits; outsourced activities
- ✓ Test Sample Process Management - receiving, storage, sampling and process flow of samples through the laboratory including testing to sample disposal
- ✓ QMS elements – Deviation, RCA, CAPA, Change management
- ✓ Customer Focus – additional requirements (Stability Trails / Investigation testing / Transport Validation), client complaints
- ✓ Out of Specification management - application of root cause analysis principles
- ✓ Self-Inspection process
- ✓ Quality measurement, including trend analysis and Senior management reviews and continual improvement

COURSE OUTCOMES:

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

- ✓ Knowledge of the concepts of GLP included in the QMS requirements, based on theory from the Guidelines.
- ✓ Awareness of how the QC role is integrated into the QMS implemented at their site.
- ✓ How they can contribute to identifying areas of both compliance and non-compliance in on-site or at contract laboratories.
- ✓ Awareness of the practical implementation of the process flow of samples through the laboratory.
- ✓ Awareness of how to review the individual requirements to support decision making in terms of managing risk and identifying areas for continuous improvement initiatives.
- ✓ Awareness of the responsibility of senior management to be actively involved in the review of quality measurements reported by the laboratory personnel, in order to ensure a quality culture is entrenched in the company.

PRESENTER:

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 manufacturers of medicines and for Applicants of registered medicines. The products range from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; biosimilars and medical devices; 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 Quality Management System (QMS) / Pharmaceutical Quality Systems (PQS) processes and compilation of SAHPRA Inspection deficiency responses, amongst other service offerings.