SAAPI 2026 WORKSHOP OUTLINES

QA REQUIREMENTS FOR QC LABORATORIES – 22 & 23 APRIL 2026

WORKSHOP 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), amongst other guidelines. 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). Both QC and QA personnel are required to participate in the management reviews of process performance, product quality and the Pharmaceutical Quality System (PQS) 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 8-hour workshop is presented over two (2) consecutive mornings on 22 and 23 April 2026, from 09:00 to 13:00 each day. It is hosted by SAAPI and presented virtually via MS Teams.
It covers multiple PQS elements based on relevant pharmaceutical guidelines. Specific elements will be addressed in each module as described in the Course Contents section below, with provision of practical examples for many elements. This workshop provides either an introduction to the requirements of quality assurance functions and oversight, including management of the PQS, within 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 / Persons in their self-inspection activities, preparation for local health authority inspections or contract auditor roles.

It will assist one to identify areas of process improvement or more effective implementation and for documented evidence of your attendance on such a course.

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 PQS 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 / Persons working in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that an effective PQS 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 CONTENT:

- ✓ Regulatory Guidelines and references – WHO, PIC/S, USP and key master documentation requirements: SMF, Quality Manual, VMP, Quality Contracts
- ✓ Application of the PQS 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
- ✓ PQS elements – Deviation, RCA, CAPA, Change management, Effectiveness Checks
- ✓ 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 reviews, 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 PQS requirements, based on theory from the Guidelines.
- ✓ Awareness of how the QC role is integrated into the PQS 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 Kietzmann

Owner and Director of pharmaceutical consulting company: PharmaConsult (Pty) Ltd.

Over 40 years' experience in the Industrial Pharmaceutical sector.

Core activities include quality and compliance consulting support for the pharmaceutical industry in: training; inspection readiness including gap analysis; conducting cGxP audits; cGxP CAPA Response inspection remediation; PQS elements compilations; technology transfer process of Quality sections from the registered dossier to the site of manufacture / analysis; Assessment of personnel for contracted facilities.