

## **SAAPI 2026 WORKSHOP OUTLINES**

### **cGWP and cGDP FOR LICENSED PHARMACEUTICAL FACILITIES: 16 APRIL 2026**

#### **WORKSHOP INTRODUCTION:**

Pharmaceutical Warehousing and Distribution of human and veterinary medicines, as per the Medicines and Related Substances Act 101 of 1965, need to adhere to current regulatory requirements of Good Warehouse Practice (GWP) including Good Storage Practice (GSP) and Good Distribution Practice (GDP), across the supply chain lifecycle of each product, based on SAHPRA, WHO and additional guidelines. The South African Health Products Regulatory Authority (SAHPRA) requires that all facility personnel are adequately trained. In this workshop we will discuss both the theory as well as provide examples of compliant implementation of practical expectations to ensure that they are implemented correctly to protect the integrity of the medicinal products and to improve compliance and audit readiness. Examples of non-compliance or deficiencies in fully addressing the issues will be provided to highlight expectations of the relevant requirements.

Topics are listed in the Course Content section below.

This 4-hour workshop, held by SAAPI via MS Teams, provides either an introduction to the requirements of cGWP and cGDP or provides a refresher course for reflection of the applicable areas within your company, 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 Assurance personnel and Responsible Pharmacists working in or contracting with licensed pharmaceutical warehouses managing Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that facility personnel are appropriately trained in cGWP and cGDP requirements and are effectively implementing these activities.
- Warehouse and Distribution Facility Personnel who are responsible for embedding the requirements of a comprehensive pharmaceutical quality system (PQS) in the facility to support a quality culture.
- Warehouse and Distribution Operational personnel who are involved in areas related to ensuring compliance with cGWP & cGDP requirements in their facility.
- Supply Chain personnel and Senior Management who are required to be familiar with cGWP

and cGDP requirements.

**COURSE CONTENT:**

- ✓ Introduction to cGWP, cGSP and cGDP
- ✓ Regulatory Framework
- ✓ Current cGxP key hot topics  
Awareness of cGWP and cGDP elements with examples of compliance and non-compliance include:
- ✓ Organisation and Management
- ✓ Pharmaceutical Quality System – and Quality Risk Management
- ✓ Personnel requirements and responsibilities
- ✓ Premises and Equipment requirements – Environmental monitoring
- ✓ Supplier Qualification
- ✓ Customer / Client Verification
- ✓ Inventory Controls – Computer Systems Validation, Security & Counterfeit medicines
- ✓ Good Documentation Practices – PQS elements with Data Integrity focus, Record Keeping
- ✓ Disposal of products – acceptable segregated storage requirements for returns, recalls, rejects, products under investigation or in quarantine
- ✓ Distribution – Transport validation; use of couriers and personal collection
- ✓ Effectiveness checks on cGxP training – includes various techniques to apply
- ✓ On-line Assessment – issued at the end of the workshop, to be completed on-line within 24 hours of the workshop

**COURSE OUTCOMES:**

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

- ✓ Knowledge of the concepts of the elements included in good warehouse, storage and distribution practices.
- ✓ How one can contribute to identifying areas of both compliance and non-compliance.
- ✓ Awareness of the applicable national and international regulatory guidelines.
- ✓ Awareness of Regulatory expectations regarding the implementation strategies of the Guidelines.
- ✓ Awareness of the responsibility of a Facility involved in the supply chain routing, to

communicate effectively with the Manufacturer / Holder of a Certificate of Registration of the medicinal products to fully understand both the quality aspects and handling requirements of the product and sharing of data generated as part of the PQS, for all products both incoming and returned.

- ✓ Individual training requirements and documenting assessment evidence of such.

**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.

