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

SAAPI

Supplier Management - Qualification of Suppliers and Conducting Audits on Outsourced Contract – Acceptor Sites and compilation of Technical Quality Agreements.

Date: 19 August 2026 – 09:00 to 12:15 on-line via MS Teams

PRESENTER: Rosemary Kietzmann

Owner and Director of pharmaceutical consulting company: PharmaConsult (Pty) Ltd.
Core activities include quality and compliance consulting support for the pharmaceutical industry including: training; inspection readiness and gap analysis; conducting cGxP audits; inspection CAPA Plan remediation; technology transfers; compiling operational PQS documentation.

COURSE INTRODUCTION:

Holders of a Certificate of Registration (HCR) for medicinal products need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP (SAHPGL-INSP-02) and the PIC/S Guides to GMP (PE 009-17), Part I, Chapter 7: Outsourced Activities which provides guidance on the roles and responsibilities of Contract Givers and Contract Acceptors. The South African Health Products Regulatory Authority (SAHPRA) includes reviews evidence of the process performed by the HCR to document qualification and approval processes for each outsourced activity, and of the HCR's contracts entered into with outsourced service providers involved in any part of the lifecycle of the registered products. The expectation is that the HCR personnel are suitably trained and possess the requisite level of knowledge to enable them to competently perform a comprehensive review and assessment and external cGxP inspections of proposed or of existing Contract Acceptor sites, where applicable, on a risk-based approach, on Warehouses, Manufacturers and Packers, Quality Control Laboratories – analytical chemistry and microbiology, Distributors, Printed artwork producers, API and IPI sites, Retention sample storage, Document storage, Stability Trials laboratories, Packaging suppliers, Utilities providers and such like. Any cGxP activity that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. HCR cGxP Auditors are required to establish appropriate Standard Operating Procedures and an Audit Schedule that is based on the assessment of risk, to inspect these sites for compliance to ensure that all registered medicines are of the required quality, safety and efficacy.

There is consensus within the local pharmaceutical industry that contract-giver companies must exercise Chapter 7 oversight of their contract manufacturers and should not wait for an inspector to identify gaps at outsourced sites.
The RPs of HCR companies are required to commit that they implement and execute a robust pharmaceutical quality system that includes alignment with Chapter 7.

In light of the recent industry communication and knowledge referred to above, each company should be working with each of their Contract-Acceptor facilities to ensure that this knowledge is shared and escalated internally to assist each facility to implement compliant cGxP processes and to adhere to cGMP requirements appropriately.

Each contract-giver site is expected to implement and perform due diligence on their contract-acceptor sites to provide evidence that the Contract Acceptor meets the predefined criteria for qualification and acceptance by the HCR. The frequency of ongoing inspections is required to be stated in order to ensure that each product remains compliant during its life-cycle. In addition, a contractual agreement is required to be compiled and approved between both parties to ensure that roles and responsibilities are clearly specified for each party and signed off in agreement.

This short course held by SAAPI via MS Teams, introduces personnel involved in managing and monitoring outsourced activities, to key requirements in terms of the process to define each supplier type, to qualify suppliers, and the requirements for various audit programs, liaison with Senior Management at both parties and requirements for the TQA between the two parties. Practical tools, documentation and relevant examples will be included in order to prepare you to conduct your vigilance of outsourced sites to maximum benefit to ensure that your objective is met.

WHO SHOULD ATTEND THE COURSE:

- Pharmacists (Regulatory and Quality Assurance) and Quality Assurance personnel, in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that their outsourced activities comply with the Guidelines, are implemented and beneficial in terms of reducing risk and providing evidence of continuous improvement initiatives, as well as Senior Management who wish to develop their knowledge in this area.

- Personnel from Contract Acceptor sites involved in the supply chain will benefit in terms of awareness of the requirements to prepare for their Contract Giver's requirements for compliance with cGxP.
- Pharmaceutical Sites – Manufacturing, Packing, Testing
- Applicant only Sites (Importing &/or Procuring from local contract sites)
- Warehouse & Distribution sites
- QC Laboratories

KEY ARES IN THIS SESSION INCLUDE:

- ✓ Supplier classification and processing on a risk-based approach for qualification and approval processes
- ✓ Definition and Types of External cGxP audits
- ✓ Regulatory Guidelines and references
- ✓ Objectives and expectations for the external audit process
- ✓ Qualification process to appoint suppliers with inclusion in the ASL
- ✓ Requalification process - Risk rating review and effectiveness check
- ✓ Compilation of a comprehensive TQA – acceptable good practices to ensure clarity of each party's roles.