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

SAAPI 2026 WORKSHOP OUTLINES

CURRICULUM 1: STRUCTURE OF A COMPREHENSIVE PHARMACEUTICAL QUALITY SYSYTEM

The approach to the 2026 SAAPI Short-course workshops has been enhanced to present them in a modular way where specific cGMP and regulatory requirements are grouped into curriculums consisting of multiple sessions and each session leads on to the following session within each curriculum.
A life cycle approach to each curriculum ensures that we address all areas in the training materials within the scope of each topic.

In Curriculum 1, we are exploring the topic: Structure of a comprehensive Pharmaceutical Quality System (PQS).
We discuss answers to the question: What is a comprehensive PQS?
Based on ICH Q10 and with reference to PIC/S and WHO Guidelines, we start with understanding the core requirements in Session 1 and work our way up to discussing how we can assess all data to advance our facility's PQS to reach a mature state – the optimised best-in-class level.

Curriculum 1 consists of 3 separate workshops:
Session 1 (04 Feb 2026), Session 2 (11 Feb 2026) & Session 3 (04 Mar 2026).

In this series of *three* separate short workshops, presented on-line via Teams from 09h00 to 12h15 each session, we will work through the various components of a Pharmaceutical Quality System (PQS) to understand what contents are required and the extent of the scope of these contents. Each workshop session is designed to prepare for the following session so that we build on the foundations laid in the previous session for each Curriculum. It will be beneficial for a delegate to attend all 3 sessions in each Curriculum for continuity of the related topics, to join the dots, however a delegate may also select their session of choice to attend and still obtain the benefits of those individual workshops.

In Session 1 (04 Feb 2026), we return to the basics as a starting point for the Responsible Pharmacist or delegated quality assurance colleague or relevant personnel, in human and veterinary medicines pharmaceutical facilities. We explore key criteria for setting up the structure of a PQS in a tiered

approach. We then delve deeper into each supporting element and include a practical implementation, hands-on approach to completing these requirements.

Key areas in this session include:

Content of a PQS and Regulatory References;
How to compile a Site Master File (SMF), a Quality Manual and a Validation Master Plan (VMP);
How to compile an effective SOP - Back to Basics;
How to compile a PQS record - Linked to an SOP;
How to Compile a PQS Register;
And finally, an overview of the requirements of Good Documentation Practice (GDocP).

The goal of this session is to set the foundation for implementing a PQS on which to build the processes required to support the core PQS, including the PQS elements and the PQS enablers. These will be discussed in detail in Curriculum 2: Understanding Core PQS Elements (4 sessions).

In Curriculum 1, Session 2 (11 Feb 2026), we challenge the effectiveness of our PQS contents by exploring how to conduct an effective self-inspection process and we look into personnel aspects for qualifying and certifying an internal auditor.

In Curriculum 1, Session 3 (04 Mar 2026), we delve into the assessment of the data that we are required to record / save throughout the implementation process of each PQS and how to interpret the data to make key decisions related to continuous improvement initiatives and process improvements. We include the role of senior management's participation in this process as well as look into the requirements of a comprehensive and unambiguous Technical Quality Agreement (TQA) to support clarity between all parties to enable quality and regulatory compliance.

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 in: training; inspection readiness including gap analysis; conducting cGxP audits; inspection remediation; technology transfers.