MASTER PHARMACEUTICAL QUALITY SYSYTEM (PQS) DOCUMENTATION WORKSHOP: 15 JUL 2026

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 presented in multiple short sessions to enable personnel to attend while still having time in the day to complete operational requirements.

Based on ICH Q10 and with reference to PIC/S and WHO Guidelines, we include understanding the core requirements of a compliant PQS and in further workshops we 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.

In this workshop, presented on-line via Teams from 09h00 to 12h15, 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.

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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; compiling operational PQS documentation.