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# Qualification and Validation Requirements - Relevant to FPP Manufacturers and to HCRs managing outsourced activities Date: 29 July 2025, 08h30 – 12h30 via MS Teams

**PRESENTER:** Rosemary Kietzmann
Pharmaceutical Quality Consultant

Rosemary is the owner and Director of consulting company PharmaConsult (Pty) Ltd., which provides comprehensive quality management activities, training sessions, cGxP inspections & gap analysis audits, compilation and implementation of theoretical and practical Pharmaceutical Quality System (PQS) processes and compilation of SAHPRA Inspection deficiency responses, amongst other service offerings.

**COURSE OUTLINE:**

Qualification of facilities, utilities and equipment is a critical step in a pharmaceutical manufacturing facility because the process is intended to provide confirmation that equipment possesses the attributes required by each process required to be executed, has been installed appropriately and is capable of performing within the specific operational parameters required to produce each batch of product meeting the registered specifications. The type and degree of qualification needs to be conducted following an impact assessment, in conjunction with risk management tools, to determine which components of a process have the most potential for impact on the form, fit and function of the product. The process involves identification of systems with direct impact, indirect impact or no impact on product quality. From this point, qualification protocols are developed to assess the suitability of each system / piece of equipment.

Following the above process, the traditional Validation “V” Model is then implemented to provide the documented evidence of a successful Qualification process from the User Requirement Specification (URS) through to the Performance Qualification (PQ) stage, which follows the Installation Qualification (IQ) and Operational Qualification (OQ) stages, amongst other stages. This is usually applied to direct-impact systems. A Commissioning approach may be concluded for indirect-impact systems.

Product and Process knowledge are crucial in the determination of requirements for facilities, utilities and equipment supporting the manufacturing process.

Successful Process Qualification activities confirm the process design and set the foundation for the successful Validation of manufacturing and packaging processes used to produce commercial finished pharmaceutical products (FPP) with established scientific evidence that a process is capable of consistently delivering quality products.
Decisions are made on the Process Validation Strategy approach required for each process type and these conclusions are compiled in the Process Validation Strategy / Plan report per product - There are several approaches to conducting comprehensive Validation activities – Prospective, Concurrent and Traditional, Continued Process Verification or a hybrid of these.

Comprehensive Documentation is mandatory to ensure that the Q&V processes are recorded in a manner that provides evidence of compliance and adheres to data integrity requirements. The Validation Master Plan provides the framework for the implementation of each Validation Strategy / Plan that requires execution. Thereafter detailed protocols are required to be compiled that clearly indicate all steps required in each process. Based on the data generated throughout the Q & V processes, the final Validation Report is compiled to support verification to proceed with the process under review.

This workshop will prepare both the local manufacturing facility and the HCR facility who manages contract facilities, with insights into what is required to ensure effective and compliant Q & V activities are in place with the related GMP documentation required to support a successful execution of Q & V processes.

In addition, we will briefly mention Validation requirements for: Cleaning processes; Computerised systems; QC Equipment; Analytical Methods; Storage and Transport.

Practical tools, documentation and relevant examples will be included in order to assist you with the planning and preparation that is required to ensure a successful process.

In this workshop, held over one (1) morning via MS Teams, we will discuss the following topics which include examples of documents to compile:

- Regulatory and GxP reference documents
- Qualification and Validation Terminology with definitions
- Types of Validation Approaches / Strategy including Impact assessments on a risk-based approach
- A brief introduction to Good Engineering Practice (GEP)
- Understanding the requirements of the Validation V Model – including DQ, IQ, OQ and PQ
- What to prepare – a practical list of documents required with supporting examples: VMP, Validation Strategy / Plan, PPQP and PPQR / PVP and PVR with suggested contents based on WHO Guidelines
- Sampling requirements for Validation studies – Introduction to ISO 2859-1:1999 AQL sampling plan
- Introduction to Statistical Process Control (SPC) using the Process Capability Tool (Cp & Cpk) Brief overviews of the following topics:
- Cleaning process validation requirements
- Computer Systems Validation requirements
- Transport Validation and Verification requirements
- Analytical Test Method Validation (ATMV) / Verification (ATMVe) requirements and Qualification requirements for Laboratory equipment
- Storage Validation requirements including temperature mapping studies

**WHO SHOULD ATTEND THE COURSE:**

- Production Pharmacists together with Validation Specialists and Pharmaceutical / Industrial Engineers assigned the responsibility for managing the Q & V activities on site.
- Quality Assurance personnel, Pharmacists and Quality Control Responsible Persons, Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for review and approval of documentation related to Q & V activities.
- HCR RP's and CMO QA personnel managing the Technology Transfer process for the launch of a registered finished product into the local market or for export and for finished product

transfers to alternate manufacturing sites. Q & V activities follow the Technology Transfer process.

- Quality, Regulatory, Supply Chain, Qualification and Validation, Manufacturing & Maintenance personnel and other associated Subject Matter Experts who are required to be part of the cross functional team who contribute to the execution of each Validation Strategy / Plan.