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Pharmaceutical Quality System (PQS) Element - Self Inspections – Schedule, Checklists and Verification Process Date: 21 August 2025, 08h30 – 11h00 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 PQS processes and compilation of SAHPRA Inspection deficiency responses, amongst other service offerings.

COURSE OUTLINE:

cGMP requires that all registered pharmaceutical facilities implement the requirements for performing a Self Inspection (SI) program to ensure compliance across all activities, either performed at the facility or managed by the facility. The process is intended to minimise risk, improve communication and accountability within the company and to ensure that pharmaceutical companies consistently meet the required standards of cGxP and Pharmaceutical Quality Systems and that these remain in a state of control. Practical tools, documentation and relevant examples will be included in order to prepare you to conduct your Self Inspection program to maximum benefit to ensure it is comprehensive and adds value as a continuous improvement initiative. The focus will be on ensuring that Verification processes are included in the process to comply with data integrity principles, rather than approaching the process as a tick-box exercise. The scope does not include how to qualify SI auditors nor the full process for conducting Self inspections.

In this short workshop, we will briefly discuss the guideline requirements for performing a self inspection, followed by examples on how to practically compile:

- A SI Schedule – with examples on how to group departments / areas including examples of what to inspect under each grouping;
- Assigning frequency of SI activities according to a quality risk-based approach;
- Various approaches used for conducting a SI;
- SI Checklists - with references to various sources for assistance with preparation;
- Examples of what not to do and how to correct the usual format of SI checklists;

- Suggested starting points for compiling SI Verification actions;
- Multiple examples of Verification actions;
- Example of a format for inclusion of the verification checks performed;
- Example of a SI Register.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for managing / performing Self inspection activities, including compilation of the Self inspection schedule and checklists.
- Responsible Pharmacists and/or Subject Matter Experts who are required to be part of the quality review &/or approval team for assessment to determine Facility suitability and compliance with cGMP, quality and regulatory requirements.