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Pharmaceutical Quality System (PQS) Elements - CAPA, Change Management and Effectiveness Checks Date: 20 May 2026, 09h00 – 12h15 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:

To facilitate successful outcomes for process improvements and continuous improvement initiatives, it is important for pharmaceutical personnel to fully understand the principles and quality systems requirements related to the CAPA and Change Management Systems. Best practices incorporate accessing knowledge from multiple sources and records to make informed decisions – this is a fundamental part of the ICH Q10 PQS framework. Effective CAPA processes must be implemented to prevent recurrence of quality issues and to improve or enhance the current PQS. Personnel are required to be equipped with practical tools for compiling the documentation, for performing analysis of the proposed CAPA and Change Management activities and completing the successful implementation of the actions required. Once implemented, a review of the effects of the changes is required as part of a formalised, documented effectiveness check procedure. There should be a CAPA lifecycle approach to record metrics for management oversight and contribute to continuous improvement initiatives.

In this short workshop, we will work through the theory and requirements for translating the Investigation root cause statement into meaningful corrective actions, with further preventative actions as required & how to record these actions. Will discuss how to assess, plan and execute a Change Control record with related change actions. We will explore the link in the quality system between all three elements, concluding with Effectiveness Checking. Practical examples will be presented as discuss the concepts, to illustrate the theory. We will review relevant terminology and practical examples of the basic formats for: a CAPA and a Change Control Register; an Effectiveness

check process flow diagram and record template. Thereafter we will work through multiple case studies for various scenarios from source documents listed below, in which we will review suggested content for each of the PQS records – CAPA, Change Control and Effectiveness Checks, that are required to be compiled to progress these source documents:

- Case Study 1: Deviation raised during the manufacturing process
- Case Study 2: Quality complaint for a finished product released to the market
- Case Study 3: Process Capability out of specification result for a finished product
- Case Study 4: Deviation raised during the packaging process

Finally, we will review suggested points to include in an Effectiveness Check SOP.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for any of the following actions: reviewing the outcome of Root Cause Analysis problem statements; compiling related CAPA actions into formal records; part of the Change Management team for reviewing and approving proposed changes; for conducting effectiveness checks on closed CAPA and Change Control records; reporting outcomes in the Quality Management Review process. This includes personnel responsible for managing contract acceptor sites and performing oversight roles related to the contractor's / supplier's quality system.
- Responsible Pharmacists and/or Subject Matter Experts who are required to be part of the quality review team for assessment of proposed CAPA, change controls and effectiveness checks to determine suitability and compliance with cGMP and Regulatory requirements.
- Senior Management, whose leadership and active participation in the Quality Management System is essential, to make decisions regarding provision for appropriate resources such as personnel, budget and time to organise, plan and execute comprehensive CAPA and Change Management systems.