



Pharmaceutical Quality System Element - QUALITY ISSUES
Deviations & Investigations using Root Cause Analysis Tools

Date: 06 May 2026, 09h00 – 12h15 via MS Teams

PRESENTER: Rosemary Kietzmann
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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:

Deviation handling is part of conducting current Good x Practice requirements during the life cycle of pharmaceutical products. Deficiencies reported as a result of recorded deviations and quality audit observations must be addressed with the due investigation initiatives related to the classification of each issue. Failure to demonstrate an effective investigation program to facilitate compliance with cGxP is often reported as a deficiency by Health Authorities. Reference: FDA 483s annual publication.

In this short workshop, we examine closely the topics of Deviation and RCA and answer the questions: What is a deviation? How do we structure a deviation investigation procedure? What RCA tools should we consider and how do we effectively implement them? What are the benefits of implementing a comprehensive RCA process?

The principles are based on the ICH Q10 framework included under PQS elements and the PIC/S Guideline.

We work through the theory and requirements for implementing a structured deviation process flow that includes a stepwise explanation of what actions should be completed during each step. We discuss how to apply relevant investigation processes and explain some of the frequently used root cause analysis (RCA) tools and how to apply them in an effective manner. We will review relevant terminology and examples of: a Deviation Report; a RCA Report template; a Deviation Register.

Thereafter we will work through multiple practical applications for various scenarios:

- A review of a template for the Deviation Report and RCA Report



- Case Study 1: Deviation with investigation using RCA tools
- Case Study 2: 5 Whys application for an Operator error
- Case Study 3: Deviation & RCA Tools - 5 Whys & Ishikawa applied for a manufacturing process change; Executed Deviation Report with executed RCA Investigation
- Examples of Audit deficiencies and decisions taken with assessment of suggested ways to manage them within the PQS
- A review of a RCA Investigations SOP.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for either compiling Deviation Reports & Registers, reviewing and responding to audit deficiencies &/or conducting quality investigations using RCA tools & /or for conducting the review of the above from contract acceptor sites.
- Responsible Pharmacists and/or Batch Release Pharmacists who are required to comply with the GMP requirements for Handling of Deviations, to assess the impact of the deviation and its associated risk category, and for reviewing related RCA investigations, wherever they occurred during the manufacturing, testing & transport processes relating to the batch under review, prior to making their batch disposition decision.
- 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 Deviation and RCA investigation activities.