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Technology Transfer Process and Protocols- Relevant to Sending Units and Receiving Units Date: 22 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:

Technology Transfer is a logical procedure that controls the transfer of any product or process, including knowledge and documentation and professional expertise. It may involve development, manufacturing or testing sites. (WHO TRS No. 1044, 2022, Annex 4). When a product is identified to be launched in South Africa or for provision of continuous supply of already launched product, the Holder of Certificate of Registration (HCR) for the product is required to manufacture and test the product as per the Regulatory dossier approved by the local Health Authority (SAHPRA). Where a change in the site of manufacture or/and the site of analytical testing from the registered site is necessary, the HCR (as the Sending Unit) is required to identify a suitable site and to perform a comprehensive transfer of technology process with this site (the Receiving Unit). In addition, the HCR is required to manage a contract site according to the required cGxP processes for Outsourced Activities (PIC/S PE 009, Chapter 7).

This workshop will prepare both the local HCR facility and the related identified Receiving Unit site for executing a comprehensive Transfer of Technology process, as per the four phases specified in a Technology Transfer Project, as per WHO guidance. It relates to manufacturing facilities and to analytical FPRC laboratories.

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 transfer.

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
- Overview of the Technology Transfer (TT) process for business continuity
- What to prepare – a practical list of documents required to be shared by both the Sending Unit (SU) and by the Receiving Unit (RU)
- The four phases of a TT Project
- TT process flows
- Quality Risk Management impact assessment for both parties
- Requirements of a comprehensive TT Project Plan
- Suggested Table of Contents for the TT Plan / Protocol – to be compiled by both the SU and the RU
- TT Project review and close-out
- Requirements for the Analytical Method Transfer (AMT) process and compilation of the AMT Protocol

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Responsible Pharmacists and Quality Control Responsible Persons, Scientists / Specialists, in Human and Veterinary Medicines, who are responsible for managing the Technology Transfer process, for planning, preparation and internal training of personnel for executing the project. This applies to both the HCR facility (SU) and to the manufacturing &/or testing facility (RU).
- Quality, Regulatory, Supply Chain, Qualification and Validation and Manufacturing personnel and other associated Subject Matter Experts who are required to be part of the cross functional team who contribute to the execution of the project.