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HCR MANAGEMENT OF TECHNOLOGY TRANSFER, QUALIFICATION AND VALIDATION PROCESSES AT CMOs or INTERNAL FACILITIES

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B. Sc (Chemistry & Biochemistry)

Rosemary has spent more than 35 years working in the pharmaceutical industry, specifically in Quality Control, Quality Assurance, Regulatory Affairs and Technical Operations including Supply Chain, for local and international manufacturers of medicines and for Applicants of registered medicines. The products range from: biosimilars in medical device presentations; sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; homeopathic and herbal preparations; OTC products.

She has extensive knowledge of managing QC and QA departments and is passionate about ensuring quality is built into each product by applying an effective quality management system and following cGMP requirements. Her passion is training people who wish to fully understand how the QMS works and who want to contribute positively and make a difference in their organisations.

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

COURSE INTRODUCTION:

Pharmaceutical Companies who are the Holders of the Certificate of Registration (HCR) supplying medicinal products to patients in South Africa, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the PIC/S Guide to GMP for Medicinal Products and relevant international guidelines including WHO. In order to launch a new medicinal product in the South African market or to perform a site transfer of a commercialised product to an alternate facility, the HCR is required to follow a set of activities as part of the product life cycle management. There must be a risk-based and science-based process to achieve the state of control required. This forms a foundation for ensuring compliance that all registered medicines, scheduled substances and medical devices are handled accordingly to produce the required level of quality, safety and efficacy.

Activities required prior to launch or site transfer include, but are not limited to: CMO/s selection, qualification and approval; Identification of Source Documentation required – Quality & Regulatory; Technology Transfer between Sending Unit and Receiving Unit/s; Due diligence and Gap Analysis; Quality Risk Management assessment; Project Management; Change Management and life cycle approach; Control Strategy- with related Protocols and Reports; Qualification and Validation – includes statistical sampling plans.

As the HCR in SA, how do your QA / Regulatory / Compliance personnel address and effectively manage all these requirements when subcontracting many of these processes to third party contract-acceptor sites, either located locally or internationally? How do you plan these activities? How involved are you or should you be with the Receiving manufacturing and testing sites? Does your site, as the Sending Unit, have relevant protocols and procedures in place that govern these activities?

This workshop, held by SAAPI via MS Teams over two separate sessions on two consecutive days, aims to provide to delegates, a forum in which to discuss the Technical Transfer processes and to obtain information on the Qualification and Validation requirements to be addressed between Contract Giver and Contract Acceptor sites. This includes theory on the Quality & Validation processes which will be explained. Sampling requirements related to these processes will also be discussed. The intention is to enable delegates to consider ways to proceed in a compliant manner as part of the requirement of continuous improvement initiatives in the pharmaceutical industry.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Science personnel, in Human and Veterinary Medicines who are responsible for ensuring that a newly registered medicine to be launched as a commercialised product, as well as marketed products undergoing a site transfer, are manufactured, tested and released in compliance with both GMP requirements and according to the registered dossier specifications.
- Personnel who are involved in areas related to Product Launch Management / Product Life-cycle Management / Project Planners / Technology Transfer / Qualification & Validation, amongst others pertinent to your facility.

- 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, financing and time to organise, plan and execute the above-mentioned activities.

COURSE CONTENT:

- ✓ Regulatory Guidelines and references
- ✓ Qualification and Validation terminology
- ✓ Brief overview of Launch readiness and Site transfer strategies
- ✓ Personnel roles and responsibilities
- ✓ Introduction to Technology Transfer principles
- ✓ Identification of Source documents required from both Sending Unit and Receiving Unit – Quality and Regulatory
- ✓ Technology Transfer documentation – project management phases
- ✓ Brief Quality Risk Management overview and application related to introduction of a new product / process
- ✓ Introduction to Qualification and Validation principles
- ✓ Overview of ISO 2859 – 1:1999 Sampling procedures for inspection by attributes, Part 1
- ✓ Qualification & Validation Documentation – VMP; Validation Strategy / Plan; PVP; PVR; VSR

COURSE OUTCOMES:

At the end of this workshop Delegates should have a clear understanding of the following:

- ✓ Knowledge of the multiple GMP Guidelines available on the topics included in the workshop.
- ✓ How to review a pFMEA for inclusion of a new product / process, from a contract-acceptor site.
- ✓ Awareness of the requirements of Technology Transfer as an integral part of product life cycle management.
- ✓ What roles are required of the HCR, to manage product launch or site transfer activities and documentation, prior to producing commercial product.

- ✓ Understanding of the theory of Qualification and Validation and roles and responsibilities of each site.
- ✓ How to ensure that the Validation protocols include all CPPs and CQAs with associated compliant statistical sampling plans.
- ✓ How delegates can prepare and/or review CMO Qualification and Validation Records to identify both compliance and non-compliance by the CMO.
- ✓ Awareness of what GMP documentation should be compiled, saved and included at which site.
- ✓ Awareness of the responsibility of the HCR to manage the contract sites that they appoint.