PharmaConsult (Pty) Ltd
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TRAINING FOR PHARMACEUTICAL SELF INSPECTION AUDITORS of Applicant and Manufacturing Facilities 24 & 25 July 2024 (8:30 – 12:30)

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COURSE INTRODUCTION:

Pharmaceutical Medicines Manufacturers, both in the capacity as Applicants and / or contract manufacturers and Applicants importing medicines into South Africa for distribution or manufacturing products at local contract sites, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP (SAHPGL-INSP-02) and current PIC/S PE 009-17. South African Health Products Regulatory Authority (SAHPRA) is responsible for arranging for their GMP Inspectors to inspect these sites for compliance to ensure that all registered medicines are of the required quality, safety and efficacy.

SAHPRA requires each site to implement and perform routine cGxP activities, including GMP, GDocP, GWP, GDP compliance and compliance with the registered product dossier, throughout the entire life cycle of each product in order to remain compliant at all times. This includes internal periodic reviews by means of self-inspections of the following: the Quality Management System (QMS); Personnel; Premises & Equipment; Documentation; Artwork & Labelling; Production; Quality Control; Audits; Outsourced activities; Storage and Transport, all in order to ensure that there is a state of control. It has been observed that personnel at times lack a structured training program to address attributes required by inspection team members, to be proficient in and capable of performing a comprehensive self-inspection program.

This one-day course, held over two mornings by SAAPI via MS Teams, introduces personnel involved in managing and participating in the self-inspection program, to key requirements in terms of qualification of the personnel included in the self-inspection team, planning, preparation, training staff in audit skills, conducting the inspections on the scheduled days and activities to be performed, compilation of the deficiencies noted, be part of the root cause analysis investigation team, suggesting corrective actions in response to the deficiencies observed, discussions with the relevant departments and personnel and closing out the process. Practical tools, documentation and relevant examples will be included in order to prepare you to implement your Self Inspection program to maximum benefit to ensure a smooth experience for all involved as well as adding value as a continuous improvement initiative.

WHO SHOULD ATTEND THE COURSE:

Pharmacists (Regulatory and Quality Assurance) and Quality Assurance personnel, in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that

their Companies adhere to the cGMP requirement for conducting Self-Inspections on an annual basis as well as senior management who wish to develop their knowledge in this area, from:

- Pharmaceutical Production Sites – Manufacturing, Packing
- Applicant only Sites (Importing &/or procuring from local contract sites and Marketing)
- Wholesale & Distribution sites

COURSE CONTENT:

- ✓ Regulatory Guidelines and references
- ✓ Purpose and Benefits of the Self-Inspection process
- ✓ Self Inspection Program:
- ✓ Self inspection internal controls – ICH Q10; Schedule and format for the SOP; QRM
- ✓ Qualification and Approval of Inspectors
- ✓ Composition and key competencies of the Self-Inspection Team for various departments
- ✓ Self Inspection Processes -Various approaches used for conducting the Self-Inspection
- ✓ Self Inspection SOP contents with practical application for compiling each section
- ✓ Self-Inspection cGxP Inspection Contents, Checklists and Aide Memoirs covering expectations of requirements in the areas to be inspected on site
- ✓ Conducting the self inspection process for QMS elements with examples of what to prepare for your QMS inspection
- ✓ Regulatory elements and examples of what to prepare for your Regulatory inspection
- ✓ Production areas and examples of what to prepare for this section
- ✓ Warehouse and distribution areas requirements
- ✓ QC Laboratory requirements
- ✓ Self-Inspection Report, classification of observations and post inspection activities, including CAPA, gap analysis and effectiveness checks – includes a practical session
- ✓ Examples of noted Deficiencies

COURSE OUTCOMES:

At the end of this course the attendees should have a clear understanding of the following:

- ✓ Understanding of key requirements for personnel performing self-inspections as well as the training program required to qualify these inspectors, captured in an SOP
- ✓ Knowledge of the concepts of the requirements that need to be in place in order to prepare your site for the self-Inspection process and compilation of a comprehensive SOP
- ✓ Site preparation activities required in terms of preparing the Self Inspection Schedule on a risk based approach
- ✓ Compiling the Self Inspection Report and communication

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- ✓ Follow up actions required based on the Self-Inspection Report, including the CAPA response format required with timelines, together with effectiveness checking
- ✓ Communication requirements with the senior management personnel to ensure that they are suitably trained in expectations of involvement with the Self-Inspection process and the benefits and outcomes of the process

PRESENTER:

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 manufacturers of medicines and for Applicants of registered medicines. The products ranged from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; biosimilars and medical devices; homeopathic and herbal preparations; OTC products.

She has extensive knowledge of conducting numerous cGMP inspections nationally and internationally and is passionate about ensuring quality is built into each product by applying an effective quality management system and following cGMP requirements. Furthermore, Rosemary has led or been part of multiple cGMP Self-inspection teams, not only used for annual compliance purposes but also for preparing the local facility for Health Authority inspections and for Global or Group Audits. She has also performed inspections of facilities as part of a due diligence gap analysis process when considering contracting with or purchasing such facilities.

Rosemary is the owner and Director of consulting company PharmaConsult (Pty) Ltd., which provides expert project management activities, training sessions and implementation of theoretical and practical QMS processes, amongst other service offerings.