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SAHPRA INSPECTION READINESS

PRESENTER: Rosemary Kietzmann
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 manufacturers of medicines and for Applicants of registered medicines. The products ranged from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; 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.

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.

COURSE INTRODUCTION:

Pharmaceutical Medicines Manufacturers and Applicants importing medicines into South Africa for distribution, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP (4.01). Our 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 cGMP activities, including quality control compliance and compliance with the registration dossier, throughout the entire life cycle of each product in order to remain compliant at all times. This includes regular reviews by means of self-inspections of the following: the Quality Management System (QMS); Personnel; Premises & Equipment; Documentation; Production; Quality Control; Audits; Outsourced activities including Supplier approval for multiple components, all in order to ensure that there is a state of control.

This workshop held by SAAPI via MS Teams in several session over 2 half - days, introduces personnel involved in managing Health Authority inspections, particularly their site's SAHPRA Inspections, to key requirements in terms of planning, preparation, training staff in audit skills, hosting the day, activities to be performed, compilation of the responses to the findings and closing out the process. Practical tools, documentation and relevant examples will be included in order to prepare you to implement your Inspection readiness to maximum benefit to ensure a smooth experience for all involved.

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 are prepared for Health Authority Inspections as well as senior management who wish to develop their knowledge in this area, from:

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

COURSE CONTENT:

- ✓ Definition and Types of Inspections
- ✓ Regulatory Guidelines and references
- ✓ Purpose of an Inspection
- ✓ Benefits of Inspection Readiness and an Inspection readiness process
- ✓ Self-inspection internal control
- ✓ Composition and key competencies of the Inspection Team
- ✓ Various approaches used for conducting the Inspection
- ✓ Checklists covering expectations of requirements in the areas to be inspected on site
- ✓ SAHPRA communication with pre-Inspection requirements
- ✓ Personnel preparation for the Inspection
- ✓ Inspection Day activities
- ✓ SAHPRA Inspection Report and deficiency classification and fees
- ✓ Examples of noted Deficiencies
- ✓ SAHPRA Inspection Report CAPA report compilation as per SAHPRA Guidelines
- ✓ SAHPRA Resolution letter – GMP certificate and renewal process

COURSE OUTCOMES:

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

- ✓ Knowledge of the concepts of the requirements that need to be in place in order to prepare for a SAHPRA Inspection
- ✓ Appointment of the Company's Inspection Team with relevant training completed
- ✓ Site preparation activities required in terms of preparing the logistics, correct personnel on duty, access-controls and documentation for the Inspection period
- ✓ Interpretation of the Inspection Report and the CAPA response format required with timelines
- ✓ Communication with the senior management personnel to ensure that they are suitably trained in expectations of involvement with Inspection meetings