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cGMP for RESPONSIBLE PHARMACISTS of Applicant and Manufacturing and Warehouse Facilities

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; biosimilars; allopathic, generic and complementary medicines; 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.

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:

Manufacturers of pharmaceuticals need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SAHPRA SA Guide to GMP (SAHPGL-INSP- 02). This guideline includes Section 4 which provides the requirements for the PIC/S Guide to GMP, Annexure 16, which specifies country specific requirements for the role of the Responsible Pharmacist in South Africa. The responsibilities of the RP are also clearly stated in the SAHPRA GWP Guideline (SAHPGL-INSP-03)

SAHPRA requires the Responsible Pharmacist (RP) to be aware of and involved with routine activities performed throughout the business – both on site and at Contract sites. This includes: Legal compliance; the Quality Management System (QMS); Regulatory Affairs; Personnel; Premises & Equipment; Documentation; Production; Quality Control; Audits; Outsourced activities including

Supplier approval for multiple components; warehousing storage conditions and transportation, all in order to ensure that there is a state of control.

This 2- day course held over 2 mornings (8:30 am to 12:30 pm) by SAAPI, introduces personnel involved in these areas, to the fundamental principles of implementing a comprehensive overview of the legal requirements of fulfilling this role, competency requirements, activities required to be included in the job description, and responsibilities required based on the guidelines . It is focussed on cGxP requirements related to ensuring compliance of the quality of the product that is released to patient. Benefits include using this approach to ensure that the role is understood by Senior Management and to meet expectations of the Regulators.

This will be of particular interest to Pharmacists responsible for taking on the role of Responsible Pharmacist in one of multiple environments as outlined below.

WHO SHOULD ATTEND THE COURSE:

- RPs - at Applicant sites with their own local manufacturing facilities or Applicant sites importing finished product and/or manufacturing at local contract manufacturing sites
- Production Pharmacists and Quality Assurance Pharmacists working in the sites above, who may deputise for the RP or wish to understand the role of the RP / Deputy RP
- Pharmacist Assistants (Basic and Post Basic) working in the sites above
- Pharmacists or Quality Assurance personnel in other disciplines who wish to develop their knowledge in these areas

COURSE CONTENT:

- ✓ Regulatory Guidelines and references
- ✓ Legal compliance including SA Pharmacy Council requirements
- ✓ Human Resources requirements
  - ➢ Organogram
  - ➢ Job descriptions and KPIs
  - ➢ Educational assessments
  - ➢ Training
  - ➢ Competency assessments

- Hygiene and PPE
- Letters of delegation

✓ Ethical considerations

✓ Integration into the Quality Management System (QMS) - Documentation

- QTA / Supply Agreements / PMP / SLA / SOP Database / Data Integrity
- Master batch document controls

✓ Product handling

- Artwork and Promotional Material
- Launches
- Storage and transportation verification
- Samples and Batch release

✓ Regulatory Affairs

- New/Generic product submission
- Variations

✓ Quality Assurance- implementation of the QMS / PQS activities

- Technology Transfers
- Audits
- Deviations / RCA / Change controls / Effectiveness checks / CAPA
- Stability
- Validation
- QRM

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 an RP takes on when accepting this role

✓ How to incorporate these activities into the organogram and job description

✓ Practical involvement in the activities required for active participation and approval by the RP

✓ Who can be part of the RP's delegated responsible personnel

✓ Acceptance of the legal ramifications of this role