PharmaConsult (Pty) Ltd
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GWP TRAINING WORKSHOP

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 managing QC and QA departments and performing cGxP inspections. She assists Wholesalers and Contract Warehouses with implementation of a comprehensive Quality Management System and SAHPRA requirements in a practical approach. If personnel truly understand the reason for each activity they are involved in, they will be able to use the quality systems effectively towards continuous improvement initiatives. 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 Wholesalers and Distributors, storing and distributing products for human and veterinary use, as per the Medicines and Related Substances Act 101 of 1965, need to adhere to current Good Wholesaling Practices (cGWP) requirements, based on the SA Guide to GWP (4.02). The South African Health Products Regulatory Authority (SAHPRA) requires a detailed process for training of all staff which needs to be compiled into a comprehensive Standard Operating Procedure (SOP). This workshop includes working through multiple areas included in the Guidelines but more importantly providing practical examples of how to ensure that they are implemented and used as per current expectations. Examples of non-compliance or deficiencies in fully addressing the issues will be provided to highlight expectations of the relevant requirements.

SAHPRA requires each Wholesaler site to implement and perform routine training.
Periodic training on the following elements are required: the Quality Management System (QMS); Personnel; Premises & Equipment; Documentation; Supplier and Customer Qualification / Verification;

Outsourced activities. All need to be in order to ensure that there is a state of control.

This 5-hour course held by SAAPI via MS Teams, provides either an introduction to the requirements of cGWP or provides a refresher course for reflection of the applicable areas within your company to identify areas of process improvement or more effective implementation and for documented evidence of your attendance at such a course.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Responsible Pharmacists and QA personnel, in warehouses managing Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that cGWP training requirements are compiled, implemented, recorded, assessed and maintained / updated.
- Personnel who are responsible for compiling, implementing, using and reviewing QMS elements and conducting the monthly Quality Review Meetings, including the QRM meetings as well as providing feedback in terms of quality metrics / measurements to the periodic Senior Management Meetings.
- Warehouse and Distribution Managers & Supervisors who are involved in areas related to ensuring compliance to cGWP requirements in their facility.
- Senior Management who are required to be involved in embedding the Quality focus at their company and to make training on cGWPs available to all employees who are involved with any part of the cGxP process.
- Responsible Pharmacists or other personnel wishing to obtain knowledge of the requirements of cGWP compliance.

COURSE CONTENT:

- ✓ Introduction to cGWP
- ✓ Regulatory Guidelines and Licensing requirements
- ✓ Current key cGWP hot topics
  Awareness of cGWP elements with examples of compliance and non-compliance include:
- ✓ Organisation and Management
- ✓ Quality Management System
- ✓ Personnel requirements
- ✓ Premises and Equipment requirements
- ✓ Supplier Qualification
- ✓ Customer / Client Verification
- ✓ Good Documentation Practices – includes Data Integrity, Legal records and Computer Systems Validation criteria
- ✓ Disposal of products – acceptable segregated storage requirements for returns, recalls, rejects, products under investigation or in quarantine
- ✓ Distribution – Transport validation; use of couriers and personal collection
- ✓ Effectiveness checks of cGWP training – includes various techniques to apply

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COURSE OUTCOMES:

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

- ✓ Knowledge of the concepts of the elements included in cGWP requirements.
- ✓ How they can contribute to identifying areas of both compliance and non-compliance.
- ✓ Awareness of the cGWP national and international regulatory guidelines.
- ✓ Awareness of Regulatory expectations regarding the implementation strategies of the Guidelines.
- ✓ Awareness of the responsibility of a Wholesaler to communicate effectively with the Manufacturer / Holder of a Certificate of Registration of the medicinal products to fully understand both the quality aspects and handling requirements of the product and open sharing of data generated as part of the QMS.
- ✓ Individual training requirements and documenting evidence of such.