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Annual cGMP REFRESHER TRAINING

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 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 (Part I). 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 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.

SAHPRA requires each site to implement and perform routine training that includes: Induction training, SOP training, Job specific training, On-going / continuous training, Refresher cGMP training

and For Cause training. In addition, the SOP needs to include information as to how the company assesses the effectiveness of the cGMP training.

Periodic training on the following elements is required: Regulatory requirements; the Quality Management System (QMS); Personnel; Premises & Equipment – qualification and validation; Documentation; Supplier Approval; Production; Quality Control; Audits; Outsourced activities contracts; Warehousing and Distribution. All need to be in order to ensure that there is a state of control.

This workshop, held by SAAPI via MS Teams over two separate sessions on two consecutive days, provides to the delegates, either an introduction to the requirements of cGMP or provides a refresher course for reflection of the applicable areas within your company and for documented evidence of your attendance at such a course. The intention is to not only understand the concepts of cGMP but also to work through the benefits associated with striving 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 (Act 101 of 1965) who are responsible for ensuring that cGxP training requirements are compiled, implemented, recorded, assessed and maintained / updated as per the applicable GMP Guidelines – working in Manufacturers / Warehouse & Distribution / HCR facilities.
- Personnel who are involved in areas related to ensuring compliance of the medicinal product's cGxPs – Supply Chain / Procurement; Engineering and Maintenance; Finance; IT; Security; Marketing & Sales; Medical Affairs; Product Trainers, amongst others pertinent to your facility.
- Senior management who are required to be involved in embedding the Quality focus at their company and to make training on cGxPs available to all employees who are involved with any part of the cGMP process. Senior management should sign off the Training program on an annual basis.

COURSE CONTENT:

- ✓ Regulatory Guidelines and references
- ✓ Introduction to cGxPs and benefits
- ✓ Current key cGxP topics

  Awareness of cGMP elements with examples of compliance and non-compliance which include:
- ✓ Key personnel and documenting training
- ✓ Quality Management System / Pharmaceutical Quality System – System requirements and Quality Review Metrics / Measurements
- ✓ Personnel requirements
- ✓ Supplier Management
- ✓ Premises and Equipment requirements – GAMP; Qualification and Validation
- ✓ Good Documentation Practices – includes Data Integrity and Computer Systems Validation criteria
- ✓ Production requirements - reference to the registered dossiers and master manufacturing controls; APQRs; VMP programs
- ✓ QC testing – laboratories and the PIT process; stability program
- ✓ Warehousing and Distribution – including freight forwarders / clearing agents, couriers and personal collection; transport validation & verification
- ✓ Contract Giver – Contract Acceptor Contracts & SLAs and Vendor audits and approval process
- ✓ Effectiveness checks of cGxP and QMS principles – including Self-Inspections
- ✓ Measurement of Quality and Continuous Improvement initiatives

COURSE OUTCOMES:

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

- ✓ Knowledge of the concepts of the elements included in cGMP requirements.
- ✓ Awareness of how the management role is integrated into the QMS / PQS implemented at their site.
- ✓ How delegates can contribute to identifying areas of both compliance and non-compliance.

- ✓ Awareness of the cGxP national and international regulatory guidelines.
- ✓ Awareness of other functions performed on site and how they are linked or affect each other within the cGMP process.
- ✓ Awareness of the responsibility of the HCR to manage the contract sites that they appoint.
- ✓ Identification of continuous process improvement practices which may benefit the company's overall performance.
- ✓ Individual training requirements and documenting evidence of such.