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cGMP TRAINING – FOR APPLICANTS USING CONTRACT MANUFACTURING SITES

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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 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 Applicants contracting with international manufacturing sites and importing medicines into South Africa for distribution, or contracting with local manufacturers, 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) 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 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. A Training Matrix / Program is required to be in place. All training sessions need to be recorded, accessible for review and pertinent to the position of the individual employed by the company. 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 are required: the Quality Management System (QMS); Personnel; Premises & Equipment; Documentation; Production; Quality Control; Audits; Outsourced

activities including Supplier approval for multiple components. All need to be in order to ensure that there is a state of control.

This one-day course held by SAAPI via MS Teams, provides either an introduction to the requirements of cGMP Training 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.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and 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.
- All employees who are involved in areas related to ensuring compliance of the medicinal products cGxPs – Supply Chain / Procurement; Finance; IT; Security; Data Controllers; Marketing & Sales 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 hot topics
  Awareness of cGMP elements with examples of compliance and non-compliance include:
- ✓ Key personnel
- ✓ Quality Management System / Pharmaceutical Quality System
- ✓ Personnel requirements
- ✓ Premises and Equipment requirements
- ✓ Good Documentation Practices – includes Data Integrity and Computer Systems Validation criteria
- ✓ Contract Production requirements including responsibilities of the contract acceptor and reference to the registered dossiers and master manufacturing controls; APQRs; QMS, QRM and VMP programs
- ✓ QC testing – by contract laboratories and the PIT process; stability program
- ✓ Contract Warehousing and Distribution – including freight forwarders / clearing agents, couriers and personal collection
- ✓ Contract Giver – Contract Acceptor Contracts & SLAs and Vendor audits and approval process
- ✓ Effectiveness checks of cGxP training – includes various techniques to apply

- ✓ Documenting training – SOPs, Training schedule / matrix, Assessments, Records, Identification of additional training needs

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 cGMP requirements.
- ✓ Awareness of how their role is integrated into the QMS / PQS implemented at their site.
- ✓ How they 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 an Applicant to manage the contract sites used in a detailed and comprehensive manner.
- ✓ Individual training requirements and documenting evidence of such.