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cGMP TRAINING FOR PHARMACEUTICAL MANAGEMENT PERSONNEL of Applicant and Manufacturing Facilities

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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 range from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; biosimilars and medical devices; 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 Quality Management System (QMS) / Pharmaceutical Quality Systems (PQS) 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 SA Guide to GMP and the PIC/S GMP Guidelines. 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.

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; Complaints and Recalls; Self Inspections; Warehousing and Distribution. All need to be in order to ensure that there is a state of control.

This workshop, held via MS Teams in one morning session, provides to the Management Team, 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 aim is to explain various QMS principles and to provide examples of how to apply them within multiple cross-functional areas an organisation, how to review compliance of each, ways in which Management can support these principles, including resource management, with examples of ramifications of non-compliance. This includes discussions on the benefits associated with striving to proceed in a compliant manner as part of the requirement of continuous improvement initiatives in the pharmaceutical industry, and opportunities for identification of process / product optimisation.

WHO SHOULD ATTEND THE COURSE:

- This short course workshop is aimed at members of the Management Team, specifically non-Quality Assurance personnel, but rather those from inter-department / Group or Region / related functions, including all Managers / Supervisors / Team Leaders, from – Supply Chain / Procurement; Manufacturing, Packaging, Warehouse; Engineering and Maintenance; Finance; IT; Security; Marketing & Sales; Commercial / Business Development; Medical Affairs; Product Trainers, amongst others, pertinent to your facility. All should be aware of the requirements of various Pharmaceutical Guidelines that pertain to implementing effective and compliant cGMP principles at their Facility.
- Senior Management who has the ultimate responsibility to ensure an effective QMS is in place, who are required to be involved in embedding the Quality focus at their company and to make informed decisions based on attendance at or review of the periodic Quality Management Review meetings or reports. To ensure that product and process knowledge is managed throughout all lifecycle stages and that managerial responsibilities are clearly specified. Their leadership and active participation in the QMS is essential to ensure compliance with the management responsibilities stated in the Quality Manual.

COURSE CONTENT:

- ✓ Scope of cGMP applications – setting the scene for various Facility types
- ✓ Regulatory Guidelines and References
- ✓ cGMP Terminology
- ✓ Introduction to cGMPs and the QMS / PQS and expectations of senior management and management responsibilities
- ✓ Benefits of Compliance with cGMP
- ✓ Discussion on multiple cGMP elements with examples of cGMP inter-department compliance and non-compliance
    - How to build cGMP compliance into all job functions
- ✓ How is Quality measured – Cost of Quality discussions
- ✓ Continuous Improvement process
- ✓ Data Integrity principles & Computer Systems

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 the management role is integrated into the QMS / PQS implemented at their site.
- ✓ How management can contribute to identifying areas of both compliance and non-compliance.
- ✓ Awareness of the cGxP national and international regulatory guidelines.
- ✓ Awareness of multiple 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 used in a detailed and comprehensive manner.
- ✓ Identification of continuous process improvement practices which may benefit the company's overall performance.