PharmaConsult (Pty) Ltd
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SAAPI

cGMP TRAINING FOR PHARMACEUTICAL SUPPLY CHAIN PERSONNEL FROM A QUALITY ASSURANCE PERSPECTIVE

Applicant and Manufacturing Facilities

21 AUGUST 2024 (8:30 – 12:30)

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WORKSHOP INTRODUCTION:

Pharmaceutical Medicines Manufacturers, both in the capacity of Applicants with their own manufacturing facilities and / or appointed contract manufacturers locally or international sites, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP and current PIC/S Guidelines and on Regulatory compliance requirements. The South African Health Products Regulatory Authority (SAHPRA) is responsible for assessing compliance by each licensed facility to ensure that all registered medicines are of the required quality, safety and efficacy.

SAHPRA requires each site to implement and perform routine current Good x Practices (cGxP) activities, including those to support GMP, GDocP, GWP, GDP compliance and compliance with the registered product dossier, throughout the entire life cycle of each product in order to remain compliant at all times. This includes all personnel involved in the supply chain process, for marketed products.

This workshop, held by SAAPI, in one morning session via MS Teams, introduces personnel involved in supply chain / procurement, to key aspects of cGxP, the Quality Management System (QMS) including Quality Risk Management (QRM) and includes the impact and collaboration required in the relationship between supply chain and quality / compliance department's personnel. Delegates will be exposed to oversight of quality aspects and practical examples will be discussed on the effect / impact on supply chain activities. By initiating a mutual understanding of each department's focus areas, we hope to provide insights into how to connect in order to benefit all involved as well as adding value as a continuous improvement initiative. Please refer to the Workshop Content below for a detailed list of topics that will be discussed.

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WHO SHOULD ATTEND THE WORKSHOP:

- Supply Chain personnel – including demand and supply planners, procurement / purchasing personnel / buyers, administrators, officers, manufacturing site liaison managers.
- Commercial team members – such as program managers, sales and marketing personnel, product launch team, brand management, key account management, finance team
- QA, Regulatory and Compliance colleagues responsible for managing the quality aspects of supply from the various facilities – internal and external and product storage and distribution.

WORKSHOP CONTENT:

- ✓ Brief insights into the Regulatory process for registering medicines, guidelines and references and the role of the Responsible Pharmacist
- ✓ Overview of Good x Practices
- ✓ Sales &Operations Planning (S&OP) process integration with Quality compliance requirements
- ✓ Master Quality documentation insights: Policies and procedures
- ✓ Vendor / Supplier / Contractor / Service Provider – Categorisation, Qualification and Approval process - selection process, audits, contracts
- ✓ Brief introduction to Quality Risk Management (QRM) and impact on decision making across the supply chain
- ✓ Overview of Pharmaceutical Quality Systems (PQS) / Quality Management System (QMS) elements – theory and examples of the impact of quality actions on supply chain activities
- ✓ Performance reviews / KPIs / metrics – supply chain and quality objectives for monitoring and re-qualification criteria

WORKSHOP OUTCOMES:

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

- ✓ Key concepts of Regulatory and Quality Management and their impact on Supply Chain activities / objectives

- ✓ Knowledge of the basic concepts of the requirements of the PQS / QMS that must be in place and the possible impact on supply
- ✓ Collaboration required between the supply chain and quality teams in order to meet company objectives – both from a compliance and a commercial point of view with the goal of achieving improved efficiencies
- ✓ Communication requirements with senior management personnel to ensure that they are informed of potential risk to supply based on quality and compliance reasons, together with areas of continuous improvement initiatives introduced to improve supply of products

PRESENTER:

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; biosimilars and 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. Furthermore, Rosemary has led or been part of multiple cGMP Self-inspection teams, not only used for annual compliance purposes but also for preparing the local facility for Health Authority inspections and for Global or Group Audits. She has also performed inspections of facilities as part of a due diligence gap analysis process when considering contracting with or purchasing such facilities.

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 and auditing amongst other service offerings.