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PHARMACEUTICAL QUALITY SYSTEM FOR QA COMPLIANCE – theory and practical implementation
Dates: 25 to 27 June 2024

PRESENTER: Rosemary Kietzmann
B. Sc (Chemistry & Biochemistry)

WHO SHOULD ATTEND THE WORKSHOP:

- Quality Assurance Pharmacists and Pharmaceutical Scientists / Assistants / Engineers / Auditors / Officers and Responsible Pharmacists working in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that an effective pharmaceutical quality system (PQS) or quality management system (QMS) is designed, developed, documented in the Quality Manual and implemented throughout all stages of the lifecycle of medicinal products.
- Managerial and operational personnel from HCR offices, pharmaceutical manufacturers including CMOs and pharmaceutical warehouse and distribution facilities, who are responsible for reviewing their current PQS / QMS and for enhancing it to meet with current expectations and global best practices.

COURSE INTRODUCTION:

Quality Management is the sum total of all quality elements and this workshop is designed to identify the multiple elements associated with implementing a comprehensive and compliant system. A Quality System is the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met.

The basic concepts of a Quality System include Quality Management, GMP and Quality Risk Management (QRM) which are inter-related.

A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that:

Product realisation is achieved by designing, planning, implementing, maintaining and continuously improving a system that allows the consistent delivery of products with appropriate quality attributes. (PIC/S, Part I, Ch. 1)

These three half-day morning sessions are presented virtually via MS Teams. Elements listed in the Course Contents below will be addressed form the view point of what documents and records would

a Health Authority require you to have in place in order to comply with the requirements, with inclusion of practical examples where appropriate. These sessions provide either an introduction to the requirements of the PQS or provide a refresher course for reflection of the applicable areas within your company with a view to linking the various processes for enhanced understanding, continuous improvement initiatives and improved decision making. In-depth training on each of these elements is not in scope of this workshop. Other workshops provide for these.

COURSE CONTENTS FOR THE SESSIONS:

- ✓ Regulatory Guidelines and references
- ✓ Basis for the PQS – established quality management system with SMF, Quality Manual with Policy and VMP and SOPs; knowledge management; managerial responsibilities; continuous improvement initiatives
- ✓ GMP requirements - Approved procedures and instructions, in accordance with the Pharmaceutical Quality System; Record keeping during manufacture which demonstrates that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected; Good documentation practice and Data Integrity principles; Training management
- ✓ Quality Risk Management
- ✓ Supplier management program and supplier audits
- ✓ Outsourced activities and contracts
- ✓ State of control elements – technology transfer, qualification and validation; effective monitoring systems – quality reviews; senior management reviews; statistical reviews of processes; APQR
- ✓ Batch release process, including handling of deviations and CAPA and responsibilities of the release pharmacist
- ✓ Change Management controls with Effectiveness Checks
- ✓ Investigations and Root Cause Analysis
- ✓ Quality Control
- ✓ GWP and GDP
- ✓ Self-Inspections
- ✓ Complaint handling

- ✓ Case Studies / Scenarios

COURSE OUTCOMES:

At the end of these workshop sessions the delegates should have a clear understanding of the following:

- ✓ Knowledge of the concepts of the elements that must be included in a PQS, based on theory from the Guidelines.
- ✓ Awareness of how the delegate's role is integrated into the PQS / QMS implemented at their site.
- ✓ How they can contribute to identifying areas of both compliance and non-compliance.
- ✓ Awareness of the practical implementation of the elements and how they link.
- ✓ Awareness of how to review the individual elements to support decision making in terms of managing risk and identifying areas for continuous improvement initiatives.

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 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.