PharmaConsult (Pty) Ltd
Reg. No. 2018/030383/07
Cell: 082 457 1380
Email: rkietz2@gmail.com

FIVE QUALITY MANAGEMENT SYSTEM ELEMENTS WORKSHOP

DEVIATIONS, CAPA, CHANGE CONTROL, EFFECTIVENESS CHECKS AND QUALITY METRICS REPORTING

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 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.

COURSE INTRODUCTION:

Pharmaceutical manufacturers, in the capacity of the Holder of the Certificate of Registration of a product (HCR) - either contracting with international manufacturing sites and importing medicines into South Africa for distribution, or contracting with local manufacturers or manufacturing themselves locally, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP and the PIC/S Guide to GMP, amongst others. They are required to comply with Quality Management System (QMS) / Pharmaceutical Quality System (PQS) elements. In addition, Good Documentation Practice, with sound data integrity principles is required to be implemented. The South African Health Products Regulatory Authority (SAHPRA) requires a set of

standard operating procedures (SOPs) to be compiled and made effective, describing the processes to be followed for all elements, together with related protocols, forms and registers / logs, associated with the related SOP. The attainment of this quality objective is the responsibility of senior management and all facility personnel and approved contract acceptor sites. This forms a foundation for ensuring compliance that all registered medicines are handled accordingly across the life-cycle, to produce the required level of quality, safety and efficacy.

Quality Management is the sum total of all quality elements and these workshop sessions introduce the five concepts and how they are related and assessed in order to identify trends and identify continuous improvement opportunities and avoid future failures.

These two half-day morning sessions to be presented on 24 & 25 April 2024, are presented virtually via MS Teams. Specific elements will be addressed in each session as described below, with provision of practical examples for each element with delegate involvement populating records. These sessions provide either an introduction to the requirements of the QMS 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 and decision making.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Scientists / Personnel and Responsible Pharmacists including batch release pharmacists, working in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that an effective QMS is designed, developed and implemented.
- Personnel from supporting departments across the supply chain, who are responsible for managing cGxP in their areas, such as but not limited to Supply Chain, Manufacturing / Packing and Storage of products.

COURSE CONTENTS FOR THE SESSIONS:

- ✓ Regulatory Guidelines and references
- ✓ The CAPA cycle theory and linking of the various elements.
- ✓ Deviation handling – unplanned from various sources; classification and timelines for closure;
  Deviation Register – implementation for different scenarios with practical activity.
- ✓ Corrective Actions – use of CAPA form and understanding of preventative actions;
  CAPA Register – implementation and review process with practical activity.
- ✓ Change Control – implementation of CC protocols;
  Change Control Register – implementation for different scenarios with practical activity.
- ✓ Effectiveness Checks – including quality risk-based change management.
- ✓ Case Studies / Scenarios – practical compilation of a CAPA Cycle document related to situations presented to delegates (individual or group work) with delegate's presentations of completed activities.
- ✓ Quality Metrics reporting – requirements including formal process and benefits from such reviews.

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 included in the five QMS requirements, based on theory from the Guidelines.
- ✓ 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 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.

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