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QUALITY MANAGEMENT SYSTEM ELEMENTS WORKSHOPS – THREE INDIVIDUAL SESSIONS WITH DIFFERENT COURSE CONTENTS

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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 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 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 (4.01) and the PIC/S Guide to GMP (PE009-14). In addition, facilities that are licensed to warehouse and distribute pharmaceutical products as well as sites that are licensed to perform analytical and microbiological testing on pharmaceutical products, are similarly required to comply with Quality Management System (QMS) elements, also referred to as the Pharmaceutical Quality System (PQS) elements. The QMS incorporates Quality Risk Management

(QRM), Good Manufacturing Practice (GMP), Quality Management, Quality Control and Product Quality Reviews, all of which are inter-related. The South African Health Products Regulatory Authority (SAHPRA) requires a set of standard operating systems (SOPs) to be implemented, 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 staff, suppliers and distributors. This forms a foundation for ensuring compliance that all registered medicines are handled accordingly 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 concepts required and how they are related and assessed in order to identify trends and identify continuous improvement opportunities.

The three half-day workshops to be presented in June 2021, hosted by SAAPI and presented virtually via MS Teams, cover different QMS elements in each session and may be attended individually or as a set. Specific elements will be addressed in each session as described below, with provision of practical examples for each element, however there will be some overlap during discussions. 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 of linking the various processes for enhanced understanding and decision making.

WHO SHOULD ATTEND THE COURSE:

- Quality Assurance and Regulatory Affairs Pharmacists and Personnel and Responsible 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.
- All employees who are involved in applying and using QMS elements in their job functions – Supply Chain / Procurement; Finance; IT; Data Controllers; Quality Control personnel; Warehouse and Distribution personnel - amongst others pertinent to your facility.
- Senior management whose leadership and active participation in the QMS is essential.

COURSE CONTENTS FOR EACH OF THE THREE SESSIONS:

SESSION 1 – The Corrective Action – Preventative Action (CAPA) Cycle and Annual Product Quality Review (APQR) Reports.

- ✓ Regulatory Guidelines and references
- ✓ The CAPA cycle theory and linking of the various elements.
- ✓ Deviation handling – planned, unplanned; classification and timelines for closure.
  From various sources – facilities, processes, systems, personnel, QC results, storage and distribution;
  Deviation Register – implementation for different scenarios.
- ✓ Root Cause Analysis – introduction to multiple tools; practical examples provided.
- ✓ Corrective Actions – use of CAPA form and understanding of preventative actions;
  CAPA Register – implementation and review process.
- ✓ Change Control – implementation of CC protocols and effectiveness checks;
  Change Control Register – implementation for different scenarios.
- ✓ Trend Analysis – review tools and application of continuous process improvement identification.
  Out of Trend Register – implementation based on review of other QMS Registers.
- ✓ APQR – Template containing the multiple contents of the APQR Report;
  APQR annual schedule and timelines;
  Practical examples of how to combine information from multiple sites;
  Use of the APQR data to support Risk Management, includes an introduction to understanding Process Capability statistics and Communication requirements to senior management.

SESSION 2 – Supplier / Vendor Qualification and Approval Process; Quality Risk Management (QRM); Technical Quality Agreements (TQAs); Management Quality Review Meetings.

- ✓ Regulatory Guidelines and references
- ✓ Vendor, Supplier, Contract- Acceptor definitions;

Their identification, qualification and approval processes with associated documentation;

List of approved vendors, suppliers, contract-acceptors.

- ✓ Contract Giver – Contract Acceptor Technical Quality Agreements (TQAs) for outsourced activities – template and discussion on roles and responsibilities;

  Contract signatory requirements;

  Approved list of valid contracts;

  Use of Service Level Agreements.
- ✓ Quality Risk Management – introduction to the theory based on FMEcA principles and HACCP terminology with practical applications;

  Risk Register – template provided with examples of how to compile, implement, review and continuously update.
- ✓ Management Quality Review meetings – requirements including schedule, format, personnel required to prepare data to share, personnel required to attend, formal minutes, follow-up actions.

<u>SESSION 3</u> – Master Documentation Control; Data Integrity (ALCOA +); Finished product Transport Validation; Self-Inspections; Trainer Qualification Process.

- ✓ Document Control Requirements to manage master documentation across the company;

  Discussion on the unique numbering, approval, review, changes, revisions, signing, effective date definition, distribution, withdrawal, archiving and retention processes;
- ✓ Format of master documentation systems – manual issuance or electronic platforms;

  Access controls;

  Distribution for training and review of training records.
- ✓ Discussion on the data integrity principles according to ALCOA+ with examples of practical implementation.
- ✓ Transport Validation Studies –

  Handling of imported products;

  Handling of locally manufactured products distributed to warehouses;

Validation criteria required – vehicles; containers; cold-chain validation; data logger controls including packing configuration, downloading or recording the data and interpretation of data including trending.

- ✓ Self-Inspections – discussion on requirements with template for practical implementation;

  Identification of and qualification process for self-inspection team members;

  Linking self-inspection assessments to the CAPA Cycle, with effectiveness checks and completion timelines reviews;

  Self-inspection Schedule.
- ✓ Trainer Qualification Process – identification of elements required to certify a trainer;

  How is the effectiveness of training assessed?

  Training matrix requirements.

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 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.
- ✓ Awareness of the responsibility of senior management to be actively involved in the QMS elements in order to ensure a quality culture is entrenched in the company.
- ✓ Individual training requirements and documenting evidence of such.