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HOW TO COMPILE QUALITY MANAGEMENT SYSTEM DOCUMENTATION WORKSHOPS – TWO SESSIONS COVERING FOUR QMS ELEMENTS: 14 & 15 SEPTEMBER 2022 – 8 AM TO 12 PM DAILY

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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 range from: sterile blood plasma-derived therapeutic preparations; allopathic, generic and complementary medicines; homeopathic and herbal preparations; OTC products and biosimilars.

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 (PE009-16). 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 two half-day workshops to be presented in Sept 2022, 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 personnel working in QA Operations or QA Compliance who actively compile SOPs and QMS documents included in these sessions.
- Can be from manufacturing sites or from HCR sites where QA /RP needs to compile HCR site SOPs and some VPs for transport/ cold chain sample process and such like. Also for QA

reviewers of such QMS documents to identify what to look out for during reviews prior to approval and to have a follow up strategy to review site specific QMS records

- Intended to be a practical session and theory.
- Senior management whose leadership and active participation in the QMS is essential.

COURSE CONTENTS FOR EACH OF THE TWO SESSIONS:

SESSION 1: 14 Sept 2022

1. Compilation of Standard Operating Procedures – creation, updating, distribution control over the process and product lifecycle.

- ✓ Regulatory Guidelines and references
- ✓ Introduction to the requirements of a Quality Management System
- ✓ 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;
- ✓ SOP Template and fundamentals for compilation of an SOP
- ✓ SOP Register with version history
- ✓ Practical examples of how to prepare flow diagrams to facilitate SOP authoring.

2. Quality Risk Management (QRM)

- ✓ Regulatory Guidelines and references
- ✓ Quality Risk Management – introduction to the theory based on FMEcA principles and HACCP terminology with practical applications;
- ✓ Product and Process QRM strategies
- ✓ Risk Register – template provided with examples of how to compile, implement, review and continuously update.
- ✓ Management Quality Review meetings – requirements to review risk

SESSION 2: 15 Sept 2022

3. Validation Protocols and Reports

- ✓ Validation Master Plan
- ✓ Product and Process Validation Studies – pFMEA Reports; PPQ protocols; PVP and PVR records
- ✓ 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.

4. Effectiveness Checks

- ✓ Reason for conducting these
- ✓ Link to CAPA and Change Controls
- ✓ Suggested format and timing
- ✓ Link to Management Quality Review Meetings

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.