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ANNUAL PRODUCT QUALITY REVIEWS (APQR)

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

She has extensive knowledge of compiling numerous APQRs and uses this compliance requirement to look for continual process, product or systems improvements as part of the product lifecycle approach required in our Industry.

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, amongst other service offerings.

COURSE INTRODUCTION:

Pharmaceutical Medicines Manufacturers and Applicants importing medicines into South Africa for distribution, need to adhere to current Good Manufacturing Practice (cGMP) requirements, based on the SA Guide to GMP (4.01). Our South African Health Products Regulatory Authority (SAHPRA) is responsible for arranging for their GMP Inspectors to inspect these sites for compliance to ensure that all registered medicines are of the required quality, safety and efficacy.

SAHPRA requires each site to implement and perform routine cGMP activities, including the compilation and review of an annual Product Quality Review Report for each product, in order to ensure that there is a state of control or to identify trends or areas of concern.

This one-day course held by SAAPI via MS Teams over two sessions on consecutive days, introduces personnel involved in managing these reports, to key requirements in terms of planning, preparation and activities to be performed, liaison with Contract-Acceptor sites for shared data and the review

and approval process. Practical tools, documentation and relevant examples will be included in order to prepare you to compile a comprehensive document which adds value to your Management Review Meetings and ensures compliance with cGMP requirements.

WHO SHOULD ATTEND THE COURSE:

Pharmacists (Regulatory and Quality Assurance) and Quality Assurance personnel, in Human and Veterinary Medicines (Act 101 of 1965) who are responsible for ensuring that their Companies execute the APQR Reports in a competent manner, as well as Senior Management who wish to develop their knowledge in this area, from:

- Pharmaceutical Production Sites – Manufacturing, Packing, Testing
- Applicant only Sites (Importing &/or Procuring from local contract sites and Marketing)

COURSE CONTENT:

- ✓ Definitions of the APR / PQR and aim of the process
- ✓ Regulatory Guidelines and references
- ✓ Requirements for establishing an APQR process on site, including personnel
- ✓ Contract Giver – Contract Acceptor roles and responsibilities
- ✓ APQR parameters to be included in each report
- ✓ Utilities APQR discussion
- ✓ Various ways to present the data – includes statistical evaluation examples based on Process Capability calculations (Cp & Cpk)
- ✓ Connection with measurement of Quality measurements / metrics – How does your site measure quality?
- ✓ Importance of linking information into the Quality Risk Management Register, including Trend analysis
- ✓ Identification of process, product, systems changes required
- ✓ Communication shared with the Senior Management Team
- ✓ Identification of Continuous Improvement (CI) opportunities with CAPA
- ✓ Identification of Revalidation requirements based on the Continuous Process Verification approach of Validation

COURSE OUTCOMES:

At the end of this course the attendees should have a clear understanding of the following:

- ✓ Knowledge of the requirements that need to be in place in order to prepare an APQR document
- ✓ Publishing the APQR Schedule required to include all products on an annual basis and assigning personnel to complete and review
- ✓ How to interpret the APQR reports to identify areas in need of improvement activities or increased risk which may require revalidation
- ✓ Interpretation of the APQR to identify those products which display adherence to their validated state
- ✓ Communication with the senior management personnel to convey a deeper understanding of each product and process with improved knowledge gained from the analysis of the data; to discuss areas of concern regarding possible contract acceptor sites / transport routes and such like.