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Pharmaceutical Batch Release Personnel & Process Requirements & APQR Related Process, with an Assessment.
Date: 12 August 2026, 09h00 to 12h15 via MS Teams

PRESENTER: Rosemary Kietzmann
Pharmaceutical Quality Consultant

Rosemary is the owner and Director of consulting company PharmaConsult (Pty) Ltd., which provides comprehensive quality management activities, training sessions, cGxP inspections & gap analysis audits, compilation and implementation of theoretical and practical PQS processes and compilation of SAHPRA Inspection deficiency CAPA Plan responses, amongst other service offerings.

COURSE OUTLINE:

It is a GMP requirement that Holders of a Certificate of Registration (HCR) from SAHPRA for each approved finished pharmaceutical product (FPP) appoint a registered Pharmacist, with necessary documented training and experience, following certification of competency, and training effectiveness assessments, who is responsible for the release for sale of the FPP.

Please note - this workshop will include discussions on the requirements for qualifying and certifying a Batch Release Pharmacist as competent together with effectiveness checks on competency and related documentation and will include a written assessment to be completed after the workshop as part of the competency assessment process.

The content includes:

The qualification and approval process expected to be performed for each batch release pharmacist assigned to perform this function;

The certification process of competency for each approved pharmacist with emphasis on the role of the RP's role in this certification process together with required documented evidence of assessment;

The process expected to be implemented for effectiveness of training related to each batch release pharmacist to re-certify a batch release pharmacist;

We will also discuss the requirements for cGMP compliant job descriptions within a controlled document system, that comply with Good Documentation Practices.

Additional personnel may support the final release process, such as those in quality assurance roles who manage the collation of all data required to be assessed by the Pharmacist, prior to the issuance of the FPP batch release certification. Control of the critical processes throughout the manufacture of each FPP batch is vital. Awareness of the requirements at each stage of manufacture and quality control analysis over the life cycle of each batch of the product is required. (SAHPGL-INSP-02: GMP for Medicines). A FPP Process Flow (Mapping) will assist the Batch Release Pharmacist in the completion of a checklist to ensure that all important release criteria have been met and in compliance with the GMP and regulatory requirements. Adherence to data integrity requirements is part of the checklist criteria – are the required documents available as evidence of compliance?

Quality Assurance personnel are usually assigned the responsibility for ensuring that documentation is compiled, executed, approved and reported within the pharmaceutical quality system. In addition to the final release Pharmacist, quality control and assurance personnel as well as Responsible Pharmacists / Persons at contract acceptor facilities are assigned responsibility for their specified area of the life cycle and where these facilities are involved in the lifecycle of the product, this should be documented in a written agreement between the sites.

In this short course workshop, we will work through the theory and requirements for conducting a comprehensive overview of each product's site of manufacture and review with suggested practical examples of how to compile these into a Batch Record Release Checklist which prompts the review to be conducted in the same way each time and supports compliance. Furthermore, we will explore the contribution of the data required to be included in the Annual Product Quality Review (APQR) Report which provides valuable information to the Pharmacist in terms of knowledge management of each product (ICH Q10).

We will be discussing the following areas as a formal approach to ensuring that each FPP batch is released to the market with documented evidence for qualified and certified competent Batch Release Pharmacists and following a comprehensive review of all data that is required by the Pharmacist to make an informed final decision for release of each batch:

- The purpose of controlling batch release

- Roles and Responsibilities – Training Requirements for certifying a Pharmacist as competent to release batches to the market and for compiling the related training documentation, job descriptions and delegation letters
- Key Pre-Requisites for FPP batch release
- Supply Chain process flows (mapping) and outsourced activities requirements
- Breakdown of key steps in the FPP manufacturing process
- Related types of certificates applicable to each stage
- Review of associated PQS records – Deviations / Change Controls / OOS or OOT investigations / Transport Verification
- Demonstration of the contents of a Batch Review Release Checklist
- FPRR Certification document for partial manufacturing and for final release to market
- Data to review in the first year of launch of a product - Trend Analysis / CAPA / Change Controls
- Annual Product Quality Review requirements related to batch release
- Key data required to be assessed by the batch release pharmacist for awareness of significant impact on the next batch/es awaiting release
- Statistical Process Control (SPC) data – brief insights into understanding Cp and Cpk
- Suggested templates for compiling related documentation
- Assessment to be completed on-line after the workshop

WHO SHOULD ATTEND THE WORKSHOP:

- Responsible Pharmacists who are responsible for ensuring that there is a comprehensive training, qualification and approval process for pharmacists assigned as competent to perform batch release together with a program to evaluate the effectiveness of training and periodic recertification
- Delegated pharmacists and quality assurance personnel who are required to be part of the quality review team for assessment of each product's executed batch data, to determine suitability and compliance with cGMP and Regulatory requirements for RP approval for release to the market.
- Quality Assurance and / or Validation Pharmacists / Scientists / SMEs / Responsible Persons, in Human and Veterinary Medicines, who are responsible for managing specified quality

elements related to the manufacture or analytical testing of each batch, including performing oversight roles related to the appointed contractors / third parties who are managing any part of the life cycle of each batch AND the contract manufacturers and contract laboratory personnel.

- Regulatory personnel who support the maintenance of the registered dossier and are responsible for compiling updated versions for submissions of variations for Health Authority approval, to ensure that the registered dossier accurately reflects the state of the current product that is released for dispensing to patients.