COGSQP-01

Maintain and Monitor Quality Management Systems to meet license requirements

Overview

This standard covers the competencies you need to monitor and maintain Quality Management Systems (QMS) to meet pharmaceutical manufacture to the requirements of the marketing authority (MA) and the organisation [Site] operating licence.

You will be required to ensure that pre-production checks, in-process quality and post production quality checks are completed in compliance with regulatory standards, licenses and procedures, completing all required documentation.

This standard has been developed for the Qualified Person who is responsible for ensuring that each individual pharmaceutical product batch has been manufactured and checked in compliance with laws in force in the Member States where certification takes place.

Performance criteria

You must be able to:

P1 identify and select appropriate pharmaceutical quality management systems and quality standards for use in the manufacturing, distribution and storage of medicinal products
P2 develop or develop with others policies and procedures to meet regulatory requirements
P3 implement and support the implementation of regulatory policies and procedures
P4 interpret and apply relevant quality standards to production in accordance with agreed procedures
P5 ensure the training of others within the organisation in the regulatory policies or procedures
P6 plan and participate in internal inspections and audits for various departments within the organisation
P7 coordinate activities with cross functional teams in the inspection and audit process
P8 compile quality statistical data and write reports summarising finding
P9 monitor quality systems to ensure their effectiveness
P10 assist in the continuous improvement initiatives to enhance product quality
P11 promote the efficiencies and cost effectiveness of the Quality Assurance team and their activities
P12 carry out activities for quality assurance inspection and audit processes across manufacturing, distribution and storage stages of the organisation
P13 provide support to other departments in the collection and recording of regulatory documents, including evidence of in-process quality check documentation
P14 collaborate with the manufacturing and packaging teams for providing line clearance
P15 carry out quality assurance activities following approved procedures and methods
P16 ensure the manufactured product meets quality and license requirements
P17 identify the cause and effects of manufacturing problems and propose effective solutions
P18 ensure manufacturing processes meet quality requirements
P19 take corrective action to return a product quality deviation back to the agreed manufacturing specification
P20 report problems with quality which cannot be resolved within your own area of responsibility to appropriate people
P21 ensure quality records are completed accurately and stored in the agreed location

P22 contribute information and support other quality teams who have responsibly for quality activities within the organisation
P23 ensure appropriate qualified support is available for internal and external

audit activities
P24 provide support to senior leaders to ensure compliance to pharmaceutical manufacture to the requirements of the marketing authority (MA) and the organisation [Site] operating licence
P25 ensure the quality management review process provides requisite information, documents, clarifications to supervisors during and following audits
P26 ensure appropriate storage, distribution or disposal of pharmaceutical products in accordance to operating procedures and regulatory requirements
P27 ensure appropriate storage or disposal of manufacturing, quality and audit records

Knowledge and understanding

You need to know and understand:

K1 the quality policy of the organisation
K2 the standard operating procedures of the manufacturing, packing and storage operations
K3 the policies and procedures for conducting and participating in audits
K4 the legal, regulatory and license frameworks relevant to the production work
K5 the format of presenting the information captured during quality checks
K6 the composition and requirements of the product manufacture
K7 the organisational requirements and quality assurance procedures
K8 the monitoring and conducting of quality checks and quality records and their appropriate completion
K9 the monitoring procedures relevant to the quality system and specifications
K10 the roles and responsibilities for implementing quality systems
K11 the limits of personal responsibility in relation to quality systems and procedures
K12 how to gather and pass on relevant information to assist in the evaluation of quality procedures
K13 the use of the Pharmacopeia
K14 current good manufacturing practices, good laboratory practices and good documentation practices and ISO guidelines
K15 packaging specifications for different products
K16 knowledge on Critical Quality Attributes (CQA), Critical Process Parameters (CPP), Critical Process Controls(CPC) and acceptance criteria
K17 qualification and validation procedures, QA procedures and schedules
K18 knowledge of instrument systems to measure quality and their calibration procedures
K19 quality management systems and documentation in the use of quality assurance and control
K20 the fundamental Science and principles related to Active Pharmaceutical Ingredients (API) and Formulation Production and Packaging
K21 the requirement of the professional bodies study guides and best practice as determined in the regulators guidance publications

Glossary

MA Marketing Authorisation (Product License)
MAH Marketing Authorisation Holder
GCP Good Clinical Practice
GMP Good Manufacturing Practice
GDP Good Distribution Practice
GxP Reference to all Good Practices
cGxP Reference to all current Good Practices, used with GMP, GCP and GDP
Member States Member state of the European Union
MHRA Medicines and Healthcare products Regulatory Agency
QMS Quality Management System
PQMS Pharmaceutical Quality Management System
Batch The manufacture of a predetermined quantity of product
ISO International Organization for Standardization (commonly ISO)
SOP Standard Operating Procedures
SOL Site Operating License

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