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## 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.

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## 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 responsibility 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

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## 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

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## 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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