COGSQP-14

Communicate and coordinate quality assurance with team members in a manufacturing environment

Overview

This standard covers the competences you need to communicate and coordinate quality assurance with team members in a manufacturing environment, engaging in the analysis of quality issues, including customer complaints and writing appropriate reports to internal and external customers.

You will be required to demonstrate that you can proactively communicate to all levels of the organisation on issues requiring intervention in delivering quality work on time, providing justification and reporting any anticipated reasons for delays and or non-conformance.

This standard has been developed for Qualified Persons working in the medicinal products sector. The Qualified Person is responsible for ensuring that each individual batch has been manufactured and checked in compliance with laws in force in the Member States where certification takes place, in accordance with the requirements of the marketing authorisation (MA) and with current Good Manufacturing Practice (cGMP).

Performance criteria

You must be able to:

P1 ensure that the manufacturing and quality teams are aware of and understand the organisations strategies.
P2 communicate the quality department objectives and provide leadership direction to the manufacturing and quality teams to achieve quality targets and goals.
P3 coordinate activities and responsibility amongst quality team members.
P4 communicate and coordinate agreed key performance indicators for the quality team.
P5 monitor quality team targets and goals against individual and quality teams objectives.
P6 support and facilitate the delivery of continuous professional development of the quality team members through on and off the job training and learning.
P7 coordinate quality assurance resources to maintain efficiency levels to ensure delivery of all quality targets.
P8 coordinate quality activities with manufacturing and other operational and quality teams.
P9 communicate and collaborate with internal and external stakeholders on aspects of quality assurance.
P10 coordinate activities and maintain relationships with suppliers, contractors and vendors, ensuring all company policies and procedures are followed.

Knowledge and understanding

You need to know and understand:

K1 the organisation and quality department strategy.
K2 the organisation's compliance policies and standard operating procedures (SOPs).
K3 the organisation's defined quality procedure for reporting compliance risks and occurrences.
K4 the organisation's range of products and licensing needs associated with them.
K5 the structural relationships of the organisation with external stakeholders associated with licensing activities.
K6 the organisation's communication process and protocol.
K7 the regulatory compliances for licensing and legal requirements.
K8 the relevant legal and contracting procedures.
K9 supply chain management, process and manufacturing operations and business structure.
K10 contracts, tariffs and government import and export regulation policy.
K11 risk and impact of not complying to defined regulations.
K12 supply chain best practices, Good Distribution Practice (GDP).
K13 methods for carrying out corrective actions outlined in the quality assurance documents and standard operting procedures (SOPs).
K14 the escalation matrix for reporting identified issues.
K15 the implications of not adhering to quality control procedures.
K16 the relationships with the organisation external technical support and professional bodies.
K17 the organsational profile in the life sciences and industrial sciences sector.
K18 Commercial awareness of national and international pharmaceutical and healthcare market with respect to similar products from other companies.
K19 how to develop and use key performance indicators (KPIs) within the quality team.
K20 the organisations HR process to affectly support and manage the quality team, including aprarsal sysytems and staff welfare matters.

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