COGSQP-12

Certify Product for release under Marketing Authority License into the supply chain

Overview

This standard covers the competences you need to certify products for release or non-release under Marketing Authority License as appropriate into EU market and or for export into the supply chain.

You will be required to demonstrate that you can support the supply chain needs for licensing activities of the Qualified Person (Medicinal Products). The standard includes the requirements to meet the regulatory compliance and effectively exchange information internal and external to the organisation.

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 the batch has been manufactured and checked in accordance with the requirements of its Marketing Authorisation (MA) license.
P2 check the manufacture and testing of the product batch is in accordance with defined release procedures.
P3 certify that the completed batch manufacturing process is in compliance with Good Manufacturing Practice (GMP) and the requirements of its MA license, and meets release requirements of the batch.
P4 ensure the transfer of products to supply chain, and or the export of the finished batch of product meets all license requirement for MA and the site operating license requirements.
P5 ensure that there are written procedures describing the actions to be taken upon receipt of a complaint, product defect or product recall.
P6 ensure all complaints, defects and recalls are investigated and documented.
P7 develop or instigate new procedures when necessary to facilitate a request to investigate the quality of a batch of a medicinal product.
P8 ensure all appropriate Corrective and Preventative Actions (CAPAs) are identified and implemented for any defect, problem or issue identified after investigation.
P9 recommend any improvements to internal procedures.

Knowledge and understanding

You need to know and understand:

K1 the requirements of the product Marketing Authorisation (MA) and manufacturing site operating licenses.
K2 the different quality management systems, including Pharmaceutical Quality System (PQS), ISO-9000, ISO-14001), current good laboratory (GCP) and manufacturing practices (GMP).
K3 the organisational procedures for manufacture and testing of the pharmaceutical product batch in accordance with defined release agreements and licenses.
K4 the batch manufacturing process and requirements of compliance with Good Manufacturing Practice (GMP).
K5 the processes of transfer of finished batch to export or supply chain and the license requirement for MA and the site operating license requirements.
K6 the written procedures describing the actions to be taken upon receipt of a complaint, product defect or product recall.
K7 the investigation procedures for complaints, defects and recalls of batch products in manufacture or supply chain.
K8 the process for communicating the actions (CAPAs) in an investigation and any recommended requirement for change.
K9 material disposal procedure, importance of appropriate disposal of material and implications of not following the material disposal procedure.
K10 the importance of identifying non-conforming products and storage of the same.
K11 the implications (impact on internal and external customers) of defective products, materials or components.
K12 the reason and impact of the occurrence of problems.
K13 measures, steps and possible solutions that have been taken and identified to address the previous problems.
K14 the documentation process for recording non-conformance issues and irregularities in process manufacturing and quality control.

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