COGSQP-11

Ensure the Manufacturing Processes meet Licensing Requirements

Overview

This standard covers the competences you need to work with the quality (licensing) team in order to ensure that the appropriate licenses are in place for carrying out pharmaceutical product manufacture and operations. The role holder liaises with the licensing authorities to ensure appropriate documents and license are available at the time of selling or importing or exporting.

You will be required to demonstrate that you can ensure 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 authority (MA) and with current Good Manufacturing Practice (cGMP).

This standard has been developed for the Qualified Person who 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 authority marketing (MA) and with current Good Manufacturing Practice (cGMP).

Performance criteria

You must be able to:

P1 adhere to the relevant health and safety procedures in the manufacturing process
P2 ensure all manufacturing processes meets national legislation and obligations of marketing authority, site operating and product license requirements and operate within the relevant Standard Operating Procedures (SOPs)
P3 ensure all equipment is checked, calibrated and validated before use in manufacturing operations
P4 ensure that the correct documentation, raw materials, equipment and consumables are available and ready for use
P5 ensure the manufacturing or packaging areas are prepared and the correct materials are ready for use in accordance to SOPs
P6 ensure that products are prepared or manufactured in accordance with the documentation, ensuring the process checks at all stages are made in accordance to license, processing and manufacturing requirements
P7 ensure any necessary sterilisation and or sanitisation processes meet SOPs and the quality assurance requirements
P8 ensure all product labels and packaging (including any secondary packaging) meet license and quality control requirements
P9 ensure all necessary reconciliation calculations are correct and accurate for the pharmaceutical product, packaging and labels
P10 complete all documentation clearly and accurately for quarantine off-specification product in accordance with the organisations requirements
P11 ensure SOPs are accurately followed when equipment is dismantled, cleaned, decontaminated, stored or disposed of correctly at the end of a manufacturing or packaging process
P12 record and report in accordance to the license agreement and quality assurance process any out of specification results or unusual events
P13 take appropriate action following an unusual event within the limits of your authority
P14 ensure all relevant documentation is completed, recorded and stored appropriately in accordance with license and the organisations requirements
P15 ensure the procedure for monitoring the manufacturing and packing environment are followed, documenting and reporting any condition outside of normal parameters, ensuring appropriate corrective action are completed

Knowledge and understanding

You need to know and understand:

K1 the requirements of each of the manufacturing licence conditions including national legislation, Marketing Authority (MA), Site Operating and Product License
K2 the importance of working within the limits of your responsibility and knowing when to seek agreement or escalation of a problem in manufacturing, packaging or product quality
K3 the use of relevant national and international guidelines, policies and procedures used in other countries that may affect the importation or export of pharmaceutical products
K4 why you should report any acts or omissions that could be detrimental to the product license requirements, individuals, yourself, colleagues or your employer
K5 the principles of current good manufacturing practice (cGMP), and other relevant current good practices (cGxP), including pharmaceutical quality management systems (QMS)
K6 the different preparations including tablets, liquids and creams.
K7 the different formulation types, including fast and slow release, micro coated and dissolving medications
K8 the importance of using approved documentation
K9 the importance of ensuring a clean working environment, including the principles of sterilisation and sanitization processes
K10 the possible sources of contamination and the appropriate methods of prevention
K11 the environmental monitoring and referral process and the actions required when condition are outside the set limits
K12 the chemical and physical properties of ingredients relevant to formulation and compounding, including any interactions between raw materials and components
K13 the principles of formulae calculations, weights and measures
K14 the principles, properties and uses of different types of containers and when to use the various types
K15 the nature and use of different product forms
K16 the principles and procedures for preparing medicinal products
K17 the reconciliation of materials, labelling and packaging requirements
K18 the reasons for safe systems of work including the quarantine requirements and the appropriate checking processes
K19 the causes and effects on product quality resulting from near misses and errors
K20 the safe disposal of waste materials and cleaning materials

K21 the importance of recording, storing and retrieving information in accordance with organisational procedures

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