COGSQP-15

Determine methods for Pharmaceutical Manufacture

Overview

This standard covers the competences you need to support and develop the processes and methods for pharmaceutical manufacturing, developing new and selecting from established practices and in accordance with approved procedures.

You will be required to demonstrate that you can develop and ensure standard operating procedures are implemented in line with legislation and organisational policy, whilst following current Good Manufacturing Practice (GMP) and other good practices where applicable (GxP). You will also be required to present records and details of the pharmaceutical work to the appropriate people.

This standard has been developed for the Qualified Person 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 Good Manufacturing Practice (GMP) and the organisation (site) operating licence.

Performance criteria

You must be able to:

P1 ensure the manufacturing activities in your area of responsibility are carried out in accordance with the health, safety and environmental policies in your organisation.
P2 implement and support the development of standard operating procedures in line with legislation and site policy.
P3 ensure that all manufacturing activities in your area of responsibility are carried out in accordance with standard operating procedures (SOPs) and compliance to licence and other regulatory (MA) requirements in your organisation.
P4 ensure manufacturing activities within your area of responsibility are carried out using appropriate personal protection equipment (PPE) as stated in SOPs.
P5 review and analyse historical manufacturing data for similar products to inform on the development of new products manufacture.
P6 determine manufacturing methods, techniques and equipment for manufacturing the product to be made.
P7 in collaboration with others, determine the costs, quality requirements and production methods needed for the product to be manufactured.
P8 collaborate and agree with others the defined sequence of operations for the product to be made.
P9 communicate to manufacturing and quality teams the information about new or revised working methods and quality control processes for new pharmaceutical products.

Knowledge and understanding

You need to know and understand:

K1 the implications of not taking account of legislation, regulations, standards and guidelines when conducting pharmaceutical manufacturing activities.
K2 the standard operating procedures, as set down in the manufacturing operating manuals and equipment manufacturers operating guides.
K3 the importance of following equipment manufacturers' operating instructions.
K4 the principles of current Good Manufacturing Practice (GMP) and other good practices (GxP) applied in the workplace.
K5 the specific hazards of specified pharmaceutical products in the manufacturing process, and the importance of protective clothing and equipment.
K6 the manufactured product and batch process tracking and records system
K7 the types of handling and sorting system, and the procedures used for products undergoing processing in the manufacturing facilities.
K8 the organisational requirements for maintaining the security of the manufacturing workplace.
K9 the lines of communication and responsibilities in the quality and wider manufacturing team, and their links with the rest of the organisation.
K10 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
K11 the range of materials and technology used in the manufacture and processing of pharmaceutical products.
K12 how to determine the appropriate manufacturing methods for the products to be manufactured.
K13 production planning, control and scheduling techniques
K14 how to establish the costs of manufacturing, and the procedures used for calculating them.
K15 the quality control techniques and standards used in manufacturing.

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