COGBENG-06

Commission the Installation of a Biomanufacturing Process

Overview

This standard identifies the competences you need to install and commission biochemical manufacturing equipment and processes that may operate under aseptic conditions.

You will be required to install and commission engineering systems for the manufacture of existing/new biological products, in accordance with approved procedures and practices. You will need to plan, schedule, install and commission equipment for a new process or scale-up of an existing process. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, demonstrate safe working practices and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

This activity is likely to be undertaken by someone whose work role carries out process engineering work activities in a biochemical environment. This could include individuals working in the following industries, Chemical, Pharmaceutical and Life Science industries.

Performance criteria

You must be able to:

P1 work safely at all times, complying with health and safety and other relevant biomanufacturing regulations, directives and guidelines
P2 ensure that your work is carried out in accordance with standard operating procedures
P3 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment
P4 establish the manufacturing methods, techniques and equipment for manufacturing the biochemical product
P5 plan the most appropriate way to install and commission the engineering product or bioprocess
P6 produce, agree and update installation and commissioning schedules and plans
P7 develop, gain agreement and review installation and commissioning budgets
P8 work in an aseptic environment
P9 carry out the installation and commissioning activities in accordance with approved methods, techniques and procedures
P10 identify and solve any installation and commissioning problems within your control and report those that cannot be solved
P11 check that the commissioning is complete, and that the equipment operates to specification and complies with all relevant regulations, directives and guidelines
P12 evaluate the results of the commissioning to determine that the costs, quality and production times needed for the bioproduct have been met
P13 complete and save relevant installation and commissioning data and documentation accurately in the appropriate information systems
P14 communicate the required information about the work done, to relevant people in accordance with organisational procedures

Knowledge and understanding

You need to know and understand:

K1 the manufacturing methods, techniques and equipment for manufacturing the biochemical product
K2 the health and safety requirements of the area in which you are carrying out the biomanufacturing commissioning activities and any specific health and safety precautions to be applied during the commissioning procedure
K3 the specific practices and procedures that you need to observe when commissioning equipment in a biochemical environment (including any specific legislation, regulations or codes of practice for the activities, equipment or materials)
K4 the implications of not taking account of legislation, regulations, standards and guidelines when working in a biomanufacturing area
K5 the standard operating procedures, as set down in local biomanufacturing operating manuals
K6 the principles of Good Manufacturing Practice (GMP) applied in the workplace
K7 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them
K8 the types of handling and sorting system, and the procedures used for products undergoing processing in the bio-manufacturing facilities
K9 the manufactured product and batch process tracking and records system
K10 the quality control techniques and standards used in manufacturing biochemical products
K11 the procedures to be carried out before starting work on the commissioning activities (such as obtaining permits to work, obtaining and complying with risk assessments and other health and safety requirements)
K12 hazards associated with carrying out engineering commissioning activities in a biomanufacturing environment and how to minimise them
K13 how to interpret drawings, specifications, manufacturers' manuals, instructions and other documentation needed to understand the requirements of the installation or commissioning activity
K14 the commissioning methods and procedures to be used, the factors that should be considered and whom to consult with in the planning process
K15 the equipment to be commissioned, its operating procedures and function, and how component systems interact
K16 the effects of scale-up, and the limitations of the biological manufacturing equipment
K17 how to assess the results of the commissioning process
K18 the importance of regularly monitoring budgets and the implications for

the business if this is not carried out
K19 how to complete and review risk assessments
K20 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
K21 the limits of your own authority and to whom you should report if you have problems that you cannot resolve

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