COGBENG-05

Produce a Design for a Biomanufacturing Process

Overview

This standard identifies the competences you need to design biochemical manufacturing processes that may operate under aseptic conditions.

You will be required to identify appropriate engineering solutions for the manufacture of existing/new biological products, in accordance with approved procedures and practices. You will be conversant with the regulatory requirements for the process and the product and with the quality control procedures that oversee manufacture. You will understand the manufacturing methods and principles used, in adequate depth to provide a sound background for carrying out the design activities to the required specification. 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 obtain accurate information on the requirements of the new or improved bioprocess
P2 evaluate potential biological routes identified to produce a biochemical product from a process engineering perspective
P3 identify the different engineering solutions to manufacturing a biochemical product, ranking them in order of suitability against the selection
P4 identify any unique or specific features of the bioprocess that need consideration to ensure that it can operate under aseptic conditions
P5 confirm and agree understanding of the design requirements
P6 obtain suitable advice and guidance to assist in the design work
P7 consider the technical feasibility and costs of the developments and improvements
P8 create designs that meet the requirements of a biochemical process applying approved engineering concepts, processes and principles to achieve the designs
P9 ensure that the designs comply with all relevant regulations, standards directives or codes of practice
P10 present the designs in suitable formats and with sufficient information to allow assessment by relevant people
P11 develop cost options for the designed process
P12 deal with problems relating to the design requirements and agree solutions
P13 produce and record detailed recommendations for future use
P14 communicate recommendations to relevant people in accordance with organisational procedures
P15 deal promptly and effectively with any problems within your control and report those which cannot be solved.

Knowledge and understanding

You need to know and understand:

K1 the principles of process engineering and how they apply in an aseptic environment
K2 the basic principles of biochemistry
K3 principles of design, design techniques and methodologies for developing design options and typical cost analysis methods and techniques normally used for engineering designs.
K4 sources and types of information relevant to the design being produced (including primary literature and biological abstracts), and how to use specialist search engines appropriate to your organisation
K5 the types of design feature that should be considered unique or specific in a biochemical process, and why it is important to give these consideration
K6 the functionality of the design including any interrelationships required with other components/products/systems or technologies
K7 the types of handling and sorting systems, and the procedures used for products undergoing processing in the bio-manufacturing facilities
K8 the effects of scale-up, and the limitations of the biological manufacturing equipment
K9 the regulations, standards, directives and codes of practice that are relevant in a biomanufacturing environment, and any implications they have on the design
K10 the principles of Good Manufacturing Practice (GMP) applied in the workplace
K11 the scope of the biological manufacturing targets for quantity, quality standards, deadlines and any other special requirements
K12 an appreciation of cost control methods and techniques used within your organisation
K13 whom to consult for advice, and the nature of their interest
K14 how design briefs are presented to the relevant people and the appropriate formats for recording design options.
K15 information and document systems and the need for effective document and data control and the implications if these are not applied
K16 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
K17 the lines of communication and responsibilities in your department, and their links with the rest of the organisation

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