COGBENG-01

Carry out Computer Modelling and Simulation of a Biomanufacturing Process

Overview

This standard identifies the competences that you need in order to use computer models to develop new and optimise existing bioprocesses.

You will be required to identify or develop appropriate computer models to simulate the manufacture of existing/new biological products, in accordance with approved procedures and practices. You will need to run computer models for the development of a new process or scale-up of an existing process. Where applicable you will compare model outputs to actual process data and adjust the model as appropriate. You will also be required to present records and details of your modelling work to the appropriate people.

You will understand the operation of a biomanufacturing process and the particular design, operations and control processes that apply. You will also understand the principles of operation of the equipment being used, its intended use, capabilities and limitations. This will enable you to adopt an informed approach in the use of modelling techniques in a bioprocess environment.

This activity is likely to be undertaken by someone with a background in process engineering in a biomanufacturing environment and conversant with computer modelling. 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 biomanufacturing process
P2 identify any unique or specific features of the biomanufacturing process that need consideration to ensure that it can comply with all relevant regulations, standards directives or codes of practice
P3 identify suitable software packages that can be used to model the bioprocess
P4 obtain suitable advice and guidance to assist in the modelling work
P5 use the appropriate equipment, hardware and software to model the biomanufacturing process
P6 establish with the business the required key outputs from the modelling exercise and confirm and agree understanding of the requirements with those responsible for the bioprocess
P7 run the computer model and evaluate results against the agreed required key outputs
P8 make adjustments to the model based on actual process data
P9 use the modelling information to aid design, scale-up, control of or improvements to the biochemical process
P10 identify any potential risks from the computer modelling exercise
P11 communicate results of the modelling exercise through scientific reports and presentations, to relevant people in accordance with organisational procedures
P12 record all relevant information in the appropriate information systems for future use

Knowledge and understanding

You need to know and understand:

K1 the specific safety precautions to be taken when working with computer systems
K2 the general principles of the biomanufacturing process including relevant regulations, standards directives or codes of practice
K3 the principles of computer modelling, available software packages and their use in modelling manufacturing processes
K4 the national, international and organisational standards and conventions that are used for computer models
K5 how computer modelling or process simulation can support understanding and development of a new bioprocess, a current manufacturing process or scale-up of process activities
K6 the unique or specific features of a biochemical process, and why it is important to give these consideration
K7 how to access the specific computer software to be used, and the use of software manuals and related documents to aid efficient operation of the relevant system
K8 the methods and techniques used to verify bioprocess designs, operations and control processes using computer models
K9 the importance of comparing process data to computer model outputs and the techniques to recalibrate the model to verify bioprocess operations and control processes
K10 how to conduct a risk assessment of the various outputs from a modelling exercise, and identify associated contingency plans to minimise their effect
K11 how to deal with computer system problems
K12 whom to consult for advice, and the nature of their interest
K13 information and document systems and the need for effective document and data control
K14 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
K15 the limits of your own authority, and to whom you should report if you have problems that you cannot resolve

COGBENG-01

Carry out Computer Modelling and Simulation of a Biomanufacturing Process

Developed by	Cogent
Version Number	2
Date Approved	30 Mar 2025
Indicative Review Date	30 Mar 2030
Validity	Current
Status	Original
Originating Organisation	Cogent
Original URN	COGBENG-01
Relevant Occupations	Engineer, Science and Engineering Technicians, Science and Mathematics Science
Suite	Bioprocess Engineer
Keywords	computer; model; modelling; simulation; biomanufacturing, bioprocess;