

## 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.

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## 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 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 the design, operation and control of a biomanufacturing process and how computer modelling can support understanding and development of the manufacturing process
  - 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 equipment and methods used to produce computer models
  - K9 the methods and techniques used to verify bioprocess designs, operations and control processes using computer models
  - K10 the use of process simulation in the development of a new bioprocess or scale-up of an existing process
  - K11 the importance of comparing process data to computer model outputs and the techniques to recalibrate the model to verify bioprocess operations and control processes
  - K12 how to conduct a risk assessment of the various outputs from a modelling exercise, and identify associated contingency plans to minimise their effect
  - K13 how to deal with computer system problems
  - K14 whom to consult for advice, and the nature of their interest
  - K15 information and document systems and the need for effective document and data control
  - K16 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
  - K17 the limits of your own authority, and to whom you should report if you have problems that you cannot resolve

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Carry out Computer Modelling and Simulation of a Biomanufacturing Process



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