COGSCIM3_04 - SQA Unit Code F7WL 04
Analysing and inputting biomanufacturing data in a Manufacturing Information Management System

Overview

This unit covers the competences you need to access, register and input batch/product data in a Manufacturing Information Management System (MIMS), in accordance with approved procedures. You are required to enter and access data to/from the MIMS using the correct protocols and procedures. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to plan the work of your team, and to set and agree individual objectives using data from the MIMS. You will help them to solve problems with the data and information, monitor their progress against the objectives you set, and provide batch/product data for manufacturing purposes.

Your responsibilities will require you to comply with organisational policy and procedures for the accessing, registration and data inputting activities undertaken, and to report any problems with the activities, materials or equipment that you cannot personally resolve, or that are outside your permitted authority, to the relevant people. You will be expected to work to verbal/written instructions and standard operating procedures, with a minimum of supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you and your team carry out.

Your underpinning knowledge will be sufficient to provide a sound basis for your work, and will enable you to adopt an informed approach to MIMS data accessing, registration and inputting procedures. You will have an understanding of the MIMS skills used, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout, and will understand your responsibility for taking the necessary safeguards to protect yourself and others in the workplace.

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Performance criteria

You must be able to:

- P1 ensure that your work is carried out in accordance with standard operating procedures
- P2 use correct passwords to access the relevant manufacturing databases, and maintain the security and integrity of information
- P3 use correct search procedures to confirm that batch demographic data on samples received are correct with existing data on the manufacturing record system
- P4 follow the correct protocols for registering new batch/product data onto the Manufacturing Information Management System (MIMS)
- P5 select the correct manufacturing data files, and accurately input batch details with the requested quality tests for each product
- P6 resolve the problems that arise when the required batch/sample information and data cannot be found or matched
- P7 perform these tasks in a timely manner, compatible with the manufacturing schedules
- P8 request help from appropriate people when you are unable to resolve problems with mismatched and incomplete batch/sample details
- P9 communicate manufacturing information to authorised people, in accordance with departmental and organisational procedures

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Knowledge and understanding

Sector specific

You need to know and understand:

K1 the health and safety requirements of the area in which you are carrying out the biomanufacturing activities

K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities

K3 the standard operating procedures, as set down in local biomanufacturing operating manuals

K4 the importance of following equipment manufacturers' operating instructions

K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace

Organisation specific

You need to know and understand:

K6 the standard operating procedures, as set down in the local manufacturing process operating manuals

K7 the data security requirements for different computer applications, and the accessing and storage of data

K8 how to access and store data, in accordance with standard operating procedures and organisational practices

K9 why it is important to maintain accurate batch and departmental records for products manufactured

K10 the policies and procedures for the accurate registration of new batches/products on the Manufacturing Information Management System (MIMS)

K11 the specific safety precautions to be taken when working with computer systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and workstation environment (such as lighting, seating, positioning of equipment), repetitive strain injury (RSI); the dangers of trailing leads and cables; how to spot faulty or dangerous electrical leads, plugs and connections)

K12 why it is important to maintain good housekeeping arrangements (such as putting disks, manuals and unwanted items of equipment into safe storage; leaving the work area in a safe and tidy condition)

K13 the importance of correct identification, and any unique organisational or manufacturing numbers

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

Equipment/Process specific

You need to know and understand:

K16 the basic set-up and operation of the manufacturing records system, and the peripheral devices that are used (such as mouse, keyboard, VDU, printer and barcode reader)

K17 the methods used for numbering and labelling liquids, compounds and products received by the manufacturing department, and the quality samples taken during processing (such as hand written or barcoded labels)

K18 the correct start-up and shutdown procedures to be used for the computer system

K19 how to access the specific computer Manufacturing Information Management System (MIMS) database to be used, and the use of software manuals and related documents to aid efficient operation of the relevant manufacturing records system

K20 how to deal with system problems (such as error messages received, peripherals which do not respond as expected, obvious faults with the equipment or connecting leads)

K21 how to communicate effectively, and how to identify key information when recording and forwarding messages accurately

K22 the test codes, coded comments, requestor and location codes, and batch/product comment codes required to input accurately and to request batch/product and manufacturing data appropriate to your area of work

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Additional Information

Scope/range related to performance criteria

You must be able to:

1. access and input batch/sample data for **all** of the following:
   - 1.1 batch number
   - 1.2 manufacturing process being done
   - 1.3 customer number
   - 1.4 quality testing requirements
   - 1.5 product number
   - 1.6 other (please specify)
2. establish data requirements for **six** of the following:
   - 2.1 product description
   - 2.2 details of the batches/products required
   - 2.3 date of sample
   - 2.4 details of resources/equipment needed
   - 2.5 batch source
   - 2.6 client's location
   - 2.7 MIMS number
   - 2.8 other (please specify)
3. complete **two** of the following departmental batch/product identification activities:
   - 3.1 writing codes on the batch/products
   - 3.2 checking batch/product codes against MIMS database
   - 3.3 adding barcodes to the batch/product
   - 3.4 scanning barcodes and checking MIMS database
4. record details of work done, and communicate the details to the appropriate people, using:
   - 4.1 verbal report

   Plus **one** method from the following:
   - 4.2 written or typed report
   - 4.3 computer-based record
   - 4.4 specific company documentation
   - 4.5 electronic mail

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