

Overview

This unit identifies the competences you need to assist with the routine maintenance, disinfecting, cleaning and calibration of equipment used for biomanufacturing processing operations, in accordance with approved procedures. You are required to check the readiness of the mechanical equipment used for lifting and moving. 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 check that the area and equipment are clear, cleaned and prepared correctly, and that the appropriate services are available, as stated in the instructions and standard operating procedures you are given. You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the manufacturing work that is undertaken. You will be required to report any problems with the health and safety procedures 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 high level of supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you 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 lifting and moving procedures. You will have an understanding of the readiness preparations and the checking 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.

Performance criteria

- You must be able to:*
- P1 ensure that your work is carried out in accordance with standard operating procedures
 - P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment
 - P3 choose the right equipment/techniques to move the materials
 - P4 check that the weight of the materials does not exceed the safe lifting capacity of the equipment chosen
 - P5 check that the materials to be moved are correct, safely loaded and secure
 - P6 move the materials to their correct location, in accordance with instructions
 - P7 identify any problems with the material transfer
 - P8 take appropriate action to solve problems which are within your permitted authority/responsibility
 - P9 report any problems that you cannot solve or that are outside your permitted authority to the appropriate person
 - P10 return any equipment you have used to its correct location on completion of the activities, and leave it in a safe and reusable condition
 - P11 complete all required documents with the specified information, in the required format and at the appropriate time
 - P12 record all information accurately and legibly
 - P13 communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures

Knowledge and understanding

You need to know and understand:

Sector specific

- 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' operational instructions
- K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace

Organisation specific

You need to know and understand:

- K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (such as biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them
- K7 the biomanufacturing materials and batch process tracking and records system
- K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities
- K9 the importance of correct identification, and any unique organisational or manufacturing numbers
- K10 the organisational requirements for maintaining the security of the workplace
- K11 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K12 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:

- K13 the area and the equipment for the lifting/moving activities
- K14 the documents that must be collated and verified for the movement of materials
- K15 the procedures for checking the availability of materials
- K16 the amounts of material required by the specification
- K17 the procedures for reporting any problems with the documentation, materials check, materials availability and materials delivery
- K18 the different types delivery procedure, and the documentation associated with these

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- K19 the range of equipment used to move materials, and which handling techniques to use
- K20 the quality standards of the materials required
- K21 what to do with damaged and incorrect materials
- K22 where materials and equipment used for their transport should be stored
- K23 the manual handling techniques that must be used in the workplace
- K24 whom to inform on completion of the materials movement

Additional Information

Scope/range related to performance criteria

You must be able to:

1. follow standard operating procedures for lifting and moving, to include **all** of the following:
 - 1.1 health and safety regulations
 - 1.2 lifting/moving equipment operating instructions
 - 1.3 safe working practices
 - 1.4 company standards and procedures
2. move materials using **one** of the following types of equipment:
 - 2.1 hand operated pallet truck
 - 2.2 power assisted pallet truck
3. carry out **all** of the following checks on the materials to be lifted and moved:
 - 3.1 the materials are as specified on the documentation
 - 3.2 the materials are stacked safely
 - 3.3 the materials are in a suitable condition for the moving operation
 - 3.4 the materials in the load are secure
 - 3.5 there are no restrictions/obstacles preventing movement
4. move **one** of the following categories of material:
 - 4.1 1 ingredients for fermentation/manufacture
 - 4.2 finished manufactured products
 - 4.3 consumable process materials
 - 4.4 waste materials
5. move material by manual lifting for **three** of the following conditions:
 - 5.1 materials on the ground
 - 5.2 materials below ground level
 - 5.3 materials at waist height
 - 5.4 materials above the head height
6. record details of the lifting/moving work, and communicate the details to the appropriate people, using:
 - 6.1 verbal reportPlus **one** method from the following:
 - 6.2 written or typed report
 - 6.3 computer-based record
 - 6.4 specific company documentation
 - 6.5 electronic mail

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