
Overview

This standard identifies the competences you need to monitor the transfer of materials 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 also 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 biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

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 preparations and checks used, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

This activity is likely to be undertaken by someone whose work role carries out Science/Bio manufacturing work activities. This could include individuals working in the following industries, Chemical, Pharmaceutical and Life Science industries.

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 monitor and lead the quality and delivery of the above outcomes for yourself and your team
- P14 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:

- 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
- K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including 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
- K13 how to monitor and lead the quality and delivery of materials in biomanufacturing process operations
- K14 the area and the pieces of equipment which should be ready
- K15 the documents that must be collated and verified for the movement of materials
- K16 the procedures for checking the availability of materials
- K17 the amount of materials required by the specification
- K18 the procedures for reporting problems with documentation, materials check, materials availability and materials delivery
- K19 the different types delivery procedure, and the documentation associated with each type
- K20 the range of equipment used to move materials, and the handling techniques to use
- K21 the quality standards of the required materials
- K22 what to do with damaged and incorrect materials
- K23 where materials, and the equipment used for their transport, should be stored
- K24 the manual handling techniques that must be used in the workplace
- K25 whom to inform on completion of the materials movement

Scope/range

1. monitor the following of standard operating procedures for lifting and moving that 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. monitor the movement of materials by both of the following types of equipment:

- 2.1 hand operated
- 2.2 power operated

3. carry out of all of the following checks on the materials to be lifted and moved:

- 3.1 they are the materials 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. monitor the movement of all of the following categories of materials:

- 4.1 ingredients for fermentation/manufacture
- 4.2 finished manufactured products
- 4.3 consumable process materials
- 4.4 waste materials

5. monitor the movement of 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 head height

6. monitor the movement of materials by three of the following mechanical aids:

- 6.1 forklift truck
- 6.2 overhead cranes
- 6.3 pallet truck
- 6.4 roller/ball conveyor surfaces

7. record details of the preparation work, and communicate the details to the appropriate people, using:

- 7.1 verbal report
- Plus one method from the following:

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- 7.2 written or typed report
 - 7.3 computer-based record
 - 7.4 specific company documentation
 - 7.5 electronic mail

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