

Overview

This standard covers the competences you need to monitor the packing of biomaterial containers by hand. Prior to undertaking the activity, and in accordance with approved procedures and practices, you will be required to carry out all the necessary preparations, within the scope of your responsibility. This may include preparing the work area, ensuring that it is in a safe condition to carry out the intended activities, and that any materials, equipment or other resources required are available and are in a safe and usable condition. 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.

On completion of the biomanufacturing activity, you will be required to return your immediate work area to an acceptable condition before undertaking further work. Use of the correct operating procedures and techniques is an important function in this role. Returning and/or storing any materials and equipment in the correct area, identifying any waste and arranging for its disposal, and reporting any defects or damage to the materials and equipment used are also part of this function.

Your responsibilities will require you to comply with organisational policy and procedures for the packing operations 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.

Your underpinning knowledge will provide a good understanding of your work, and will provide an informed approach to the completion of the packing operations in a biomanufacturing environment. You will understand the importance of doing this work efficiently and effectively, and will know what to consider when preparing and tidying up the work area before and after the packing activities. You will also know how to deal with problems, and how to achieve your work objectives and targets, in adequate depth to provide a sound basis for carrying out the activities safely and correctly.

You will understand the safety precautions required when carrying out biomanufacturing activities. You will be required to demonstrate safe working practices throughout, and will understand the responsibility you owe to yourself and others in the workplace.

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.

Monitor the packing of filled biomaterial containers in secondary biomanufacturing operations by manual methods



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 confirm that the specified services, equipment and materials are ready for use
- P4 pack filled products in the correct sequence and to the correct specification
- P5 maintain the required output rates and quality
- P6 correctly prepare the packed products for transfer and movement
- P7 finish packing operations in the correct manner
- P8 monitor and lead the quality and delivery of the above outcomes for yourself and your team
- P9 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 packing operations done by manual methods
- K14 the methods used for visually checking and for cleaning of the packing area
- K15 how to interpret and identify packaging instructions
- K16 the procedures for segregating materials and packs
- K17 the labelling requirements in the biomanufacturing area
- K18 the rate at which you are expected to work
- K19 the different types, condition and quantity of consumables required for the packing operations
- K20 how to monitor and maintain levels of packing consumables
- K21 how to prepare packs for movement and transfer, and the accompanying documentation
- K22 the quality standards to be maintained during the packing operations
- K23 the methods for maintaining personal health and safety during the packing operations
- K24 the common types of packing problem, and how these must be dealt with
- K25 the department or person to whom problems should be reported
- K26 the methods used for keeping records of the packing operations, and why this is important

Scope/range

1. monitor the carrying out of all of the following operations:
 - 1.1 adherence to procedures or systems in place for risk assessment, COSHH, personal protective equipment and other relevant safety regulations
 - 1.2 checking that all the equipment is in a safe and usable working condition (such as undamaged, safety devices in place and operational)
 - 1.3 ensuring that sufficient quantities of all required materials are obtained
 - 1.4 obtaining all the necessary data, documentation and specifications for the packing operations
 - 1.5 checking that packing of filled products is in the required batch sizes
 - 1.6 ensuring that the work area is clear and tidy, and that waste is disposed of in the correct manner
 - 1.7 ensuring that safe working practices and procedures are applied at all times
2. use three of the following types of protective clothing and equipment:
 - 2.1 laboratory coat/overalls
 - 2.2 gloves
 - 2.3 head/hair covers
 - 2.4 safety shoes/shoe covers
 - 2.5 safety glasses/visors
 - 2.6 other (please specify)
3. monitor the packing operations for two of the following types of filled product:
 - 3.1 vials
 - 3.2 syringes
 - 3.3 other (please specify)
4. monitor the checking of filled products so that they comply with two of the following quality requirements
 - 4.1 correctly formed and sealed
 - 4.2 free from filling defects
 - 4.3 other (please specify)
5. record details of the work done, and communicate the details to the appropriate people, using:
 - 5.1 verbal reportPlus one method from the following:
 - 5.2 written or typed report
 - 5.3 computer-based record
 - 5.4 specific company documentation

5.5 electronic mail

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