COGSCIM2_06

Measure, weigh and prepare compounds and solutions for biomanufacturing use

Overview

This standard covers the competences you need to measure, weigh and prepare compounds and solutions for biomanufacturing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and the measuring/weighing equipment that is used. 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 manufacturing 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.

Your underpinning knowledge will be sufficient to provide a sound basis for your work, and will enable you to adopt an informed approach to measuring and weighing procedures. You will have an understanding of the readiness preparations and checking used, in adequate depth to provide a sound background for carrying out the activities to the required specification.

You will understand the safety precautions required when carrying out the manufacturing 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.

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 use manufacturing scales for accurately weighing out materials, using metric/imperial measures
P4 accurately measure pH and conductivity of solutions in the laboratory, using correctly calibrated meters
P5 aliquot liquids into aseptic containers for manufacturing use and quality analysis
P6 measure liquids and solids for manufacturing use and analysis
P7 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' operational 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 calculate mass/mole calculations in metric measures
K14 how to select the appropriate balance and scale for the materials to be weighed
K15 how to check that a pipette is clean, dry and ready for use
K16 how to check the calibration on a pipette
K17 how to calibrate and check the calibration on a pH meter
K18 how to calibrate and check the calibration on a conductivity meter
K19 how to measure and weigh solids and liquids for laboratory use
K20 how to convert between different units of concentration (including moles/litre, grams/litre, percent mass per volume and parts per million)
K21 the pH scale (as a logarithmic scale for the measurement of the acidity of aqueous solutions), and the importance of pH to biological systems and processes

K22 how to choose the appropriate measuring equipment for the scale, accuracy and precision required for the task
K23 how to clean and maintain the pipettes, balances, pH meter probes and conductivity meter probes

Scope/range

1. use three of the following types of protective clothing and equipment:
    1.1 laboratory coat/overalls
    1.2 gloves
    1.3 head/hair covers
    1.4 safety shoes/shoe covers
    1.5 safety glasses/visors
    1.6 other (please specify)
2. carry out weighing activities using balances (scales), using two of the following accuracies:
    2.1 grams
    2.2 kilograms
    2.3 other (please specify)
3. measure out aliquots of solutions, using four of the following:
    3.1 automated pipettes
    3.2 graduated cylinders/beakers/tubes
    3.3 graduated/bulb pipettes
    3.4 volumetric flasks
    3.5 syringes
    3.6 burettes
    3.7 other (please specify)
4. measure pH and/or conductivity using two of the following:
    4.1 handheld pH meter
    4.2 combined pH/conductivity meter
    4.3 conductivity meter
    4.4 in-line pH meter
    4.5 other (please specify)
5. calibrate or check the calibration for two of the following:
    5.1 pH meter
    5.2 conductivity meter
    5.3 balance
    5.4 Pipettes
    5.5 Other (please specify)
6. make specific volumes of solutions to a specified concentration, using both of the following:
    6.1 creating a new solution by measuring and dissolving the correct amount of solute in the correct volume of diluents/solvent
    6.2 by dilution from a concentrated stock solution
7. weigh and prepare three of the following compounds and solutions:
    7.1 powders/granulations that do not readily lose or gain weight (moisture or solvent)
    7.2 solids that readily lose or gain weight (moisture or solvent)
    7.3 liquid samples (by difference)
    7.4 liquid samples (direct)

8. record details of the preparation work, and communicate the details to the appropriate people, using:
    8.1 verbal report
    Plus one method from the following:
    8.2 written or typed report
    8.3 computer-based record
    8.4 specific company documentation
    8.5 electronic mail

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