

Overview

This unit covers the competences you need to maintain health and safety in a biomanufacturing environment. You are required to observe all legal, statutory and organisational requirements, and you must be able to identify any potential hazards and risks to health and safety. You must also know what actions to take in case of an emergency and, as well as ensuring your own safety, you must show responsibility towards your colleagues and others. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP).

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 must be able to recognise the limitations of your own competence with the manufacturing work, and ask for appropriate help and advice when it is needed. You will work under a high level of supervision, whilst taking responsibility for your own actions and for the quality and accuracy of the work that you carry out.

Your underpinning knowledge will provide an understanding of your manufacturing work, in order to apply safely the appropriate scientific principles and practices. You will be competent in the safe use of the materials, equipment, consumables and instruments used to perform the manufacturing operations, and with the procedures appropriate to your job. Your depth of knowledge will be sufficient to provide a sound basis for safely carrying out the manufacturing activities, to a level that will allow the department to meet any agreed targets.

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.

Performance criteria

You must be able to:

- P1 ensure that your work is carried out in accordance with standard operating procedures
- P2 accurately assess health and safety in relation to your work and the biomanufacturing work environment
- P3 use the appropriate personal protective clothing and equipment for the work
- P4 make safe any health and safety hazards, and report them to the appropriate person as soon as possible
- P5 maintain the security of the biomanufacturing work environment, in accordance with organisational
- P6 ensure that you maintain your work area to a standard of health and safety which is consistent with local policies and legal requirements
- P7 maintain and use equipment and materials in accordance with manufacturers' instructions and local safety regulations
- P8 dispose of hazardous materials, waste and waste containers, safely and correctly
- P9 prepare, use and dispose of disinfectants, safely and correctly
- P10 carry out decontamination of work surfaces and floors effectively
- P11 take the appropriate precautions to protect yourself and others during working
- P12 follow the correct procedure, without delay, if an emergency arises or is suspected

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 manufacturing activities
- K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting manufacturing activities
- K3 the standard operating procedures, as set down in local manufacturing operating manuals
- K4 the importance of following manufacturers' 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 specific safety precautions to be taken when working with biomanufacturing equipment and computer-based systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and work station environment (such as lighting, seating, positioning of equipment), and repetitive strain injury (RSI))
- K8 the identity of health and safety representatives (such as the Manufacturing Safety Officer, Staff Health and Safety Representatives and First-Aiders)
- K9 the location and correct use of emergency equipment (such as fire extinguishers, including the situations in which different types of fire extinguisher are used)
- 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 why risks in the biomanufacturing work environment should be assessed, and the correct action to be taken
- K14 local procedures for escape (including escape routes and assembly points)
- K15 the location of fire alarms, and how to operate them

- K16 the location of spillage kits, and the procedures to follow in the event of spillages of chemicals and/or biological fluids
- K17 the control of substances hazardous to health (COSHH) regulations, and their application in the biomanufacturing work environment
- K18 the types of hazard which may occur in the manufacturing setting, and how these can be minimised
- K19 the correct storage and disposal procedures for hazardous materials (including flammables, corrosive, harmful and toxic chemicals)
- K20 the hazards associated with disinfectants and other chemicals (including toxicity)
- K21 the meaning of the terms 'disinfection' and 'decontamination', and the use of disinfectants
- K22 the reasons for disinfecting/decontaminating manufacturing surfaces and equipment
- K23 why it is important to differentiate and segregate categories of waste (such as using waste colour-coding)
- K24 the correct procedures for the storage, transport and disposal of waste

Additional Information

Scope/range related to performance criteria

You must be able to:

1. identify health and safety standard operating procedures for **all** of the following:
 - 1.1 manufacturing hazards
 - 1.2 unsafe practices
 - 1.3 spillages
 - 1.4 manual handling
 - 1.5 VDU & RSI policies
 - 1.6 other (please specify)
2. handle safely **three** of the following hazardous substances, in accordance with approved procedures:
 - 2.1 flammables
 - 2.2 toxic chemicals
 - 2.3 corrosive chemicals
 - 2.4 biological materials
3. follow established procedures for **all** of the following emergencies:
 - 3.1 workplace fire
 - 3.2 gas escapes
 - 3.3 spillage of hazardous substances
 - 3.4 other emergencies (please specify)
4. dispose of, safely, **two** of the following, in accordance with approved procedures:
 - 4.1 sharps
 - 4.2 plastics
 - 4.3 confidential records
 - 4.4 biomaterials (solid and liquid)
 - 4.5 one-use modules/components
 - 4.6 other (please specify)
 - 4.7 metal
 - 4.8 cleaning wipes/tissues
 - 4.9 chemicals (solid and liquid)
 - 4.10 aerosol containers
5. dispose of waste in **two** the following categories, in accordance with approved practices:
 - 5.1 autoclave
 - 5.2 flushing
 - 5.3 solids for recycling
 - 5.4 addition of chemicals
 - 5.5 fluids for recycling
 - 5.6 other (please specify)

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