

# SEMLATA2-16 -SQA Unit Code F7XY 04

## Following aseptic procedures in the laboratory environment



### Overview

This unit identifies the competences you need to identify and follow aseptic or clean room protocols in the laboratory, in accordance with approved procedures and practices. Prior to undertaking the laboratory activity, you will be required to carry out all the necessary preparations within the scope of your responsibility. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP).

Your responsibilities will require you to comply with any policies of your organisation in respect of preparing for work and working in aseptic or clean rooms and clean work areas. You will be required to report any problems with clean room 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. On completion of laboratory activities, you will be expected to discard personal protective equipment in the correct location, and in accordance with established policies and procedures.

Your underpinning knowledge will be sufficient to provide a sound basis for your work, and will enable you to adopt an informed approach to preparing for and working in aseptic or clean rooms. You will have an understanding of the attribute and behaviours required for clean room working, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

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

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#### Performance criteria

*You must be able to:*

- P1 ensure that your work is carried out in accordance with standard operating procedures
- P2 dress in the appropriate personal protection equipment (PPE) required for the clean room or clean work area environment, in accordance with the correct procedure
- P3 carry out visual quality checks on your personal protection equipment prior to entering the working environment
- P4 follow the correct procedures for entering and exiting the clean room or clean work area
- P5 follow aseptic techniques in the laboratory
- P6 remove personal protection equipment on completion of clean room or clean work area activities, and dispose/store in line with the correct procedure
- P7 communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures

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### 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 laboratory activities
- K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities
- K3 the principles of Good Laboratory Practice (GLP) and/or Good Clinical practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace

*You need to know and understand:*

#### Organisation specific

- K4 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
- K5 the manufactured materials and batch process tracking and records system
- K6 the types of handling and sorting system, and the procedures used for materials undergoing processing in the laboratory facilities
- K7 the importance of correct identification, and any unique organisational or laboratory numbers
- K8 the organisational requirements for maintaining the security of the workplace
- K9 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K10 the limits of your own authority and to whom you should report if you have problems that you cannot resolve

*You need to know and understand:*

#### Equipment/Process specific

- K11 the specific safety precautions to be taken when working in a clean room or clean work area environment
- K12 the correct fitting and use of clothing and personal protective equipment that must be worn in a clean room or clean work area (such as for body, hands, eyes, ears, feet, mouth and face)
- K13 hazards associated with working in a clean room or clean work area, with laboratory equipment (such as heat, radiation, chemicals, static electricity, high voltages, trapping points on equipment)
- K14 how to put on clean room clothing and footwear correctly
- K15 the procedures for entering and exiting the clean room or clean work area, and the authority needed to do so
- K16 the classification of the relevant clean room or clean work area, and how this impacts upon you
- K17 the industry standards/classifications for clean rooms and clean work areas

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- K18 the company requirements for clothing and personal protective equipment, and the reasons why such clothing and equipment must be used
- K19 the procedures and methods for maintaining issued clothing and personal protective equipment
- K20 how to apply procedures for dealing with damaged or dirty clothing and personal protective equipment
- K21 how to store clothing and personal protective equipment correctly
- K22 the laundering/cleaning/maintenance procedures relating to the issued clothing and personal protective equipment
- K23 the aseptic techniques that are applied and used in the laboratory
- K24 how to dispose correctly of single-use personal protective equipment
- K25 the policy and procedures relating to personal items (such as body lotions, makeup, jewellery, contact lenses, footwear, own clothing)

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### Additional Information

#### Scope/range related to performance criteria

*You must be able to:*

1. prior to entering clean room, carry out all of the following:
  - 1.1 use the correct issue of job instructions and specifications
  - 1.2 follow risk assessment procedures and COSHH regulations
  - 1.3 ensure that you are appropriately dressed and uncontaminated before entering the area
  - 1.4 carry out your activities in line with organisational procedures
  - 1.5 store accurate records of your activities, in accordance with appropriate procedures
2. satisfy **all** the following company clean room/clean work area requirements:
  - 2.1 use appropriate clothing/personal protective equipment (PPE) (such as suits, gowns, coats, hoods, hats, caps, helmets, other headwear, boots, overshoes, other forms of footwear, safety goggles, visors, gloves)
  - 2.2 comply with hazard protection (such as breathing apparatus, gloves, apron/smock, other forms of PPE or clothing required)
  - 2.3 deal appropriately with damaged or dirty clothing/PPE (such as reporting damage, replacement, safe removal and cleaning or disposal, subjected to acid/hazardous substance spills, damaged/dirty labelling)
  - 2.4 store specified clothing/PPE correctly when not in use
  - 2.5 ensure the proper cleaning/laundrying/maintenance of clothing/PPE
  - 2.6 dispose of single-use clothing and equipment in the correct location
  - 2.7 report any hazards or breaches of protocol
3. use **three** of the following types of personal protective equipment for clean room working:
  - 3.1 body suit
  - 3.2 gloves
  - 3.3 air supply
  - 3.4 face mask
  - 3.5 respirator
  - 3.6 other (please specify)
4. use personal protective equipment in **one** of the following clean room environments:
  - 4.1 health/disease screening
  - 4.2 drug development
  - 4.3 biochemical processing
  - 4.4 agro-biotech research
  - 4.5 biotechnology processing
  - 4.6 other (please specify)
5. identify and follow protocol methods and procedures that satisfy **all** of the following:

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- 5.1 the safety of people
- 5.2 containment/integrity of the clean room/work area
- 5.3 containment/integrity of the specimen/product
- 5.4 appropriate industry standards and protocols
- 6. record details of the work activity, 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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