Marking Guide

To support delivery of the Pharmaceutical Manufacturing Operator Induction Skill Set (FBPSS00051)

Introduction

This resource contains suggested assessment tasks for *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set.*

The units of competency in this skill set are:

- FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements
- FBPWHS2001 Participate in work health and safety processes
- FBPPHM3002 Operate a pharmaceutical production process
- FBPPHM3003 Work in a controlled environment

The *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set* is designed to address the skills and knowledge required of pharmaceutical manufacturing operators, for workers entering the pharmaceutical manufacturing industry. This skill set may provide an induction to work in that setting. This skill set is also designed to support ongoing professional development for experienced pharmaceutical manufacturing operators.

This Guide

The Assessor Guide includes the following items:

- Suggested Assessment Task 1: Knowledge Questions
- Suggested Assessment Task 2: Scenarios
- Suggested Assessment Task 3: Observation Checklist
- Assessment Mapping for *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*

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Certain questions in the assessments were sourced from the World Health Organization, Pharmaceutical GMP Questions. Documents made available by WHO.

Suggested Assessment Tasks

Please note that these tasks are given as a guide only, and may not be sufficient or relevant to the needs of the package; consult the training package requirements for details. Suggested mapping information for tasks is provided at the end of this guide.

The assessor must ensure that assessments are contextualised, meet the principles of assessment and the rules of evidence, and satisfy all performance evidence, performance criteria, knowledge evidence, foundation skills, assessment conditions and other requirements of each training package.

Full details for each unit may be referenced at:

- https://training.gov.au/Training/Details/FBPPHM2001
- https://training.gov.au/Training/Details/FBPWHS2001
- https://training.gov.au/Training/Details/FBPPHM3002
- https://training.gov.au/Training/Details/FBPPHM3003

The assessor must also ensure that the assessment is conducted safely, and the environment meets health and safety requirements prior to and during assessment. Personal protective equipment such as gowns, masks, hair nets, gloves, etc. must be provided to candidates. If at any time during the assessment process you consider that any person may be at risk, you must immediately abort the assessment session.

Assessment Task 1: Knowledge Questions

Task 1 contains 51 suggested knowledge questions.

Some of the questions must be answered about specific workplaces, using situations, roles, procedures and documents particular to one real workplace. However, all questions should be contextualised in this manner before delivery, when possible.

Questions can be delivered and answered in written form or orally, in a face-to-face or online environment, with careful consideration given to the rules of evidence.

Suggested answers to selected questions are marked in red, but answers are given as a suggestion only and should be checked by the assessor for accuracy, sufficiency and currency. Assessors are expected to use judgement based on their own industry expertise and formal descriptions of competency. The assessor must ensure that the assessment is conducted safely, and the environment meets health and safety requirements prior to and during assessment.

1. Describe what Good Manufacturing is, and why it is important to pharmaceutical manufacturing.
Answer could resemble: Good manufacturing practices (GMP) are minimum requirements for manufacturing that ensure that goods are consistent and high quality from batch to batch. This ensures that the goods are not contaminated, and they do not cause harm to the end user.

2. Describe at least 2 guidelines of Good Manufacturing Practices (GMP).

Answer could include, for example:

- preventing contamination (including specific practices to do so)
- consistency from batch to batch
- documenting and recording
- checking for quality at many stages
- quality management system.

3. Describe at least 2 consequences of failing to follow GMP requirements.

Answer could include, for example:

- harm to the end user from contamination or other sources
- loss of sales/materials
- suspension or cancellation of license
- conditions on the license
- legal consequences
- role/job/organisation consequences.

4. Which of the following are sources of GMP that apply to a specific work area?

Select all that apply

A. Standard Operating Procedures Manual
B. Documents and forms used to record information about the process
C. Checking the Internet with a Google search
D. Asking your union representative
E. Induction training
F. On the job training
G. Peers, leading hands and supervisors
H. Job descriptions

5. True or false?

The operation of the quality system is everyone's responsibility. The production of safe, high quality product is important to the jobs of everyone in the enterprise.

TRUE

6. The purpose of GMP requirements are primarily:

Select all that apply

A. To ensure that all products are tested according to specifications
B. To ensure that all products are made in accordance with the formula
C. To minimise risks inherent in production that cannot be prevented thorough testing of finished products
D. To prevent harm from occurring to the end user
E. To only prevent cross-contamination

7. You have been given the task of preparing and dispensing materials for a pharmaceutical batch. Where would you identify the GMP requirements for this task?

Select all that apply

A. Batch documents
B. GMP Guide
C. Workplace Health and Safety manual
D. Google
E. Standard Operating Procedures

8. Personal hygiene behaviour and activities should include:

Select all that apply

A. Bathing daily, keeping hair clean and covered and nails clean and trimmed
B. Wearing clean clothes and/or uniform
C. Not wearing excessive jewellery in the workplace (wedding bands are usually allowed)
D. Carrying personal effects into processing areas
E. Washing and drying hands after contamination has occurred
F. Eating in your work areas

9. Which of the following statements about personal protective equipment are true?

Select all statements that are true

A. All uniforms, clothing, footwear, PPE and equipment are inspected by staff regularly (and before use) to ensure that they are clean and in good repair.
B. Any disposable PPE used, such as hairnets, earplugs or gloves, must be recycled to save the environment.
C. Any PPE that is worn, damaged or too old may be putting the worker's health at risk as the equipment may not be effective, may pose a risk to the worker, and may increase the risk of contamination
D. Special working shoes, or overshoes, are worn in manufacturing areas. The shoes should be cleaned and disinfected at prescribed intervals and worn only within the work area
E. Clothing or uniforms washed and stored at home must be treated in the same way as those in the workplace: they must be allowed to air dry and stored in a secure place, such as a locker or change room, to ensure they remain clean and uncontaminated

10. Which of the following statements about raw materials, product and packaging are true?

Select all statements that are true

A. It is not necessary to store raw materials separate to the production areas
B. Packaging materials in sealed containers do not need to be stored in a quarantine area.
C. Starting materials do not need to be tested on receipt if the owner of the vendor is known personally to the manager of the buying facility
D. Quarantined materials are usually labelled in yellow. Approved material are usually labelled in green. Rejected materials are usually labelled in red.

11. Describe at least 6 types of contamination in the work area, and the possible source of this kind of contamination

Contamination type	Possible source of this contamination
Possible answers can include, for example: bacteria, mold, pest waste, hair, dirt, metal shavings, etc.	Possible answers can include, for example: ill people, poor hygiene, dirty tools, facilities, pests, clothing, equipment, lack of sanitisation, air flow problems, etc.

12. Indicate which statement describes an internal audit, and which statement describes an external audit.

A. This kind of audit is a regular audit of the workplace or part of the general responsibilities of the staff, such as to being observant and identifying potential or actual non-compliances.

Audit type: __Internal_____

B. The purpose of this kind of audit is to assess the organisation for compliance with the relevant manufacturing standards, conditions specified in the manufacturing licence and relevant marketing policies and procedures.

Audit type: _External_____

13. Contamination and cross-contamination can be avoided by:

Select all that apply

A. Performing cleaning and sanitisation activities
B. Deodorising all work areas
C. Carrying out waste management activities
D. Following PPE requirements
E. Controlling access and entry to the production areas

14. Which of the following are GMP requirements for documentation?

Select all that apply

A. To put the pharmacopeial specifications for raw materials into a company authorised document
B. To tell workers what to do and when
C. To make sure the process operators have something to do while waiting for a manufacturing step to finish
D. To provide an audit trail in the case of a customer complaint

15. Quality assurance is the responsibility of:

Select one

A. The top management of the company only
B. Only the staff in the quality control department
C. Staff at many different levels and in many different departments across the company
D. Only those people who make the product

16. Fill out the following table to describe at least 2 control methods for maintaining GMP, their purpose, consequences of lack of control, and how each control is monitored.

Control type	Control purpose	Consequences of lack of control	How is the control monitored?
Answer could include at least 2 common control types	Answer could include at least 2 correct control purposes	Answer could include at least 2 consequences	Answer could include at least 2 methods of monitoring the control
Wearing of PPE such as hair covering	To prevent hair contaminating the product	Product is contaminated by hair and is recalled	Hair covering is monitored by all staff and supervisors
Processing one product in the process room at any one time	To prevent cross contamination between products	Product is contaminated by other materials and is recalled	Line clearance procedures between products are followed

17. Describe at least 2 environmental procedures, including waste collection and handling procedures, that are usually followed in a pharmaceutical workplace, or are followed in your own workplace.

Answers will vary, but could include at least 2 environmental procedures specific to the GMP guide or the relevant workplace e.g.?

After processing a batch of products all remaining materials are removed from the room and disposed o according to the relevant SOP

Between batches all equipment is cleaned according to the relevant SOP and recorded in the cleaning logs

18. Describe at least 2 ways of reporting and recording information required by GMP in a pharmaceutical workplace.

Answers will vary, but could include, for example:

- reporting incidents/injuries/safety issues, including paperwork used and person to report to
- labelling
- recording other information.
- Completing appropriate batch records
- Completing cleaning logs

19. For your own work, role and responsibilities (or the responsibilities of a specific pharmaceutical role), list the following:

- **at least 2 pieces of legislation relevant to your work, role and responsibilities**
- **at least 2 regulations relevant to your work, role and responsibilities**
- **at least 2 standards relevant to your work, role and responsibilities**
- **at least 2 codes of practice relevant to your work, role and responsibilities**
- **at least 2 industry standards/guidance notes relevant to your work, role and responsibilities.**

Legislation	Answers will vary, but could include, for example, Work Health and Safety Act of 2011, Occupational Health and Safety Act 2004, Therapeutic Goods Act 1989.
Regulations	Answers will vary, but could include, for example, Work Health and Safety Regulations 2011, Occupational Health and Safety Regulations 2017, Therapeutic Goods (Manufacturing Principles) Determination 2020.
Standards	Answers will vary, but could include 2 relevant Australian Standards e.g.? AS/NZS 3666.2-2011 Air-handling and water systems of buildings - Microbial control, AS ISO 14644.1:2017 Cleanrooms and associated controlled environments.
Codes of practice	Answers will vary, but could include, for example, Electrical Safety Code of Practice 2013, etc. Code of Practice-Managing electrical risks in the workplace , Code of Practice-Hazardous manual tasks; 3. Code of Practice-First aid in the workplace.
Industry standards/ guidance notes	Answers will vary, but could include, for example, the GMP Guide, Guide to Good Manufacturing Practice for Medicinal Products. Poisons Standard February 2021 (SUSMP No. 32), Australian Code for the Transport of Dangerous Goods by Road & Rail

20. If you find manufacturing equipment that is defective, what should you do?

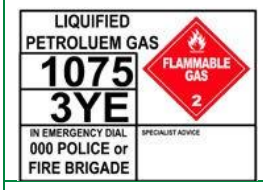
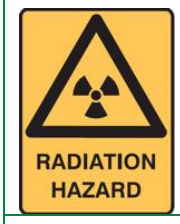
Select all that apply

A. Label the item as defective
B. Remove and isolate it, and repair it as soon as possible
C. Clean it, and update the cleaning procedure
D. Use it at half capacity

21. If you make a mistake filling in documentation, what should you do?

Select all that apply

A. Cover the mistake with correcting fluid
B. Punch a hole through the paperwork to take it out of circulation
C. Completely cover the mistake with a dark black pen
D. Cross through the mistake with a single line, record the date and initial or
- sign it

22. What is the meaning of the following signs, and what safety procedures need to be followed?	
	Answers could include, for example: Workers and other persons, including managers and visitors, should never enter the area without wearing appropriate personal hearing protectors and eye protection, regardless of how short the time they stay in the area..
	Used to provide warning when a hazard or a hazardous condition is likely to be life threatening. This sign indicates conditions are likely to be life threatening by the presence of 11,000 volts. Extreme care must be taken in the area.
	This is the location of first aid equipment. It can be used in the case of emergency or injury.
	Sharps are deposited in this container, and procedures must be followed when using sharps, disposing of sharps, and disposing of the contents of this container
	This is the Hazchem sign for liquified petroleum gas, and it has emergency and material information which can be relayed to the emergency services in the case of an emergency.
	This sign indicates a radiation hazard, and protective procedures must be followed in this area
	This symbol indicates an explosive hazard An Explosive sign serves as a constant warning to workers entering the area that serious hazards exist and that safety is essential

	This symbol indicates a toxic hazard generally used as a warning of danger of death, particularly in regard to poisonous substances
	This sign indicates the location of a fire extinguisher
	This sign indicates that hearing protection, head protection, foot protection and safety vests must be worn in the area

23. What is the difference between a hazard and a risk?

Answer could resemble:

A hazard is something that could cause harm or injury. A risk is the likelihood of the hazard happening, and how serious the harm or injury could be.

24. Describe at least 6 workplace health and safety hazards found in a pharmaceutical workplace.

Answers could include, for example:

- chemicals
- contamination of various kinds
- bodily fluids
- sharps
- noise
- manual handling
- ergonomics
- tripping hazards
- equipment and machinery

25. What are 3 potential consequences of not following safe work practices?

Answers could include, for example:

- injury
- illness
- fire and/or emergency situation
- loss of life
- loss of job
- legal and financial consequences

26. Name the 6 elements of the Hierarchy of Control, and put them in order from most effective to least effective.

Most Effective to Least Effective	Element Of Hierarchy of Control
1. Most effective	1. Elimination
2.	2. Substitution
3.	3. Isolation
4.	4. Engineering
5.	5. Administration
6. Least effective	6. PPE

27. For the following common workplace hazards, describe at least 1 safety measure could be used to control the hazard, and state which part of the hierarchy of control they belong to

Hazard	Safety measures to control the hazard
Chemicals	Answer could include at least 1 reasonably practicable control measure for each of the hazards. E.g. chemicals: wearing of appropriate PPE such as goggles, chemical resistant gloves and aprons
Bodily fluids	Avoiding skin contact with bodily fluids
Sharps	Disposing of sharps in appropriate sharps container
Noise	Wearing of appropriate PPE such as earmuffs or ear plugs
Manual handling	Following appropriate manual handing procedures as detailed in manual handling code of practice
Work postures	Following appropriate procedures as detailed in manual handling code of practice
Underfoot hazards	Use of appropriate signage and barricades
Moving parts of machinery	Use of appropriate machine guards

28. Describe at least 3 sources of information about health and safety that can be found in the workplace.

Answers could include, for example:

- Safety Data Sheets
- policies and procedures
- Standard Operating Procedures
- legislation, etc.

29. Describe the roles and responsibilities of the following, in regards to health and safety in the workplace.

Job title/group	Roles and responsibilities in WHS
Employees	Answer could resemble: All employees have a duty of care around WHS
Health and safety representatives (HSRs)	These are elected and specially trained representatives of a work group
Health and safety committees	This is a committee made up of HSR's and management who meet regularly to discuss and resolve WHS matters
Supervisors	This is the person who the operator works with and takes instructions from on a day to day basis
Managers	This is the person at the head of the organisation and whom the WHS Act hold them ultimately responsible for the safe operation of the enterprise.
Employers	This is the person at the head of the organisation and whom the WHS Act hold them ultimately responsible for the safe operation of the enterprise

30. Describe at least 3 potential emergency situations, the alarms and signals associated with the situation, and the required response to each situation.

Potential emergency situation	Alarms and signals	Required response
Answer could include at least 3 potential emergency situations Injury to worker	Answer could include at least 3 correct alarms and signals for each emergency, internal call procedure, e.g. announcement for first aider to attend a specific area, call 000	Answer could include a description of evacuation, first aid, wardens, fire response, worker starts first aid until designated first aider responds. Workers on site administer first aid until ambulance arrives.
Equipment fire	Internal call procedure, e.g. announcement for fire crew to attend a specific area, call 000	Worker fights fire until designated fire crew responds. Workers on site fight fire until fire engine arrives.
Emergency evacuation	Internal call procedure, e.g. announcement to evacuate premises call 000	Workers/ first aiders and fire wardens/ fire crew take necessary action until emergency services arrive

Note: The following question must be answered for a particular workplace. Assessors should be familiar with the specific workplace environment the answer relates to, and should ensure that candidates are provided sufficient guidance to answer these questions for that workplace.

31. Fill out the table below to identify workplace-specific information for hazards, potential emergencies, designated persons and work procedures relevant to your own workplace or a workplace you are familiar with.

Hazards of this particular work environment	Answer will be specific to workplace, but could include at least 3 hazards present: Alcohol based disinfecting solutions
	Dispensing of chemicals designated as poisonous
	Machine guards on equipment
Potential emergencies relevant to this particular workplace	Answer will be specific to workplace, but could include at least 3 potential emergencies specific to workplace Potential fire arising from use of alcohol disinfecting procedures
	Worker injury arising from inhalation of poison
	Worker injury arising from equipment guard removal or damage
Designated person or persons for raising issues about health and safety	Answer will be specific to workplace, but could include at least 1 job title, role or person WHS representative
Organisation and work procedures related to performance of own work	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and performance of own work Leading Hand or supervisor
Organisation and work procedures related to specific hazards and risk control	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and hazards/risk control SOP relating to dispensing of poisonous materials using appropriate PPE, fume hood, dust extraction
Organisation and work procedures related to reporting of hazards, incidents and injuries	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and reporting hazards/incidents/injuries Completion of Incident Report

Organisation and work procedures related to consultation	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and consultation SOP for consultation matters relating to Workplace Health and Safety Committee
Organisation and work procedures related to use of personal protective equipment	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and PPE SOP relating to wearing of different PPE in different areas of the facility
Organisation and work procedures related to emergency response	Answer will be specific to workplace, but could include at least 1 procedure relevant to workplace and emergency response SOP for Emergency Evacuation

32. Fill out the table to describe how product quality and Good Manufacturing Practice (GMP) compliance can be impacted by the performance, functionality, construction and instrumentation of processing equipment and utility systems.

Processing equipment performance impacts product quality and GMP by:	Answer could include discussion of the general principles regarding pharmaceutical equipment are that equipment layout and design must aim: • to minimize risks of error • to permit effective cleaning and maintenance • to avoid cross-contamination, dust and dirt build-up • to avoid any adverse effect on the quality of products • to avoid any adverse effect on the health of operators • Processing equipment performance may impact product quality and GMP by producing rejected product e.g. ampoule sealing flames amy be incorrectly set and thus a number of deformed glass ampoule seals are produced and then rejected.
Processing equipment functionality impacts product quality and GMP by:	Processing equipment functionality impacts product quality and GMP by producing, for example, blister packs with missing or doubled up tablets. This fault is caused by using a wrongly sized tool to produce a pocket too large for that particular tablet.
Processing equipment construction impacts product quality and GMP by:	Processing equipment construction impacts product quality and GMP by introducing corroded metal into the process. For example, using steel painted equipment instead of stainless steel of appropriate quality.
Processing equipment instrumentation impacts product quality and GMP by:	Processing equipment instrumentation impacts product quality and GMP by not providing appropriate feedback to the operator. For example, using a non-calibrated scale for dispensing, or checking tablet weights during in-process testing.

33. Describe at least 10 common GMP non-conformances and unusual events found in a pharmaceutical production environment.

Answer could include all of the following:

- missing, illegible or inaccurate records
- failure to follow workplace procedures
- failure of cleaning regime
- damaged goods, including; starting materials, components, intermediates and finished products
- product diverted from normal course of process
- loss of sterility or pressure
- spills
- out of limit situations including; yields, reconciliations, in process controls and in process checks
- damage or poor maintenance of plant or equipment
- signs of inadequate cleaning or pest infestation

34. Describe the meaning of the following concepts associated with control of GMP processes.

Process variation	Answers could resemble: Special causes or variation (such as an equipment malfunction) or normal process variation
Critical quality attribute	Characteristics (chemical, physical, biological and microbiological) attributes that need to be within acceptable quality limits
Critical process parameter	A parameter that has an impact on a critical quality attribute

35. Describe the functions and limitations of personal protective equipment and contamination prevention clothing in the work process

Answer could resemble:

PPE includes items like safety goggles, face masks, ear plugs, hard hats and work gloves. It can help prevent contamination and prevent some harm to the worker, but should be used in combination with other control methods from the hierarchy of control to increase safety and adhere to GMP requirements.

- PPE that is worn incorrectly, dirty, damaged or old may:
- not effectively protect the worker from the hazard
- present a new risk to the worker (such as straps on equipment getting caught in machinery)
- increase the risk of contamination to the product.

36. Describe how the following GMP requirements are used, and why they are important

GMP requirement	How it is used and why it is important
Identification and traceability	Answers could resemble: Records for sampling, inspecting, testing of materials, intermediates and bulk and finished products need to be kept to identify the components in a batch. This means that there will be traceability on what happened in the event of a product failure.
Yields and reconciliation	Yield calculations and reconciliation procedures are of critical importance because they indicate if product has been lost or is unaccounted for.
Segregation and storage	Cross contamination can occur, such as when active chemicals in a product contaminates that of another, which could change how the drug works, rendering it inactive or make it dangerous.

37. Describe how status labels (physical and electronic) are used in GMP compliance.

Answer could resemble:

Materials will be received, held pending test in a status of quarantine. These materials are either labelled with a Yellow quarantine label, or a computer quarantine record status applied. Quarantined materials are held in a separate quarantine materials store.

Materials approved are released for use. Released materials are either labelled with a Green approved label, or a computer released record status applied and held in store.

Materials that are not approved are rejected and are either labelled with a Red rejected label, or a computer rejected record status applied. Rejected materials are held in a separate rejected materials store.

38. Describe the purpose of the following methods used to monitor the production process

Inspecting	Answer could include at least 1 purpose of inspecting during the production process E.g. conducting a line clearance inspection before the next product is prepared for production
Measuring	Answer could include at least 1 purpose of measuring during the production process E.g. as dispensing of raw materials for the production batch
Testing	Answer could include at least 1 purpose of testing during the production process E.g. as conducting pH tests during the production process

39. Describe the purpose and methods of monitoring the following items during the production process.

Environment	Answer could describe the purpose and at least 1 method of monitoring the environment during the production process E.g. monitoring the temperature and relative humidity in the process room to ensure that the processing temperatures and relative humidity are within the operating parameters specified in the batch documents or SOP
Product appearance	Answer could describe the purpose and at least 1 method of monitoring product appearance during the production process E.g. inspection of the of glass ampoules for particulates to ensure that there are no visual particulates in the ampoules
pH	Answer could describe the purpose and at least 1 method of monitoring pH during the production process E.g. withdrawal of a sample for testing using a pH meter in the in-process laboratory to check if the pH is within the specified range in the batch documents
Volume or weight	Answer could describe the purpose and at least 1 method of monitoring volume or weight during the production process E.g. using a calibrated scale for dispensing raw materials to ensure that the weight dispensed is accurate
Temperature	Answer could describe the purpose and at least 1 method of monitoring temperature during the production process E.g. using a calibrated thermocouple to ensure that an autoclave has reached the designated temperature for the sterilising process as specified in the batch documents or SOP

40. Which of the following statements about international nomenclature and classification of controlled environments and clean rooms is correct?

Select the correct statement

A. Australia and the United States use the same classification for clean rooms
B. Australia and Europe use the same classification for clean rooms
C. Europe and the United States use the same classification for clean rooms

41. For each ISO classification system, put the associated GMP grades of clean room from Grade A to Grade D.

ISO 5 (4.8)	Grade A
ISO 5	Grade B
ISO 8	Grade D
ISO 7	Grade C

42. Describe the GMP requirements for the qualification of cleanrooms.

Answer could include discussion of:

- climatic conditions

  Reproducible climatic conditions are vital in the production of sensitive products in cleanrooms.

  - Qualification of air velocity and indoor air quality will examine constant temperature and humidity values in the cleanroom:
  - Individual measurements of temperature and relative air humidity
  - Implementation of climatic mapping in cleanroom areas
  - Definition of critical monitoring points
  - Commissioning, validation and calibration of monitoring systems
- differentials pressure
  - The protection of cleanroom areas against contamination from less clean areas is ensured by a differential pressure concept with controlled overpressure. By measuring the pressure and the air flow velocity, operational safety can be increased and the quality of the products ensured.
  - Qualification pressure measurements in cleanrooms are:
    - Verification of differential pressure cascades
    - Differential pressure measurement on the filter
- microbial monitoring
  - In addition to classification measurements, microbiological sampling is necessary. The microbiological limit values for this are laid down in the PIC/S GMP Guideline, Annex 1. Qualification microbiological measurements in cleanrooms comprise:
    - Classification measurement (microbiological)
    - Air testing (active air germ collection or sedimentation)
    - Surface testing (direct sampling/contact test)
    - Determination of sampling points, frequencies and action limits
    - Sampling
    - Determination of total bacterial count
    - Identification of germs (up to genus or species).
- airborne particle counts
  - In cleanrooms, the concentration of airborne particles is one of the decisive parameters for a suitable process environment. After qualification, particle monitoring ensures that the established air quality is maintained.
  - Qualification particle measurements in cleanrooms are:
    - Classification measurement/determination of the particulate purity class
    - Recovery time measurement/recovery test
    - Filter leak test/integrity test

43. Describe at least 8 key design requirements for controlled environments and cleanrooms for product protection.

Answer could include discussion of:

- layout and architecture
- product and process requirements for clean air
- filtration, including High Efficiency Particulate Air (HEPA) filters and the theory of particle filtration
- airlocks for materials, equipment and people
- turbulent and laminar air flows
- pressure differentials
- box-within-a-box principle
- cleanability and maintainability

44. Describe how each of the following elements contributes to controlling contamination in a controlled environment

Element of operation	How it helps control contamination
Clean rooms, including how they are certified	Answer could include details of certification, and at least 1 way clean rooms help control contamination Cleanrooms require temperature and pressure control, as well as separation from the outside environment and other operations, but these must be controlled to specific standards. Cleanrooms are classified by the maximum acceptable numbers of particles (by size) in the air per cubic meter, and must be regularly tested to ensure compliance to that standard, e.g. AS ISO 14644.1:2017 Cleanrooms and associated controlled environments.
Controlled, non-classified environments	Answer could include at least 1 way controlled non-classified environments help control contamination A packaging area is an example of a controlled, non-classified environment. The packaging area is separated from a non-classified environment such as a warehouse by a door, or even an airlock. Specific PPE is required in a packaging area and this is different to the PPE required in a warehouse. This helps to prevent contamination of the packaging area from dust and dirt from the outside environment.
Clean zones	Answer could include at least 1 way clean zones help control contamination Different clean zones have different air qualities and air pressure requirements. This means that the areas where the product is most at risk are protected by the most stringent air quality requirements and are at a higher air pressure to the adjacent areas. This ensures that contamination is controlled by the flow of clean air away from the most sensitive areas.
Monitor and test systems	Answer could include at least 1 way monitor and test systems help control contamination Cleanroom differential pressure monitors are designed for continuous monitoring of differential pressures to ensure that the cleanroom is operating within design parameters
Isolator technology	Answer could include at least 1 way isolator technology helps control contamination Barrier isolation technology refers to where people are completely removed from the operating environment. This is an effective method to control contamination, as removing the person from the environment gets rid of the primary source of contamination. It is still necessary to practice good aseptic technique when handling products and support materials.

At rest and in operation	Answer could include at least 1 way monitor and test systems help control contamination GMP Guidelines require that cleanrooms are tested at rest and in operation in accordance with AS ISO 14644-1. Classification should be clearly differentiated from operational process environmental monitoring.
Gowning and cleaning	Answer could include at least 1 way gowning and cleaning help control contamination The primary purpose of cleanroom gowning is to protect the product and the environment from microbial contamination. When used correctly, cleanroom gowning greatly reduces the microorganisms released by personnel. Achieving microbial control within a cleanroom is the use of defined cleaning techniques, together with the application of detergents and disinfectants.

45. How do controlled environments operate to control contamination when they are at rest?

Answer could include at least 1 way controlled environments operate to control contamination when they are at rest.

Positive air pressure relative to the next zone controls contamination by avoiding the ingress of air from the surrounds.

46. How can improper cleaning of a controlled environment or cleanroom lead to product contamination? How can it pose a safety hazard?

Answer could include at least 1 way improper cleaning can lead to product contamination, and 1 way improper cleaning can pose a safety hazard.

Improper cleaning of a controlled environment or cleanroom may result in residues from previous products contaminating the next batch, thus leading to a rejection of product.

Improper cleaning can also result in microbial contamination of the cleanroom leading to a safety hazard.

47. Why is proper selection of equipment and materials important for cleaning?

Answer could include at least 1 reason proper selection of equipment and materials is important in cleaning

Proper selection of cleaning equipment and cleaning agents is essential to prevent contaminating the controlled are with dirt, product residues or microbes.

All cleaning equipment must be high quality (e.g. no damage, etc.) and clean. Cleaning equipment may be sterilised, for example in an autoclave for use in a cleanroom, or be sanitised for use in other controlled areas. Dedicated cleaning equipment is required for use in cleanrooms.

Cleaning agents used include water (for rinse/wash/sanitising operations) and approved cleaning compounds and agents. Alcohol as a cleaning agent reduces potential moisture contamination and also acts as a sanitiser (to kill microbes on the surface where it is applied).

48. Describe how and why the following controlled environment operating conditions are measured, conducted or recorded.

Controlled environment operating conditions	How and why it is measured, conducted or recorded?
Differentials pressures	Answer could briefly describe how and why differentials pressure is measured Generation of a positive pressure results in a pressure differential between areas. It is important to measure this differential pressure and monitor it constantly. Differential pressure measuring instruments are used for this purpose.
Particle counts	Answer could briefly describe how and why particle counts are measured GMP Guidelines specify the maximum permitted number of particles for grades of cleanroom. Particles may also carry microbes and both particles and microbes can contaminate the product. A particle counter is used to detect and count particles in the controlled area. Particle counters may be a single instrument or a multi-channel real-time monitor.
Microbial sampling	Answer could briefly describe how and why microbial sampling is conducted Microbes can contaminate the product and the production environment. Typically, nutrient agar settle pales are opened and left for a specified time in the controlled environment to catch any microbes present. These agar plates are then incubated, and the resulting microbes classified and counted.
Laminar air flow	Answer could briefly describe how and why laminate air flow is measured Laminar Air Flow (LAF) provides a work area with aseptic/sterile conditions for the exposed product (e.g. filling of an ampoule). LAF has continuous displacement of air (it provides streamline flow of air) that passes through a HEPA filter that removes the particulates from the air. A LAF unit is generally tested on an annual basis or after any mechanical or electrical maintenance. LAFs are generally tested by specialist contractors who use a variety of air flow meters and particle counters as part of cleanroom certification.
Humidity	Answer could briefly describe how and why humidity is measured Humidity control in a controlled environment is important to prevent microbial growth and corrosion, condensation on work surfaces and contamination leading to product degradation. High humidity causes fine powders to absorb moisture, e.g. clogging the powder feed to a tableting press. Humidity in air ducts creates moist places for bacterial colonies to grow and causes process contamination. A variety of humidity measuring instruments are used depending upon the production environment.

Temperature	Answer could briefly describe how and why temperature is measured It is important to maintain a standard temperature in cleanrooms to keep employees comfortable. Temperature and humidity are related. High temperature can cause staff to sweat, and they release a higher amount of particles into the controlled environment, potentially contaminating the environment and compromising production standards. A variety of thermometers or temperature gauges are used to check the room temperature.
Room status	Answer could briefly describe what room status is and why it is important. Room status is designated by signs, boards or logs to indicate that the room is clean and ready for use. This is important so that production does not commence before the room is properly cleaned and sanitised.
Cleanliness status	Answer could briefly describe what cleanliness status is and why it is important Equipment status is designated by equipment tags and/or logs to indicate that the equipment is clean and ready for use. This is important so that production does not commence before the equipment is properly cleaned and sanitised.

49. What is the relationship between hygiene and microbiology?

Answer could resemble:

Microorganisms can abound on body surfaces and in the nose, mouth, throat and intestines. Personal hygiene activities refer to those acts carried out by the worker to control contamination of their hands, clothes, utensils, etc. The primary reason for good personal hygiene is to avoid contamination of product, materials, or environment by people working in the area. Good personal hygiene prevents contamination through transfer of dust and microorganisms via workers hands, clothing and personal habits.

50. What are at least 6 safety risks associated with controlled environment and cleanroom operators?

Answer could include:

- physical behaviour, including how to walk and stand in a cleanroom
- personal hygiene
- psychological
- workplace attitudes and habits
- communications between workers
- electrostatic discharge

51. What are at least 11 contamination risks associated with controlled environment and clean room operations?
Answer could include: • number of personnel in the controlled environment • activities being undertaken • leaks • malfunctioning equipment • low differential pressures • high particle counts • incorrect air flow and velocity • humidity • temperature • room status inactive or in alarm • lack of cleanliness

Assessment Task 2: Scenarios

Task 2 contains 6 suggested scenarios for candidates to respond to.

The scenarios are designed to be delivered in a pharmaceutical manufacturing workplace, with access to procedures, documents, tools, equipment, signage, PPE, etc., but they can also be delivered in a simulated environment that accurately represents workplace conditions. Real workplace procedures that cover all aspects of the task requirements should be supplied for each of the scenarios, whether simulated or delivered in a workplace.

Scenarios can be delivered in written form, role-played or discussed orally, in a face-to-face or online environment, with careful consideration given to the rules of evidence. Suggested topics to cover are given below each scenario, and can be provided to the candidate as a guide to their response.

The task is given as a guide only, and the assessor must check its accuracy, sufficiency and currency. The assessor must ensure that the assessment is conducted safely, and the environment meets health and safety requirements prior to and during assessment.

Scenario A: Stages of the pharmaceutical production process

A new employee has joined your work team and the team leader has asked you to assist in their on-the-job training. You will be training them in the stages of the pharmaceutical manufacturing process.

Select a product that is made in your workplace. Deliver an on-the-job training session you could conduct with the new team member that takes them through every stage of the manufacturing process for that product.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
All stages of the pharmaceutical manufacturing process, and a general overview of GMP requirements for each stage Details/notes:	

The purpose of each stage Details/notes:	
The methods used for each stage Details/notes:	
The outcomes of each stage Details/notes:	
Control points used in each stage, including methods used to monitor the process, and items that are monitored Details/notes:	
The procedure for checking materials are suitable for use, including release status Details/notes:	
The flow of materials Details/notes:	
The flow of people Details/notes:	
The flow of waste Details/notes:	
The flow of the manufacturing process Details/notes:	
The effect of at least 2 outputs on downstream processes of each stage Details/notes:	
At least 3 common GMP non-conformances and unusual events for the process, and how to control and/or rectify them Details/notes:	
At least 3 workplace procedures for reporting and recording information Details/notes:	

Resources/procedures/equipment used:	
Other topics/evidence covered:	

Scenario B: Equipment

You have been asked to train a new employee on a piece of manufacturing equipment they are unfamiliar with.

Select a piece of pharmaceutical manufacturing equipment in your workplace. Deliver an on-the-job training session you could conduct with the new team member that takes them through the operating principles of this equipment.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
The applications of this equipment Details/notes:	
The main equipment components Details/notes:	
The operating capacities and parameters of the equipment Details/notes:	
At least 3 typical equipment faults and related causes of each Details/notes:	
At least 2 signs and symptoms of faulty equipment and 2 early warning signs of potential problems Details/notes:	
The status, location and purpose of guards Details/notes:	
The purpose and location of sensors and related feedback instrumentation Details/notes:	

At least 3 ways product quality and GMP compliance can be impacted by the equipment Details/notes:	
Resources/procedures/equipment used: Details/notes:	
Other topics/evidence covered: Details/notes:	

Scenario C: Pre-start checks

You have been asked to train a new employee in the pre-start check requirements of your pharmaceutical process. Deliver an on-the-job training session you could conduct with the new team member that takes them through all pre-start check requirements.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
Carrying out required area or line clearances Details/notes:	
Carrying out differential pressure checks or room status checks Details/notes:	
Inspecting equipment condition to identify any signs of wear Details/notes:	
Confirming that equipment is clean or sanitised Details/notes:	
Confirming appropriate settings and/or related parameters Details/notes:	
Confirming product details and ingredients Details/notes:	

Procedures to follow in the event of a non-conformance Details/notes:	
Resources/procedures/equipment used:	
Other topics/evidence covered:	

Scenario D: Working in controlled environments

You have been asked to train a new employee in the procedures for working in a cleanroom. Deliver an on-the-job training session you could conduct with the new team member that takes them through the GMP requirements and workplace procedures for working in controlled environments and cleanrooms.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
Personal hygiene requirements Details/notes:	
Personal protective clothing items required, and the checks required before use Details/notes:	
Personal protective clothing storage requirements Details/notes:	
Personal protective clothing disposal requirements Details/notes:	
Cleanroom garments, including types, materials, processing and reprocessing Details/notes:	
Clothing and footwear requirements for working in and moving between work areas Details/notes:	

Requirements for approving and taking commodity items into the cleanroom Details/notes:	
Restrictions on movement of personnel to minimise cross-contamination Details/notes:	
At least 2 workplace cleaning standards and environmental requirements relating to own work Details/notes:	
Responsibilities of general cleaning staff and how to work with a cleaning team Details/notes:	
At least 2 common practices inconsistent with GMP in a controlled environment, and how to control/rectify them Details/notes:	
Resources/procedures/equipment used:	
Other topics/evidence covered:	

Scenario E: Safety and emergency procedures

You have been asked to train a new employee in the safety and emergency procedures for working in a pharmaceutical processing environment. Deliver an on-the-job training session you could conduct with the new team member that takes them through the emergency and safety information they will need.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
At least 2 potential emergency situations, the related alarms and signals, and what to do in the event of those emergencies Details/notes:	
Requirements of emergency shutdowns Details/notes:	

Procedures to follow in the event of a power outage Details/notes:	
At least 5 safety signs and their meanings Details/notes:	
At least 3 hazards of the particular work environment, and how to control them Details/notes:	
At least 3 contamination risks associated with the cleanroom, and how to control them Details/notes:	
Designated person for raising issues about health and safety Details/notes:	
At least 3 organisation and work procedures related to safety in the workplace Details/notes:	
At least 2 ways emergency, incident/injury, hazard and other safety issues are reported in the workplace Details/notes:	
Resources/procedures/equipment used:	
Other topics/evidence covered:	

Scenario F: End-of-batch procedures

You have been asked to train a new employee in the changeover and end-of-batch processes for the workplace. Deliver an on-the-job training session you could conduct with the new team member that takes them through all of the changeover processes they will need to follow.

Use the equipment, procedures, locations, roles, documents and information in your workplace and/or provided by your assessor.

Topics	
The product and process changeover procedures and responsibilities for the workplace Details/notes:	
End-of-batch procedures for product sampling Details/notes:	
End-of-batch procedures for environmental sampling Details/notes:	
End-of-batch procedures for line clearances and cleaning (full or partial) Details/notes:	
End-of-batch procedures for yield calculation Details/notes:	
End-of-batch procedures for materials reconciliation Details/notes:	
End-of-batch procedures for changing equipment status (sterile/clean to dirty/clean) Details/notes:	
Requirements of routine shutdowns Details/notes:	
Isolation procedures and responsibilities Details/notes:	
Lock out procedures and responsibilities Details/notes:	

Tag out procedures and responsibilities Details/notes:	
Requirements for completion of workplace documentation for end-of-batch and changeover Details/notes:	
Resources/procedures/equipment used:	
Other topics/evidence covered:	

Assessment Task 3: Observation Checklist

Task 3 contains suggested observable tasks to be demonstrated.

This task is designed to be delivered in a pharmaceutical manufacturing workplace, with access to procedures, documents, tools, equipment, signage, PPE, etc., but it can be delivered in a simulated environment that accurately represents workplace conditions. It can be delivered face-to-face or adapted for observation via video recording or conferencing software, with careful consideration given to the rules of evidence.

The task is given as a guide only, and the assessor must assess its accuracy, sufficiency and currency. The assessor must ensure that the assessment is conducted safely, and the environment meets health and safety requirements prior to and during assessment.

Step 1: Located information and planned work activities	
1a. Candidate referred to legislation, SOPs and other documents to: • identify at least 2 roles and responsibilities of health and safety representatives and committees in the workplace • identify at least 2 rights and 2 responsibilities of self and others under application health and safety legislation (Attach documents candidate referred to, or record them in the space provided; also note which roles/responsibilities candidate identified)	
1b. Candidate located at least 3 sources of information on GMP requirements (including, for example, SOPs, handbooks, procedures or other documents) related to their job role, and identified at least 6 GMP requirements for pharmaceutical manufacture tasks, including at least 3 tasks related to their own job role (Attach documents candidate referred to, or record them in the space provided; also note the tasks the candidate identified)	
1c. Candidate accessed at least 2 sources of workplace information to confirm production requirements, and clarified these product requirements with at least 2 peers and/or supervisors, using open and closed questions and active listening skills to summarise instructions (Attach documents candidate accessed, or record them in the space provided; also note people candidate clarified requirements with, and what candidate asked)	
1d. Candidate planned work activities to meet requirements of GMP and pharmaceutical manufacture tasks, according to workplace information and supervisor instructions, clarifying with peer/supervisor when needed (Attach evidence of planning, or record the observed planning activities in the space provided)	
1e. Candidate confirmed work requirements and control measures associated with at least 3 work tasks (Record observed confirmed work requirements, control measures and tasks in the space provided)	
1f. Candidate interpreted at least 3 pieces of work safety signage, including signage for: • personal protective equipment • emergency equipment	

• dangerous goods class signs • specific hazards, such as sharps and radiation. (Record details of signage)	
1g. Candidate identified at least 4 controlled environment contamination risks, in the work area or in general (Record details)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant	

Step 2: Prepared to enter a controlled environment	
2a. Candidate ensured personal hygiene meets GMP requirements, including, for example: • well-groomed hair, beards, moustaches, nails • clean clothes/uniform • PPE – shoe coverings, masks, gloves, hair nets, etc. • not talking sneezing, coughing or eating near exposed product • not smoking or chewing gum (Record observed and verbalised hygiene practices of candidate)	
2b. Candidate reported injuries and health issues to designated personnel (team leader or supervisor), including: • at least 1 injury (cuts, scratches, rashes, wounds, boils, etc) • at least 1 incident • at least 1 reportable illness (Simulate if necessary)	
2c. Candidate removed jewellery and makeup according to workplace procedures and information	
2d. Candidate washed hands and rubbed them with an alcohol-based formulation according to workplace procedures	
2e. Candidate sourced at least 3 items of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures, including: • following changing procedures • ensuring correct fit • demonstrating correct use (Record details of candidate PPE selection, change procedures, use and fit details)	
2f. Candidate stored at least 1 item and disposed of at least 1 item of personal protective equipment and contamination prevention clothing according to workplace procedures (Record storage and disposal details)	

2g Candidate checked operating conditions of the controlled environment according to at least 2 pieces of workplace information and Good Manufacturing Practice (GMP) requirements, including: • differentials pressures • particle counts • microbial sampling • laminar air flow • humidity • temperature • room status • cleanliness status	
2h. Candidate entered controlled environment according to workplace procedures and instructions, in a manner to minimise contamination (Record details of instructions, and how candidate minimised contamination)	
2i. Candidate complied with area entry and exit procedures according to workplace procedures and instructions when moving around the workplace, in a manner to minimise contamination (Record details of instructions, and how candidate minimised contamination)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant	

Step 3: Prepare and dispense materials and components	
3a. Candidate confirmed at least 1 batch of incoming goods corresponded to workplace documentation, handling goods with GMP and safe work practices and workplace procedures (Record documentation and incoming goods details and GMP practices)	
3b. Candidate cleaned and labelled at least 3 containers with prescribed data, according to safe work and workplace procedures (Attach evidence of labelling and cleaning, and safe work procedures)	
3c. Candidate quarantined incoming goods, including: • at least 1 release status • at least 1 reject status • following GMP requirements and workplace procedures • applying safe handling practices when moving materials and items. (Record details of release and reject status and evidence of GMP and safe handling)	
3d. Candidate delivered materials in required quantities and sequence according to batch and production requirements, applying safe handling and GMP practices when moving materials and items (Record details of materials, GMP and safe handling practices)	
3e. Candidate recorded dispensed material, including:	

• weight and/or volume • following batch and production requirements. (Record details , including documents used to record information)	
3f. Candidate labelled dispensed materials for each batch and stage according to production requirements (Record details)	
3g. Candidate took commodity items into the controlled environment according to GMP and workplace procedures, applying safe handling practices when moving materials and items (Record details of GMP, and safe handling)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant	

Step 4: Set up, operate and monitor the production process	
4a. Candidate carried out pre-start checks on equipment according to workplace procedures, including: • confirming cleaning requirements and equipment status • carrying out required area or line clearances • inspecting equipment condition to identify signs of wear • confirming all safety equipment is in place and operational • confirming that equipment is clean or sanitised • confirming that equipment is correctly configured for processing requirements • following work procedures and workplace instructions to ensure safe work.	
4b. Candidate confirmed equipment and materials meet production requirements (Record production requirements and equipment details observed, or attach evidence)	
4c. Candidate started up production process, and delivered materials in required quantities and sequence for start, according to batch and production requirements and safety procedures (Record details)	
4d. Candidate undertook cleaning and housekeeping, and maintained cleanliness and tidiness to meet GMP requirements, at least 4 times, following work procedures and workplace instructions (Record details)	
4e. Candidate added and loaded materials at least 2 times, in correct quantities and sequences according to batch and production requirements and following work health and safety procedures (Record details of materials, quantities and sequence)	

4f. Candidate checked process control points and conducted inspections at least 3 times, to confirm process remains within limits, including: • environment • product appearance • pH • volume or weight • temperature (Record details)	
4g. Candidate conducted product sampling at least 3 times, to confirm process remains within limits (Record details)	
4h. Candidate conducted process control testing at least 3 times, to confirm process remains within limits (Record details)	
4i. Candidate adjusted process at least 1 time, according to workplace procedures, to ensure process remains within limits (May be simulated; Record details)	
4j. Candidate checked and adjusted equipment performance at least once, according to safe work requirements, GMP and work instructions (May be simulated; Record details)	
4k. Candidate identified performance that fails to meet GMP requirements, and reported to relevant personnel (May be simulated; Record details)	
4l. Candidate made adjustments after identifying performance that fails to meet GMP requirements (May be simulated; Record details)	
4m. Candidate identified out of limit products or processes, and reported according to workplace procedures (May be simulated; Record details)	
4n. Candidate conducted work according to workplace environmental procedures, using at least 2 procedures related to environmental requirements (Record details)	
4o. Candidate identified and followed appropriate control measures (according to GMP requirements and workplace procedures) for at least 3 instances of contamination or potential contamination, including any condition that may cause shedding of abnormal numbers or types of contaminants (Record details)	
4p. Candidate handled and disposed of at least 2 materials that are contaminated or non-conforming, according to safety, GMP and work procedures	

(Record details)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant	

Step 5: Participate in WHS activities	
5a. Candidate identified at least 3 hazards in the work area, and assessed the risk of each hazard (Record details)	
5b. Candidate took action to control at least 2 risks for hazards, according to workplace procedures (Record details)	
5c. Candidate reported all of the following to designated personnel, in accordance with workplace procedures and giving accurate verbal or written descriptions of each: • at least 1 identified hazard • at least 1 identified inadequate control measure • at least 1 incident • at least 1 injury (May be simulated or role-played; Record details)	
5d. Candidate identified and reported, according to workplace requirements: • at least 2 processes, practices or conditions which are inconsistent with GMP • at least 2 deviations, unusual events or non-conformances. (May be simulated or role-played; Record details)	
5e. Candidate actively and constructively participated in at least 2 workplace meetings, inspections, risk assessments or other consultative activities (May be simulated or role-played; Record details)	
5f. Candidate provided input to designated safety personnel to improve at least 3 workplace health and safety systems and processes to eliminate hazards and reduce risks, according to workplace procedures (May be simulated or role-played; Record details)	
5g. Candidate responded to at least 2 emergency situations, including: • identifying the emergency situation • identifying the procedures for the emergency situation • following the organisation procedures to respond to the emergency • following communication procedures during the emergency situation (May be simulated, and should include an emergency shutdown and/or power outage; Record details)	

5h. Candidate completed at least 3 workplace records, following workplace procedures. This could include: • incident reports • hazard and risk analysis paperwork • work health and safety documents • documents associated with shifts, processes, etc. (May be simulated. Record details)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant	

Step 6: Hand over/stop process and exit production area	
6a. Candidate performed handover according to workplace procedures (Record details)	
6b. Candidate informed handover production team of process and related equipment status at completion of handover (Record details)	
6c. Candidate confirmed the workplace procedures for shutting down the process (Record details)	
6d. Candidate completed end-of-batch procedures according to batch instructions and workplace procedures, including changing equipment status (sterile/clean to dirty/clean) (Record details)	
(Note: For 6e–6h, candidate is required to follow at least 3 of the end-of-batch procedures described.) 6e. Candidate followed end-of-batch procedures for product sampling, according to batch instructions and workplace procedures (Record details)	
(Note: For 6e–6h, candidate is required to follow at least 3 of the end-of-batch procedures described.) 6f. Candidate followed end-of-batch procedures for environmental sampling, according to batch instructions and workplace procedures (Record details)	
(Note: For 6e–6h, candidate is required to follow at least 3 of the end-of-batch procedures described.) 6g. Candidate followed end-of-batch procedures for line clearances and cleaning (full or partial), according to batch instructions and workplace procedures (Record details)	

(Note: For 6e–6h, candidate is required to follow at least 3 of the end-of-batch procedures described.) 6h. Candidate followed end-of-batch procedures for yield calculation and materials reconciliation, according to batch instructions and workplace procedures (Record details)	
6i. Candidate safely shut down the process according to workplace procedures (Record details)	
6j. Candidate cleaned and maintained work area to meet workplace cleaning standards and environmental requirements (Record details)	
6k. Candidate completed at least 1 record and 1 piece of documentation according to workplace procedures (Record details or attach documents)	
6l. Candidate exited controlled environment in a manner to minimise contamination, following workplace procedures (Record details)	
6m. Candidate removed PPE and contamination prevention clothing according to workplace changing procedures (Record details)	
6n. Candidate checked, stored and disposed of at least 3 pieces of personal protective equipment and contamination prevention clothing according to: • GMP requirements • workplace procedures • manufacturer specifications • environmental requirements • work health and safety requirements. (Record details)	
Assessor to note any additional SOP or workplace requirements for compliance with workplace, GMP and health and safety requirements, where relevant.	

Assessment Mapping

The following tables map the assessment tasks with the unit requirements. This is indicated with the assessment number.

Performance Criteria

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements	Task 1	Task 2	Task 3
1.1 Locate sources of information on GMP requirements in the workplace			1b
1.2 Identify GMP requirements for pharmaceutical manufacture tasks			1b
1.3 Confirm specific GMP requirements for own work			1b
2.1 Ensure personal hygiene meets GMP requirements			2a
2.2 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures			2e, 2f, 6m, 6n
2.3 Comply with area entry and exit procedures when moving around the workplace			2h, 2i, 6l
3.1 Routinely monitor work area, materials and equipment to ensure compliance with GMP requirements			4d, 4e, 4f, 4g, 4h, 4i, 4j, 4k, 4l, 4m, 4o
3.2 Handle raw materials, product and packaging components according to GMP requirements and workplace procedures			3a, 3b, 3c, 3d, 3g, 4c, 4e
3.3 Identify contamination and follow appropriate control measures relating to work responsibilities and GMP requirements			1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
3.4 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures			5d
3.5 Maintain workplace cleanliness and tidiness to meet GMP requirements			4d, 6j
3.6 Conduct work according to workplace environmental procedures			4n
3.7 Complete documentation according to workplace procedures			3e, 5h, 6k

FBPWHS2001 Participate in work health and safety processes	Task 1	Task 2	Task 3
1.1 Identify rights and responsibilities of self and others under applicable legislation for health and safety in the workplace			1a
1.2 Obtain, fit and correctly use personal protective equipment			2e, 6m, 6n
1.3 Confirm work requirements and control measures associated with activity			1e, 5b
1.4 Plan work activities to meet requirements			1d

1.5 Interpret work safety signage			1f, 2d, 2h, 2i, 3g, 4k, 4p, 5a, 5g, 6i, 6l, 6m, 6n
1.6 Carry out pre-start checks on equipment			4a, 4b
2.1 Follow work procedures and workplace instructions to ensure safe work			1c, 2c, 2d, 2e, 2h, 2i, 3b, 3c, 3g, 4a, 4d, 4p, 5b, 5c, 5d, 5e, 5f, 5g, 5h, 6a, 6c, 6d, 6i, 6j, 6k, 6l, 6m, 6n
2.2 Apply safe handling practices when moving materials and items			3c, 3d, 3g, 4c, 4e, 4p
2.3 Undertake housekeeping in work area according to health and safety requirements			4d
3.1 Identify hazards in the work area and assess risk			5a, 5e
3.2 Take action to control risks for hazards according to workplace procedures			1e, 5b
3.3 Report hazards and inadequacies in control measures in accordance with workplace procedures			5c, 5d
3.4 Report incidents and injuries to designated personnel			2b, 5c, 5d
4.1 Identify roles and responsibilities of health and safety representatives and committees in the workplace			1a
4.2 Participate constructively in workplace meetings, inspections or other consultative activities			5e
4.3 Raise health and safety issues with designated personnel			4k, 5c, 5d, 5e, 5f
4.4 Provide input to improve workplace health and safety systems and processes to eliminate hazards and reduce risks			5e, 5f
5.1 Identify emergency situations and procedures			5g
5.2 Follow reporting and communication procedures during emergency situations			5g
5.3 Follow organisation procedures for responding to emergencies			5g

FBPPHM3002 Operate a pharmaceutical production process	**Task 1**	**Task 2**	**Task 3**
1.1 Confirm incoming goods correspond to workplace documentation			3a
1.2 Clean and label containers with prescribed data, according to workplace procedures			3b
1.3 Quarantine incoming goods including release and reject status according to Good Manufacturing Practice (GMP) requirements and workplace procedures			3c
1.4 Identify and report deviations, unusual events and non-conformances according to GMP and workplace procedures			4p, 5d
2.1 Confirm equipment and materials meet production requirements			4a, 4b

2.2 Confirm cleaning requirements and equipment status			4a
2.3 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures			2e, 2f
2.4 Enter processing and operating parameters according to safety and production requirements			4a, 4b
2.5 Check and adjust equipment performance			4c, 4j
2.6 Conduct pre-start checks according to workplace procedures			4a
3.1 Deliver materials in required quantities and sequence according to batch and production requirements			3d, 4c, 4e
3.2 Record dispensed material, including weight or volume according to batch and production requirements			3e
3.3 Label dispensed materials for each batch and stage according to production requirements			3f
4.1 Start up, monitor and control production process to maintain process within required limits			4c, 4f, 4g, 4h, 4i, 4j, 4k, 4l, 4m
4.2 Identify and report out of limit products or processes according to workplace procedures			4m
4.3 Maintain work area according to workplace cleaning standards			4d, 6j
4.4 Conduct production process according to safety and environmental requirements			4n
4.5 Complete documentation according to workplace procedures			3e, 5h, 6k
5.1 Perform handover according to workplace procedures			6a
5.2 Inform handover production team of process and related equipment status at completion of handover			6b
6.1 Confirm the workplace procedures for shutting down the process			6c
6.2 Complete end-of-batch procedures according to batch instructions and workplace procedures			6d, 6e, 6f, 6g, 6h
6.3 Safely shut down the process			6i
6.4 Complete records according to workplace procedures			3e, 5h, 6k

FBPPHM3003 Work in a controlled environment	**Task 1**	**Task 2**	**Task 3**
1.1 Obtain workplace information, including workplace procedures related to working in a controlled environment			1b, 1c, 1d, 2g
1.2 Remove jewellery and makeup according to workplace procedures			2c
1.3 Wash hands according to workplace procedures			2d
1.4 Source and fit personal protective equipment (PPE) and contamination prevention clothing prior to entering controlled environment			2e, 2f
1.5 Check controlled environment operating conditions prior to entry			2f, 2g
2.1 Enter controlled environment according to workplace procedures			2h

2.2 Take commodity items into the controlled environment according to workplace procedures			3g
2.3 Conduct work activities to minimise risk of contamination			1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
3.1 Identify controlled environment contamination risks			1g, 4o
3.2 Control environmental contamination according to GMP requirements and workplace procedures			1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
3.3 Maintain controlled environment work area according to workplace cleaning standards and environmental requirements			4d, 4n, 6j
4.1 Follow workplace procedures to exit a controlled environment			6l
4.2 Remove PPE and contamination prevention clothing according to workplace procedures			2f, 6m
4.3 De-gown according to workplace procedures			2f, 6m
4.4 Check, store and dispose of PPE according to manufacturer specifications, environmental and work health and safety requirements			2f, 6n

Performance Evidence

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements	**Task 1**	**Task 2**	**Task 3**
PE 1. Located and followed workplace information relating to GMP responsibilities			1b, 1c, 1d, 2g
PE 2. Maintained good personal hygiene consistent with GMP requirements, including:			
PE 2.a. making team leader or supervisor aware of reportable illness			2a, 2b
PE 2.b.removal of jewellery			2a, 2c
PE 2.c. removal of makeup			2a, 2c
PE 3. Used personal protective equipment and contamination prevention clothing according to workplace procedures			2e, 2f, 6m, 6n
PE 4. Used and stored personal clothing and footwear consistent with GMP requirements and workplace procedures			2e,2f, 6m, 6n
PE 5. Followed workplace procedures when moving around the workplace to maintain GMP			4d, 4n, 4o, 4p
PE 6. Followed GMP requirements when carrying out work functions			1c, 2c, 2d, 2e, 2h, 2i, 3b, 3c, 3g, 4a, 4d, 4n, 4o, 4p, 5b, 5c, 5d, 5e, 5f, 5g, 5h, 6a, 6c, 6d, 6i,

			6j, 6k, 6l, 6m, 6n
PE 7. Identified and responded to performance that fails to meet GMP requirements, including:			
PE 7.a. making adjustments			4j, 4k, 4l
PE 7.b. reporting to relevant personnel			4k, 5d
PE 8. Handled and disposed of materials that are contaminated or non-conforming			4p
PE 9. Identified and reported a situation that could compromise GMP requirements			4k, 5c, 5d
PE 10. Maintained work area in a clean and tidy state			4d, 6j
PE 11. Followed workplace procedures for documentation and recording			3e, 5c, 5d, 5h

FBPWHS2001 Participate in work health and safety processes	**Task 1**	**Task 2**	**Task 3**
PE 1. Following clear, logical verbal or written instructions			1c, 1d, 2c, 2d, 2h, 2i
PE 2. Interpreting selected pictorial/graphical and written signs/instructions			1f, 2h, 2i
PE 3. Clarifying meaning of instructions with peers and supervisors			1c, 1d
PE 4. Giving accurate verbal or written descriptions of incidents or hazards			2b, 5a, 5c
PE 5. Actively participating in inspections, meetings and risk assessments			5e

FBPPHM3002 Operate a pharmaceutical production process	**Task 1**	**Task 2**	**Task 3**
PE 1. Accessed workplace information to confirm production requirements			1c, 1d, 4a, 4b
PE 2. Selected, fitted and used personal protective equipment and contamination prevention clothing			2e, 2f, 6m, 6n
PE 3. Conducted pre-start checks, including:			
PE 3.a. carrying out required area or line clearances			4a
PE 3.b. inspecting equipment condition to identify signs of wear			4a
PE 3.c. confirming all safety equipment is in place and operational			4a
PE 3.d. confirming that equipment is clean or sanitised			4a
PE 3.e. confirming that equipment is correctly configured for processing requirements			4a
PE 4. Started, operated, monitored and adjusted equipment to achieve required outcomes, including:			
PE 4.a. adding and loading materials in correct quantities and sequences			4c, 4e

PE 4.b. supply and flow of materials to and from the process			3d, 4a, 4b, 4c
PE 5. Checked process control points and conducted inspections to confirm process remains within limits, including:			
PE 5.a. product sampling			4f, 4g, 4h, 4i
PE 5.b. process control testing			4f, 4g, 4h, 4i
PE 5.c. adjusting process according to workplace procedures			4f, 4g, 4h, 4i
PE 6. Followed end-of-batch procedures, including three of the following:			
PE 6.a. product sampling			6d, 6e, 6f, 6g, 6h
PE 6.b. environmental sampling			6d, 6e, 6f, 6g, 6h
PE 6.c. line clearances and cleaning (full or partial)			6d, 6e, 6f, 6g, 6h
PE 6.d. yield calculation			6d, 6e, 6f, 6g, 6h
PE 6.e. materials reconciliation			6d, 6e, 6f, 6g, 6h
PE 6.f. change equipment status (sterile/clean to dirty/clean)			6d, 6e, 6f, 6g, 6h
PE 7. Safely shut down the process according to workplace procedures			6i
PE 8. Cleaned and maintained work area to meet workplace cleaning standards and environmental requirements			4d, 6j
PE 9. Completed records according to workplace procedures.			3e, 5h, 6k

FBPPHM3003 Work in a controlled environment	**Task 1**	**Task 2**	**Task 3**
PE 1. Accessed workplace information to identify controlled environment work requirements			2g
PE 2. Read and interpreted workplace procedures, including pictorial and written signs/instructions applicable to working in a controlled environment			1c, 1f, 2g
PE 3. Checked operating conditions of the controlled environment according to workplace and Good Manufacturing Practice (GMP) requirements			2g
PE 4. Maintained good personal hygiene and cleanliness appropriate to working in a controlled environment, consistent with GMP requirements, including:			
PE 4.a. making team leader or supervisor aware of reportable illness			2a, 2b
PE 4.b. removal of jewellery			2a, 2c
PE 4.c. removal of makeup			2a, 2c
PE 4.d. following changing procedures			2a, 2e, 6m, 6n

PE 5. Cleaned and sanitised hands using recognised procedures for:			
PE 5.a. washing with soap and water			2d
PE 5.b. rubbing with an alcohol-based formulation			2d
PE 6. Used facility suits and personal protective equipment appropriate for the grade of controlled environment or cleanroom in a manner that does not generate additional contaminants			2e, 2f, 6m, 6n
PE 7. Entered and exited a controlled environment in a manner to minimise contamination			2h, 2i, 6l
PE 8. Identified and reported any condition that may cause shedding of abnormal numbers or types of contaminants			4o
PE 9. Identified contamination hazards typically encountered in pharmaceutical manufacturing environments and took steps to prevent identified hazards			1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5a, 5b
PE 10. Cleaned and maintained work area to meet workplace cleaning standards and environmental requirements			4d

Knowledge Evidence

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements	**Task 1**	**Task 2**	**Task 3**
Sources of advice on GMP requirements in relation to own work	4, 7, 28, 31		1b, 1c, 1d, 1e, 2g
The role of GMP in preventing contamination and potential implications of non-compliance	1, 2, 3, 6, 11, 13, 16, 27, 32, 33, 44, 45, 46, 47, 49, 51	A	1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
The relationship between GMP and the quality system, including: • personnel responsible for designing and managing GMP • personal role to maintain GMP • the role of internal and external auditors	5, 6, 12, 14, 15		
Personal protective equipment and contamination prevention clothing requirements	9, 12, 31	D	2e, 2f, 6m, 6n
Personal clothing and footwear use, storage and disposal requirements	9, 12, 31	D	2e, 2f, 6m, 6n
Storage and handling requirements for raw materials, product and packaging components relevant to work role	10	A	3a, 3b, 3c, 3d, 3g
Common types and sources of contamination in the work area including pest infestation	11, 13, 16, 27, 31, 32, 33, 44, 45, 46, 47, 49, 51		1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
Control methods and procedures used in the work area to maintain GMP, including: • the purpose of control • the consequences of lack of control • control monitoring	6, 8, 14, 16	A	1e, 5b
Performance that is unacceptable or fails to meet specifications	20, 21	A	4k, 4l, 4m

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements	Task 1	Task 2	Task 3
Actions required in response to non-conformance	20, 21	C	4k, 4l, 4m, 4p
Workplace environmental procedures	17, 31	A	4n, 6j
Workplace procedures for reporting and recording information	18, 21, 31	A, E, F	3e, 5c, 5d, 5h, 6k

FBPWHS2001 Participate in work health and safety processes	Task 1	Task 2	Task 3
Legislation, regulations, standards, codes of practice and industry standards/guidance notes relevant to own work, role and responsibilities	19, 28		1a
Safety signs and their meanings, including signs for: • personal protective equipment • emergency equipment • dangerous goods class signs • specific hazards, such as sharps and radiation	22	E	1f
The difference between a hazard and a risk	23		5a
Nature of common workplace hazards, including chemicals, bodily fluids, sharps, noise, manual handling, work postures, underfoot hazards and moving parts of machinery	24, 31, 46, 50	E	3a, 3d, 3g, 5a, 5b, 5c, 5d
Potential consequences of not following safe work practices	3, 9, 12, 16, 23, 25, 35, 36, 46		5a, 5b
The elements within the hierarchy of control	26, 27, 35		5b
Safety measures for controlling common workplace hazards	16, 27, 31	E	1e, 5a, 5b, 5c, 5e, 5f, 5g, 5h
Sources of information about health and safety in the workplace	28, 29	E	1a, 5a, 5b, 5c, 5e, 5f, 5g, 5h
The roles and responsibilities of employees for health and safety in the workplace	29, 31		1a, 5a, 5b, 5c, 5e, 5f, 5g, 5h
Roles and responsibilities of health and safety representatives, committees, supervisors, managers and employers	29, 31		1a, 5a, 5b, 5c, 5e, 5f, 5g, 5h
Workplace specific information, including: • hazards of the particular work environment • potential emergencies relevant to the workplace • designated person for raising issues about health and safety • organisation and work procedures particularly those related to performance of own work, specific hazards and risk control, reporting of hazards, incidents and injuries, consultation, use of personal protective equipment and emergency response	31	A, B, C, D, E, F	1b, 1c, 1e, 2b, 2e, 2f, 5a, 5c, 5d, 5g, 6m, 6n
Potential emergency situations, alarms and signals, and required responses	22, 30	E	5g

FBPPHM3002 Operate a pharmaceutical production process	Task 1	Task 2	Task 3

Stages of the pharmaceutical manufacturing process, including: • the purpose, methods and outcomes of each stage • control points • checking materials are suitable for use including release status • flow of materials, people and waste • flow of the manufacturing process and the effect of outputs on downstream processes	7, 10, 17, 37, 38, 39, 44, 45, 48	A	4b, 4c, 4d, 6i
Basic operating principles of equipment, requirements and parameters of pharmaceutical manufacturing equipment, including: • main equipment components, operating capacities and applications • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • status and purpose of guards • the purpose and location of sensors and related feedback instrumentation	32, 42, 44, 45, 48	B	4a, 4j, 6i
Processing equipment and utility systems and how product quality and Good Manufacturing Practice (GMP) compliance can be impacted by: • performance • functionality • construction • instrumentation	32	B	4a
Common GMP non-conformances and unusual events found in a pharmaceutical production environment, including: • missing, illegible or inaccurate records • failure to follow workplace procedures • failure of cleaning regime • damaged goods, including; starting materials, components, intermediates and finished products • product diverted from normal course of process • loss of sterility or pressure • spills • out of limit situations including; yields, reconciliations, in process controls and in process checks • damage or poor maintenance of plant or equipment • signs of inadequate cleaning or pest infestation	11, 20, 21, 24, 27, 31, 32, 33	B, C, D	4a, 4f, 4k, 4l, 4m, 4p
Terminology associated with control of GMP processes, including: • process variation • critical quality attribute • critical process parameter	16, 34, 38, 39, 48		
Functions and limitations of personal protective equipment and contamination prevention clothing relevant to the work process	9, 11, 27, 35	D, E	2e, 2f, 6m, 6n
Pre-start checks requirements, including: • carrying out required area or line clearances • carrying out differential pressure checks or room status checks • inspecting equipment condition to identify any signs of wear • confirming that equipment is clean or sanitised • confirming appropriate settings and/or related parameters • confirming product details and ingredients	32	C	4a, 4b

Methods used to monitor the production process, including: • inspecting • measuring • testing	16, 38, 39, 48	A	4f, 4g, 4h, 4i
Items to monitor during the production process, including: • environment • product appearance • pH • volume or weight • temperature	16, 38, 39, 48	A	4f, 4g, 4h, 4i
Product and process changeover procedures and responsibilities		F	6a, 6b, 6c
End-of-batch procedures, including: • product sampling • environmental sampling • line clearances and cleaning (full or partial) • yield calculation • materials reconciliation • change equipment status (sterile/clean to dirty/clean)	36, 37	F	6d, 6e, 6f, 6g, 6h
Requirements of different shutdowns, including: • emergency and routine shutdowns • procedures to follow in the event of a power outage	30, 31	E, F	5g, 6c, 6i
Isolation, lock out and tag out procedures and responsibilities		F	6i
Operating principles of process control, including the relationship between control panels and systems and the physical equipment	32, 43, 44, 48	B	
GMP requirements for production and process controls, including: • identification and traceability • yields and reconciliation • segregation and storage • status labels (physical and electronic)	36, 37		3a, 3f, 6h
Environmental issues and controls relevant to the production environment, including waste collection and handling procedures	16, 17	A, D	1e, 4n, 5a
Requirements for completion of workplace documentation	14, 18, 21	A, E, F	3e, 5h, 6k

FBPPHM3003 Work in a controlled environment	**Task 1**	**Task 2**	**Task 3**
International nomenclature and classification of controlled environments and cleanrooms	40		
GMP grades of cleanrooms and their relationship to the International Organization for Standardization (ISO) classification system	41		
GMP requirements for the qualification of cleanrooms	42		

Key design requirements for controlled environments and cleanroom for product protection: • layout and architecture • product and process requirements for clean air • filtration, including High Efficiency Particulate Air (HEPA) filters and the theory of particle filtration • airlocks for materials, equipment and people • turbulent and laminar air flows • pressure differentials • box-within-a-box principle • cleanability and maintainability	43, 44, 45, 48		
How controlled environments operate to control contamination, including: • clean rooms, including how they are certified • controlled, non-classified environments • clean zones • monitor and test systems • isolator technology • at rest and in operation • gowning and cleaning	9, 13, 16, 27, 38, 39, 44	D	1e, 2e, 2f, 2h, 2i, 4d, 6j
GMP requirements and workplace procedures for working in controlled environments and cleanrooms, including: • requirements for approving and taking commodity items into the cleanroom • restrictions on movement of personnel to minimise cross-contamination • cleanroom garments, including types, materials, processing and reprocessing • personal hygiene requirements • clothing and footwear requirements for working in and moving between work areas • personal clothing use, storage and disposal requirements • workplace cleaning standards and environmental requirements relating to own work • responsibilities of general cleaning staff and how to work with a cleaning team	7, 8, 9, 11, 16, 17, 27, 44, 45, 46, 49	A, D	1b, 1c, 1d, 1e, 2a, 2f, 2g, 2h, 2i, 4d, 4n, 6d, 6j, 6l, 6m, 6n
The role of cleaning and sanitising in preventing contamination of materials and products and protection of personnel, including: • how improper cleaning of a controlled environment or cleanroom can lead to product contamination • the need for proper selection of equipment and materials for proper cleaning	11, 13, 16, 27, 45, 46, 47		4a, 4d
Controlled environment operating conditions, including: • differentials pressures • particle counts • microbial sampling • laminar air flow • humidity • temperature • room status • cleanliness status	38, 39, 42, 43, 48	C, D	2g, 4d
Hygiene and basic elements of microbiology	8, 49	D	2a

Sources of contamination, including: • product • people • tools • facilities • equipment	11, 13, 16, 27, 44, 45, 46, 47, 49, 51	B	1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
Risks associated with controlled environment and cleanroom operators: • physical behaviour, including how to walk and stand in a cleanroom • personal hygiene • psychological • workplace attitudes and habits • communications between workers • electrostatic discharge	8, 49, 50	D, E	2a, 5a
Contamination risks associated with controlled environment and clean room operations, including: • number of personnel in the controlled environment • activities being undertaken • leaks • malfunctioning equipment • low differential pressures • high particle counts • incorrect air flow and velocity • humidity • temperature • room status inactive or in alarm • lack of cleanliness	11, 13, 16, 27, 32, 33, 44, 45, 46, 47, 49, 51	B, D, E	1e, 1g, 2e, 2f, 2g, 2h, 2i, 4o, 5b
Common practices inconsistent with GMP found in controlled environment and clean room operations, including: • damage to plant or equipment • failure of cleaning regime • signs of pest infestation • missing or inaccurate records • failure to follow workplace procedures	11, 20, 21, 24, 27, 31, 32, 33	B, D	2h, 2i, 4a

Foundation Skills

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements	**Task 1**	**Task 2**	**Task 3**
Reading			
• Identify and comprehend information about GMP requirements			1b, 1c, 1d, 1e, 2e, 2f, 2g, 2h, 2i
Writing			
• Record workplace information using appropriate language and in required format			3e, 5h, 6k
Navigate the world of work			

• Apply workplace procedures to own role and responsibilities			1b, 1c, 1d, 1e, 2e, 2f, 2g
• Understand main tasks, responsibilities and boundaries of own role			1b, 1c, 1d, 1e, 2g
Interact with others			
• Report operational and safety information to relevant personnel using required communication method			2b, 5c

FBPWHS2001 Participate in work health and safety processes	**Task 1**	**Task 2**	**Task 3**
Oral communication			
• Uses correct terms when communicating information about health and safety			1a, 2b
• Uses listening and questioning skills to clarify understanding			1c, 1d
Navigate the world of work			
• Identifies and follows explicit workplace procedures			1b, 1c, 2e, 2f, 2h, 2i
Get the work done			
• Responds to routine problems related to risks and hazards			2b, 5a, 5b, 5c, 5d, 5e, 5f

FBPPHM3002 Operate a pharmaceutical production process	**Task 1**	**Task 2**	**Task 3**
Reading			
• Identify relevant information from workplace documentation and interpret requirements for the pharmaceutical production process			1b, 1c, 1d, 2g
Writing			
• Complete workplace documentation using appropriate language and in required format			3e, 5h, 6k
Numeracy			
• Interpret material and product specifications			4a, 4b, 4c, 4e

FBPPHM3003 Work in a controlled environment	**Task 1**	**Task 2**	**Task 3**
Reading			
• Interpret signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to working in controlled environments			1b, 1c, 1d, 1f, 2g, 2h, 2i
• Access and interpret GMP information relevant to working in controlled environments			1b, 1c, 1d, 2g
Writing			
• Complete workplace documentation using appropriate language and in required format			3e, 5h, 6k

Navigate the world of work			
• Recognise and follow workplace requirements, including safety requirements and GMP, associated with own role and area of responsibility			1b, 1c, 1d, 1e, 2e, 2f, 2g
Interact with others			
• Report GMP concerns to relevant personnel using required communication method			2b, 4m, 5d

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