Assessment Tasks and Tools

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

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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

Acknowledgements

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

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

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.

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

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: _____

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: _____

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?

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.

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

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		
Regulations		
Standards		
Codes of practice		
Industry standards/ guidance notes		

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

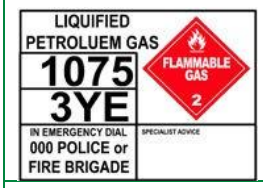
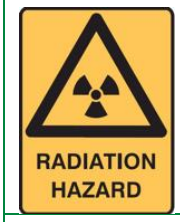
21. If you make a mistake filling in documentation, what should you do?

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?

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

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

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

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	
2.	
3.	
4.	
5.	
6. Least effective	

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	
Bodily fluids	
Sharps	
Noise	
Manual handling	
Work postures	
Underfoot hazards	
Moving parts of machinery	

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

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	
Health and safety representatives (HSRs)	
Health and safety committees	
Supervisors	
Managers	
Employers	

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

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	
Potential emergencies relevant to this particular workplace	
Designated person or persons for raising issues about health and safety	
Organisation and work procedures related to performance of own work	
Organisation and work procedures related to specific hazards and risk control	
Organisation and work procedures related to reporting of hazards, incidents and injuries	
Organisation and work procedures related to consultation	
Organisation and work procedures related to use of personal protective equipment	
Organisation and work procedures related to emergency response	

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:	
Processing equipment functionality impacts product quality and GMP by:	
Processing equipment construction impacts product quality and GMP by:	
Processing equipment instrumentation impacts product quality and GMP by:	

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

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

Process variation	
Critical quality attribute	
Critical process parameter	

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

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	
Yields and reconciliation	
Segregation and storage	

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

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

Inspecting	
Measuring	
Testing	

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

Environment	
Product appearance	
pH	
Volume or weight	
Temperature	

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)	
ISO 5	
ISO 8	
ISO 7	

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

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

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	
Controlled, non-classified environments	
Clean zones	
Monitor and test systems	
Isolator technology	
At rest and in operation	
Gowning and cleaning	

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

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

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

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	
Particle counts	
Microbial sampling	
Laminar air flow	
Humidity	
Temperature	
Room status	
Cleanliness status	

49. What is the relationship between hygiene and microbiology?

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

51. What are at least 11 contamination risks associated with controlled environment and clean room operations?

Assessment Task 2: Scenarios

Instructions to Assessors

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.	

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