



Mapping Matrix

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

| | |
|---------------------------|----------|
| Introduction | 2 |
| This Resource | 2 |
| Acknowledgements | 2 |
| Assessment Mapping | 3 |
| Performance Criteria | 3 |
| Performance Evidence | 6 |
| Knowledge Evidence | 9 |
| Foundation Skills | 15 |

Introduction

This resource refers to the suggested assessment tasks for *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set* provided in the accompanying publication “Assessor Resource – Assessment Tasks and Tools”.

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 Resource

This *Assessor Resource – Mapping Matrix* includes the following items:

- Assessment Mapping for *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*

Acknowledgements

This work acknowledges the contribution of the FDFPHGMP1A, FDFPHGMP3A, FDFZPRSYS3A and FDFZPRCR2A Learner and Trainer Guides in the development of the assessments. These Learner and Trainer Guides were produced initially with the assistance of funding provided by the NSW Department of Education and Training, Training Development Unit, through the Training Resources & Support Program, and with advice from the Pharmaceutical Product Advisory Committee. Documents made available by NSW FITC.

The contribution of WHS resources RIIWHS205D, CPCCOHS2001A AED and TWB, supplied by MTO Group are also acknowledged.

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

Disclaimer

The views expressed in this work do not necessarily represent the views of the Australian Department of Education, Skills and Employment (DESE) or Skills Impact. In addition, the DESE and Skills Impact do not give warranty or accept any legal liability in relation to the content of this work.

While these materials have been developed with the guidance and assistance of industry experts, trainers and assessors are encouraged to utilise their industry expertise in the use of these materials. Skills Impact will be pleased to receive feedback on any improvements or changes via inquiries@skillsimpact.com.au

For further information about this document or any other work being undertaken by Skills Impact, please visit: www.skillsimpact.com.au

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: <ul style="list-style-type: none"> 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 |

| FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements | Task 1 | Task 2 | Task 3 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|--------------------|
| Control methods and procedures used in the work area to maintain GMP, including: <ul style="list-style-type: none"> 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 |
| 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> performance functionality construction instrumentation | 32 | B | 4a |

| | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|---------|------------------------|
| <p>Common GMP non-conformances and unusual events found in a pharmaceutical production environment, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Terminology associated with control of GMP processes, including:</p> <ul style="list-style-type: none"> process variation critical quality attribute critical process parameter | 16, 34, 38, 39, 48 | | |
| <p>Functions and limitations of personal protective equipment and contamination prevention clothing relevant to the work process</p> | 9, 11, 27, 35 | D, E | 2e, 2f, 6m, 6n |
| <p>Pre-start checks requirements, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Methods used to monitor the production process, including:</p> <ul style="list-style-type: none"> inspecting measuring testing | 16, 38, 39, 48 | A | 4f, 4g, 4h, 4i |
| <p>Items to monitor during the production process, including:</p> <ul style="list-style-type: none"> environment product appearance pH volume or weight temperature | 16, 38, 39, 48 | A | 4f, 4g, 4h, 4i |
| <p>Product and process changeover procedures and responsibilities</p> | | F | 6a, 6b, 6c |
| <p>End-of-batch procedures, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Requirements of different shutdowns, including:</p> <ul style="list-style-type: none"> emergency and routine shutdowns procedures to follow in the event of a power outage | 30, 31 | E, F | 5g, 6c, 6i |
| <p>Isolation, lock out and tag out procedures and responsibilities</p> | | 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 |

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------|----------------------------------------------------------------|
| <p>GMP requirements and workplace procedures for working in controlled environments and cleanrooms, including:</p> <ul style="list-style-type: none"> 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 |
| <p>The role of cleaning and sanitising in preventing contamination of materials and products and protection of personnel, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Controlled environment operating conditions, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Sources of contamination, including:</p> <ul style="list-style-type: none"> 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 |
| <p>Risks associated with controlled environment and cleanroom operators:</p> <ul style="list-style-type: none"> 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 |

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|---------|------------------------------------|
| <p>Contamination risks associated with controlled environment and clean room operations, including:</p> <ul style="list-style-type: none"> • 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 |
| <p>Common practices inconsistent with GMP found in controlled environment and clean room operations, including:</p> <ul style="list-style-type: none"> • 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 | | | |
| <ul style="list-style-type: none"> • Identify and comprehend information about GMP requirements | | | 1b, 1c, 1d, 1e, 2e, 2f, 2g, 2h, 2i |
| Writing | | | |
| <ul style="list-style-type: none"> • Record workplace information using appropriate language and in required format | | | 3e, 5h, 6k |
| Navigate the world of work | | | |
| <ul style="list-style-type: none"> • Apply workplace procedures to own role and responsibilities | | | 1b, 1c, 1d, 1e, 2e, 2f, 2g |
| <ul style="list-style-type: none"> • Understand main tasks, responsibilities and boundaries of own role | | | 1b, 1c, 1d, 1e, 2g |
| Interact with others | | | |
| <ul style="list-style-type: none"> • 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 | | | |

| | | | |
|-------------------------------------------------------------------------------------------------------------------------------|--|--|----------------------------|
| <ul style="list-style-type: none"> • Uses correct terms when communicating information about health and safety | | | 1a, 2b |
| <ul style="list-style-type: none"> • Uses listening and questioning skills to clarify understanding | | | 1c, 1d |
| Navigate the world of work | | | |
| <ul style="list-style-type: none"> • Identifies and follows explicit workplace procedures | | | 1b, 1c, 2e, 2f, 2h, 2i |
| Get the work done | | | |
| <ul style="list-style-type: none"> • 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 | | | |
| <ul style="list-style-type: none"> • Identify relevant information from workplace documentation and interpret requirements for the pharmaceutical production process | | | 1b, 1c, 1d, 2g |
| Writing | | | |
| <ul style="list-style-type: none"> • Complete workplace documentation using appropriate language and in required format | | | 3e, 5h, 6k |
| Numeracy | | | |
| <ul style="list-style-type: none"> • Interpret material and product specifications | | | 4a, 4b, 4c, 4e |

| FBPPHM3003 Work in a controlled environment | Task 1 | Task 2 | Task 3 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|----------------------------|
| Reading | | | |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • Access and interpret GMP information relevant to working in controlled environments | | | 1b, 1c, 1d, 2g |
| Writing | | | |
| <ul style="list-style-type: none"> • Complete workplace documentation using appropriate language and in required format | | | 3e, 5h, 6k |
| Navigate the world of work | | | |
| <ul style="list-style-type: none"> • 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 | | | |
| <ul style="list-style-type: none"> • Report GMP concerns to relevant personnel using required communication method | | | 2b, 4m, 5d |



559A Queensberry St
(PO Box 466)
North Melbourne VIC 3051

P 03 9321 3526
E inquiry@skillsimpact.com.au

Skillsimpact.com.au