



Mapping Matrix

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

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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*

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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

Contamination risks associated with controlled environment and clean room operations, including: <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
Common practices inconsistent with GMP found in controlled environment and clean room operations, including: <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



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