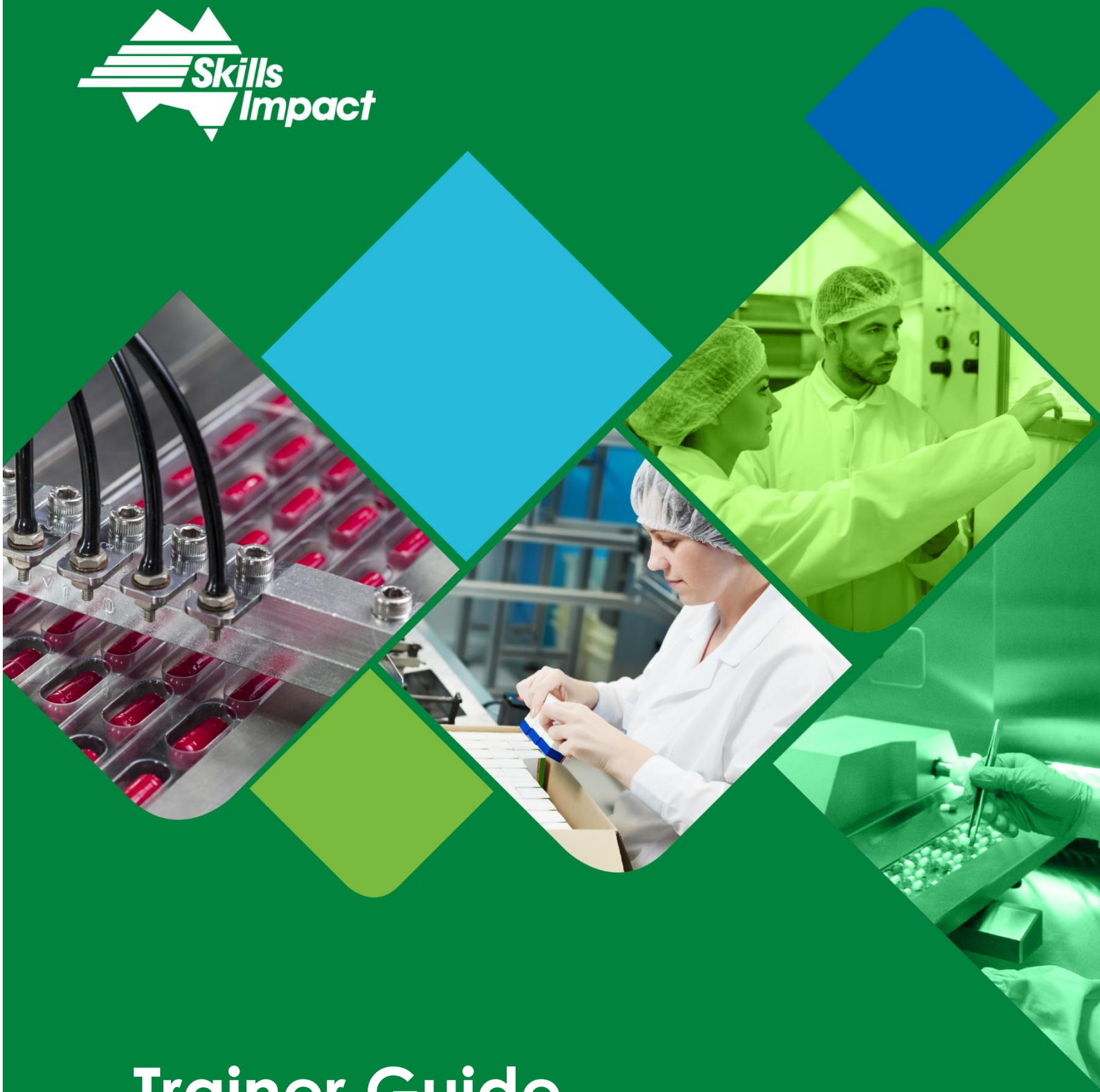


Trainer Guide

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

Contents

Introduction

This resource contains training materials for the *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*.

The 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.

There are four units of competency in this skill set. The units of competency 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 Trainer Guide

The materials in this guide address all four units of competency in the Pharmaceutical Manufacturing Operator Induction Skill Set.

The Trainer Guide includes the following items for delivering the learning components of the unit:

- delivery checklist – to assist preparations for delivering the unit of competency
- topics to cover in the skill set, including key concepts
- suggested structure and mapping of the content
- supplementary materials for learners.

The section *Topics to Cover in Pharmaceutical Manufacturing Operator Induction Skill Set* is an outline of topics to be covered in the FBPSS00051 Skill Set. This outline must be supplemented with contextualised learning materials. It provides a general overview of all the topics that must be covered across the four units in the Skill Set.

Before Delivery

Before delivering the skill set, follow your training organisation's policy and procedures for introducing and delivering the learning program to learners. This may involve:

- providing an overview of the skill set and a copy of the skill set
- providing a copy of the four units of competency
- providing copies of assessment tasks.

If you are not conducting face-to-face sessions, you may need to adjust the delivery methods. This could include:

- emailing presentations to learners
- presenting information via webinars and teleconferencing
- making recorded video sessions available through streaming services such as Vimeo, YouTube, etc.
- using a Learning Management System (LMS) for:
    - organising chat sessions to discuss questions
    - conducting group activities using online discussion forums
    - setting up online document sharing sites.

Personal protective equipment such as gowns, masks, hair nets, gloves, etc. must be provided to learners when teaching this Skill Set.

Acknowledgements

This resource acknowledges the contribution of the FDFPHGMP1A, FDFPHGMP3A, FDFPHDRM2A, FDFZPRSYS3A and FDFZPRCR2A Learner Guides. These referenced documents were produced initially with the assistance of funding provided by the NSW Department of Education and Training, Training Development Unit, through the Training Resources and Support Program, and with advice from the Pharmaceutical Product Advisory Committee. Documents made available by NSW FITC. This resource also acknowledges the contribution of RIIWHS205D & CPCCOHS2001A Assessment Evidence Documents and Task Workbooks. Documents made available by MTO Group.

This Trainer Guide was created through funding by the Australian Government.

Dr Michael Kimber of HealthStar Training is acknowledged as a significant contributing author and compiler of these materials.

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

Delivery Checklist

Before delivering the training, you must contextualise all the training and assessment materials to suit your delivery requirements. You may also need to prepare additional materials. The following table includes some common preparation tasks. Modify the table to meet your needs.

Done (✓)	Tasks
	FBPSS00051 - Pharmaceutical Manufacturing Operator Induction Skill Set Locate on http://training.gov.au and read the skill set thoroughly. Skill set may be directly referenced at: https://training.gov.au/Training/Details/FBPSS00051
	Locate on http://training.gov.au and read the units of competency thoroughly. Units of competency may be directly 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
	Training and Assessment Strategy: Check the training organisation's delivery and assessment requirements.
	Timetable: Prepare timetable of delivery dates/sessions for circulation to learners.
	Presentations: Contextualise presentations for the delivery context and learner cohort.
	Session plan: Complete the session plan and contextualise the content for the delivery context and learner cohort.
	Handouts: Prepare copies of handouts (as required) or make handouts available online.
	Learner materials: Source or assemble Learner Workbook or other learning materials; Read materials and source relevant forms and/or documents for learners (as required).
	Schedule assessments: Schedule dates, times and deadlines for assessments.
	Submission of work: Explain to learners how to submit their work. It is important to do this early, particularly for learners who are completing studies online or by distance.
	Set up support systems for learners (as required): Check with your training organisation to confirm and set up the systems you could use to support online or distance learners, for example, discussion forums, wikis, telephone support and face-to-face sessions.

Topics to Cover in the Pharmaceutical Manufacturing Operator Induction Skill Set

The following is an outline of topics to be covered in the Pharmaceutical Manufacturing Operator Induction Skill Set (FBPSS00051). This outline must be supplemented with contextualized learning materials. It provides a general overview of all the topics that must be covered across the four units in the Skill Set.

See the section Topic Mapping to Units for mapping to Elements and Knowledge Evidence across the four units in the Skill Set.

See the section *Supplementary Materials* for example documents, forms, flow charts and other materials for learners.

Topic 1. Therapeutic Goods and Good Manufacturing Practice (GMP)

Learning Objectives for this Section

- Therapeutic goods manufacture, including laws and legislation regarding therapeutic goods.
- Good Manufacturing Practice, including basic requirements of GMP, the GMP guide, and sources of information on GMP in the workplace.

Topics to cover include:

Therapeutic goods

- What therapeutic goods are
- Why manufacture of them is highly regulated
- The Therapeutic Goods Administration and its role
- The Therapeutic Goods Act 1989
- Getting a license to manufacture therapeutics (Demonstrating compliance with Therapeutic Goods (Manufacturing Principles) Determination 2020)
- Therapeutic goods made overseas

Good Manufacturing Practice (GMP)

- What GMP is
- The PIC/S GMP Guide
- The main principles and basic requirements of GMP
- How GMP is administered and controlled
- Legislation and regulatory statements
- Monitoring GMP compliance
- Quality assurance components
- International use
- Compliance audits (purpose, what is audited, common problems found and consequences of major problems)

The contents of the Guide to Good Manufacturing Practice for Medicinal Products

- The Guide to Good Manufacturing Practice for Medicinal Products (GMP Guide)
- Pharmaceutical Quality System
- Personnel
- Training
- Premises and equipment
- Critical quality attributes (CQA) and critical process parameters (CPP)
- Documentation
- Production
- Cleaning and decontamination
- Validation
- Quality control
- Outsourced activities
- Complaints and product recall
- Self-inspection
- Quality audits
- Reasons for quality auditing

Sources of GMP information in the workplace

- Standard Operating Procedures Manual
- Batch documents and forms used to record information about the process
- Internal audits and checks on the process
- Entry and exit requirements for the workplace
- Safety guidelines for equipment being used
- Maintenance and calibration programs
- Cleaning and waste management programs
- Training systems
- Incoming goods checking (raw materials and packaging)
- Induction training
- On-the-job training
- Peers, leading hands and supervisors
- Job descriptions
- Specific work area signage (such as cleanrooms, etc.)

Topic 2. Workplace Health and Safety (WHS)

Learning Objectives for this Section

- WHS laws, regulations and basic principles.
- Common hazards in the workplace.
- The process of identifying hazards and assessing risks.
- Forms and documents associated with WHS.

Topics to cover include:

WHS legislation in Australia

- Acts (what Acts are, and specific Act names and details)
- Regulations (what Regulations are, and specific Regulation names and details)
- Codes of practice/compliance codes (common industry codes of practice/compliance codes)
- Australian Standards (common AS for industry)

WHS in the workplace

- Acts and regulations associated with WHS
- The relationship between GMP and WHS
- Identifying your rights and responsibilities
- Participating in work health and safety consultative activities
- Raising health and safety issues with designated personnel (including incident and accident reports)
- Workers compensation
- Providing input to improve WHS systems and processes
- Work permits
- Disciplinary actions

Identifying hazards and assessing risk

- Rule No: 1: Never assume anything
- Common hazards in the workplace
- Recognizing hazardous materials
- Risk analysis
- Risk evaluation
- Controlling risks and hazards
- Hierarchy of control
- Conducting high risk work
- Monitoring and review
- Reporting hazards and inadequacies in control measures
- Notifiable incidents

WHS forms and documents

- Site safety inspection reports
- Risk assessment reports
- Safety Data Sheet (SDS)
- Safe Work Method Statement (SWMS)
- Job Safety Analysis (JSA)
- Incident and accident reports

Supplemental Materials: See the section *Supplemental Materials* for Example Safety Data Sheet (SDS), Incident Report Form, Safe Work Method Statement (SWMS) and Job Safety Analysis (JSA)

Topic 3. Conducting Work Safely in a Pharmaceutical Facility

Learning Objectives for this Section

- Conducting work safely, including isolation, lock-out, tag-out and process control.
- Emergency response procedures, including identifying emergencies, following procedures, and reporting and communication requirements.
- Controlled environments and housekeeping WHS requirements.

Topics to cover include:

Conducting work safely

- Following work procedures and workplace instructions
- Isolation, lock-out and tag-out procedures
- Process control and control panels
- Ensuring access to amenities
- Being ‘sun smart’
- Drugs and alcohol at work
- Plant and equipment
- Personal Protective Equipment and clothing
- Housekeeping
- Storing materials
- Preventing bullying and harassment
- Smoking on site
- Barricades
- Tools and materials selection
- Plant and equipment
- Clean-up
- JSA, SWMS, SDS
- Manual handling
- Communications equipment
- Common barriers
- Common workplace safety signage

Emergency response procedures

- Identifying emergency situations
- Emergency response procedures
- First aid response procedures
- Evacuation procedures
- Reporting and communication procedures during emergency situations
- Fire wardens, first aiders and emergency coordinators (duties, uniform, etc.)
- Using a fire extinguisher
- Applying first aid for minor injuries

Preparing for work in a pharmaceutical facility

- Controlled environments
- Personal hygiene, equipment and clothing used and worn by the staff
- Sick staff
- Injured staff
- Moving in and around the workplace
- Moving between different tasks in the workplace

Housekeeping in accordance with GMP and WHS requirements

- What is housekeeping
- Maintaining good housekeeping in and around the work area
- Maintaining workplace cleanliness and tidiness to meet GMP requirements
- Cleaning and sanitising
- Equipment and resources required for housekeeping
- Poor housekeeping
- Good housekeeping
- Pest control activities
- Waste collection, handling and recycling

Supplemental Materials: See the section *Supplemental Materials* for Sample Evacuation Procedure and Common Workplace Signage.

Topic 4. The Production Process

Learning Objectives for this Section

- Manufacturing systems, and the tools, resources, people, planning and equipment that make them work.
- Materials and components for manufacture, including process flow of materials.
- Setting up the production process for operation, dispensing materials, and operating and monitoring the process.
- Following GMP and WHS requirements during the process.

Topics to cover include:

What a manufacturing system is

- Influences on the success of an operating system
- Influences that people can have on the success of an operating system
- Influences of workplace systems on the success of an operating system
- Planning work activities to meet requirements – tools and equipment
- Using tools and equipment correctly

Materials and components

- Specifications for materials and components
- Purchasing and suppliers
- Receipt and examination
- Quality Control of materials and components
- Paperwork associated with materials and components
- Analysing and sampling

Process flow for operators, materials and components

- Process flow for Tablet Production Operator
- Process flow for Liquid Production Operator
- The flow of materials and components

Following GMP and WHS requirements when carrying out work activities

- GMP in the workplace
- Monitoring in the workplace
- Cleaning and maintaining equipment
- Cleaning operations
- Storage of cleaned equipment
- The role of operators in equipment maintenance
- Line clearance
- Entering operating parameters
- Checking equipment performance
- Setting up equipment
- Starting production
- Monitoring and encouraging the team to meet housekeeping requirements
- Monitoring during preparation
- GMP monitoring before the start the process

Setting up the production process for operation

- Planning and scheduling
- The operator's role in planning and scheduling
- Controlling resources
- Organising labour
- Working out the resources needed for a process
- Ensuring operators have the required skills
- Access to services
- Batch documentation
- Handling raw materials
- Handling high risk drugs

Dispensing materials

- Organise materials for dispensing
- GMP monitoring of raw materials

Operating and monitoring the production process

- Information to gather throughout the production run
- Monitoring the process
- Developing monitoring systems
- Different types of monitoring methods
- Monitoring of packaging operations
- Monitoring when handling finished products
- Routine GMP monitoring
- Sampling procedures
- Calibration of testing equipment
- Access to the appropriate documentation

Supplemental Materials: See the section *Supplemental Materials* for flow charts: Process flow for Liquid and Tablet Production Operators; and Flow of components/starting materials.

Topic 5. Working in Controlled Environments

Learning Objectives for this Section

- Cleanrooms, their types, their design, and their specifications.
- Clothing and cleaning requirements for cleanrooms.
- Policies and procedures to following when working in a cleanroom.
- Working in, maintaining and exiting a cleanroom.

Topics to cover include:

Cleanrooms

- Cleanroom usage
- Different types of cleanroom
- Considerations in cleanroom design
- Qualification of cleanrooms
- Special skills required to work in a cleanroom

Cleanroom air

- Permitted airborne particle concentrations
- Microbial contamination
- AS/ISO 14644-1 and U.S. Federal Standards
- Laminar flow
- Pressure measurements
- Flow measurements
- Particle measurement
- Microbiological monitoring
- Cleanroom monitoring
- Pressure differential
- Certification

Clothing types for controlled areas

- Purpose of clothing for controlled areas
- Grade D
- Grade C
- Grade A/B
- Special requirements for cleanroom clothing
- Cleaning requirements for cleanroom clothing
- Other methods to reduce contamination

Cleanroom procedures and policies

- Common policies and procedures
- Gowning – pre-change zone
- Activities in the pre-change zone
- Gowning – change zone
- Activities in the change zone
- End of gowning checks
- Hand washing
- Applying gloves

Cleanroom cleaning

- Areas to clean
- Cleaning procedures
- Cleaning equipment used
- Cleanroom testing

Working in a controlled environment

- Entering the controlled environment according to workplace procedures
- Controlling contamination
- Zones used to control contamination – pre-change, changing, buffer zone/anteroom
- Other methods used to reduce contamination when entering a cleanroom

Maintaining and exiting controlled environment

- Working effectively in the cleanroom
- Problems with protective equipment
- Sources of contamination when working in the cleanroom
- Special tasks that may need to be performed as part of working in the cleanroom
- Cleanroom housekeeping requirements
- Reporting practices inconsistent with GMP
- Steps to exiting a controlled environment

Supplemental Materials: See the section *Supplemental Materials* for charts of permitted standards for controlled environments.

Topic 6. Validation, Corrective and Preventive Actions (CAPA) and Self-Inspections (GMP Auditing)

Learning Objectives for this Section

- Validation, including the process of validation, and problems identified during validation.
- Corrective and Preventive Actions (CAPA), including corrective action activities and reporting/recording requirements.
- Self-inspection, including purpose, goals and roles in a GMP audit.

Topics to cover include:

Validation

- What is validation
- Carrying out validation and revalidation
- The process of validation
- Problems identified during validation

Corrective and Preventive Actions (CAPA)

- What is CAPA?
- Corrective action and GMP
- Process variation
- Corrective action activities
- Corrective actions of low significance
- Corrective actions of medium significance
- Corrective actions of high significance
- Reporting and recording corrective action
- Preventative measures

Self-inspections – GMP auditing

- Purpose of an audit
- Conduct of audits in the pharmaceutical industry
- Goals of a GMP audit
- The operator's role in a GMP audit
- The process of changing GMP and other workplace documents
- Change control procedures

Topic 7. Handing Over the Production Process and Completing Documentation

Learning Objectives for this Section

- Changeovers and end of batch procedures.
- Emergency, planned, routine and maintenance shutdowns.
- Completing workplace recording and recordkeeping documentation.

Topics to cover include:

Changeovers and end of batch procedures

- End of a batch procedure
- Changeover procedure

Shutting down the process

- Emergency shutdown
- Planned shutdown
- Routine stoppages
- Maintenance shutdowns

Recording workplace information

- The importance of workplace recording
- What to check when filling out and signing workplace documentation

Supplemental Training Materials

Example Safety Data Sheet (SDS)

Safety Data Sheet

Ammonia Anhydrous (Gas)

Synonyms	Ammonia gas, nitro-sill, ammonia, R 717, spirit of hartshorn, STCC 4904210, OHS01050
Molecular formula	NH_3 CAS No: 7664-41-7 EC No: 231-635-3 Annex I Index No: 007-001-00-5
Physical Properties	Appearance: colourless gas with a penetrating, suffocating odour: • Melting point: -77.7 C • Boiling point: -33.3 C • Vapour density: 0.89 g/l • Vapour pressure: 0.597 • Specific gravity: 0.77 • Flash point: 11 C • Explosion limits: 16–25% • Autoignition temperature: 650C • Water solubility: High
Principal Hazards	✱ Ammonia gas is very harmful, and may be fatal, if you inhale it. A level of just 500 ppm (that is, 1 part in 2,000) of ammonia in air is potentially fatal. ✱ Ammonia dissolves readily in water to give a very corrosive. solution. This solution can cause serious burns to the skin or eyes. ✱ Ammonia is an environmental pollutant. ✱ Ammonia has a high reactivity, and may react enthusiastically or violently with some materials, including acids and aldehydes.
Safe Handling	Wear safety glasses. It is essential that you work in a well-ventilated area, normally a fume cupboard. Ammonia is extremely soluble in water (you may have come across the ‘ammonia fountain‘ demonstration that illustrates this), so care must be taken to avoid the problem of water sucking back into the source of the gas.
Emergency	Eye contact: Immediately flush the eye with water. Exposure to ammonia vapour may cause serious eye damage, so call for medical help. Skin contact: Wash off with soap and water. If there are any signs of skin damage, call for first aid.

	If inhaled: Call for immediate medical help.
Stability	Stable. Hygroscopic. Flammable. Incompatible with acids, strong oxidizing agents. May react violently with acids, aldehydes, allylene oxides, amides, boron, boron halides, calcium, chlorine azide, chloric acid, chlorine monoxide, chlorites, halogens, heavy metals and many other materials
Toxicology	Toxic by inhalation or skin contact – may be fatal if inhaled. 500 ppm is immediately dangerous to life or health. Corrosive – may cause serious burns. This material is extremely harmful to the eyes. Respiratory irritant. Typical OEL 25 ppm. ATSDR Minimal risk levels: Inhalation acute 0.5 ppm, chronic 0.3 ppm, oral 0.3mg/kg/day.
Toxicity data	IHL-HMN TCLO 5000 ppm/5m IHL-RAT LC50 1000 ppm/4h IHL-MUS LC50 4230 ppm/1h
Risk Phrases	R10 R23 R24 R34 R50.
Environmental information	Very toxic to aquatic organisms.
Transport information	UN No 1005. Major hazard class 2.3. Subsidiary risk 8.
Personal protection	Safety glasses and gloves. Good ventilation.

The Poisons Helpline

A very useful phone number to always have on hand is 13 11 26 which is the Poisons Helpline.

Flammable Substances

Take the following precautions when dealing with a flammable substance:

1. Store in an airtight container in and a cool well-ventilated place
2. Never expose to naked flames, sparks or static electricity
3. Always wear appropriate PPE.

If a substance accidentally ignites

- Get well away
- Call for help (Dial 000 or 112 and report a fire)
- Use a fire extinguisher if ***the correct one is available,*** and you can do so safely. (see table later in this book for correct extinguisher)

Corrosive Substance

Corrosive substances are identified by the symbols to the right. If you spot any of these, you need to be very careful. Do not handle unless:

1. Stored in an airtight container in a cool well-ventilated place.
2. You have been trained in the correct way to handle.
3. You have all the correct PPE.
4. You have an emergency response plan should something go wrong.

If the substance accidentally spills

- Get well away.
- Call for help (Dial 000 or 112 and report a spill of corrosive material).
- Take care not to breath fumes from the spill.
- Wait for help and if possible can describe the substance to the emergency services.

Example Safety Data Sheet (SDS) sourced from:
MTO Group, originally sourced from a free public SDS database, published with permission from MTO Group, 2021

Example Incident Report Form

1. Workplace details

Location:

Director: Contact phone:

Setting:

2. Incident details

Day: Date: Time:

Report completed by:

3. Type of incident (indicate which is applicable)

❑ Personal injury ❑ Staff ❑ Customer ❑ Child

Name of person injured:

❑ Damage to goods (please specify):

❑ Assault ❑ Staff ❑ Customer ❑ Other (please specify):

❑ Vandalism

❑ Robbery/break-in (also complete security incident report form)

❑ Equipment failure/damage (please specify):

4. Response to incident (indicate which is applicable)

❑ First aid treatment administered (please specify what/by whom etc):

❑ Medical treatment administered (please specify where/by whom etc):

❑ Assistance sought (please specify type): ❑ Ambulance ❑ Police

❑ Equipment shut down (please specify what/when etc):

❑ Workplace closed (please specify exact time):

❑ Repair person contacted (please specify whom):

5. Other information

Who witnessed the incident? (please use full name, details of staff's job title where applicable, and telephone number/s):

NOTE: Be ***specific***. Describe in detail what actually happened, stating the ***facts*** in a clear and precise manner. Include exact location of incident, factors involved and any other details that may be beneficial. A drawing of the workplace layout, identifying where the incident occurred, would be useful.

6. Other information

This report was compiled by (full name, title and contact telephone): On (date/time):

This report is a true and accurate summary of the incident that occurred (please sign):

Incident Form sourced from:

Example Safe Work Method Statement (SWMS)

Organisation name, Company No, and Business address	Safe Work Method Statement **PROJECT:**	**SWMS No.** 011
	ACTIVITY: Installation and/or construction of stormwater drainage structures	

This SWMS has been developed in consultation with (names):		**Approval:**	
		Name:	**Position:**
		Signature:	**SWMS issued date:**

Training required to carry out the activity:	**Plant & Equipment required for this activity:**	**Plant & Equipment Maintenance checks required:**	**Codes of Practice, Legislation & Standards which apply to this activity:**
• General Induction • Site Induction • Work activity • Drivers Licences (trucks / vehicles) • Plant operator tickets (bobcat, backhoe, excavator) • Manual handling • Traffic controllers certificate **Training details are located on site project files**	• Excavator • Backhoe • Bobcat • Hiab truck crane • Star picket rammer • Lifting chains/slings • Shoring devices • Wacker plate •	• Pre-use checks on equipment • Daily inspection of PPE • Daily pre-start inspections on plant and trucks • Regular service on plant and trucks as per manufacturer recommendations •	• Workplace Health and Safety Act • OHS regulation • National Code of Practice – *Induction for construction work* • AS 1742 traffic control devices • Code of practice – *Excavation work* • Code of practice – *Moving plant on construction sites*

PPE Required for this activity:

Permits / Approvals required for this activity:
- Dial before you dig / excavation permit

Responsibilities: The Works Supervisor is responsible for: supervise the works, inspect and approve work areas, inspect and approve work methods, inspect and approve protective measures, inspect and approve plant, equipment and power tools

Example Safe Work Method Statement (SWMS) sourced from:
MTO Group, originally sourced from a free public SDS database, published with permission from MTO Group, 2021

Example Job Safety Analysis (JSA)

Name: _____

MTO GROUP

Job Safety Analysis (JSA) Worksheet

	A	B	C	D	E
1	H	H	H	S	S
2	H	H	S	S	M
3	H	H	S	M	L
4	H	S	M	L	L
5	S	S	M	L	L

H = High, S = Significant, M = Moderate, L = Low

Probability
- A – Common or repeating occurrence
- B – Know to occur "it has happened"
- C – Could occur "I've heard of it happening"
- D – Not likely to happen
- E – Practically impossible

Consequence - People
- 1 – Fatal or permanent serious injury
- 2 – Lost time injury or illness
- 3 – Medical treatment required
- 4 – First aid treatment
- 5 – Incident report only

Task analysed is:

No	Hazard List up all hazards identified for each work task	P Probability	C Consequence	Risk	Control Measure Eliminate, Isolate, minimise (state how)	Person The person responsible to make this happen
1						
2						
3						
4						
5						

Signature (person doing analysis) _____ **Signature (person responsible hazard control)** _____

Use Additional Sheets as Required – Have you dealt with all the Hazards?

Example Job Safety Analysis (JSA) sourced from:
MTO Group, originally sourced from a free public SDS database, published with permission from MTO Group, 2021

Example Evacuation Procedures

Evacuation Procedures

- Prepare to evacuate when the alarm is raised or when directed by a warden.
- Leave your worksite in a safe condition.
- Close the doors if there is a fire – DO NOT lock them.
- Help anyone in immediate danger.
- Leave the work area via the nearest safe route.
- Follow all directions from wardens and emergency services personnel.
- Move calmly to the nearest assembly point.
- Wait for the all-clear before returning to the work area.

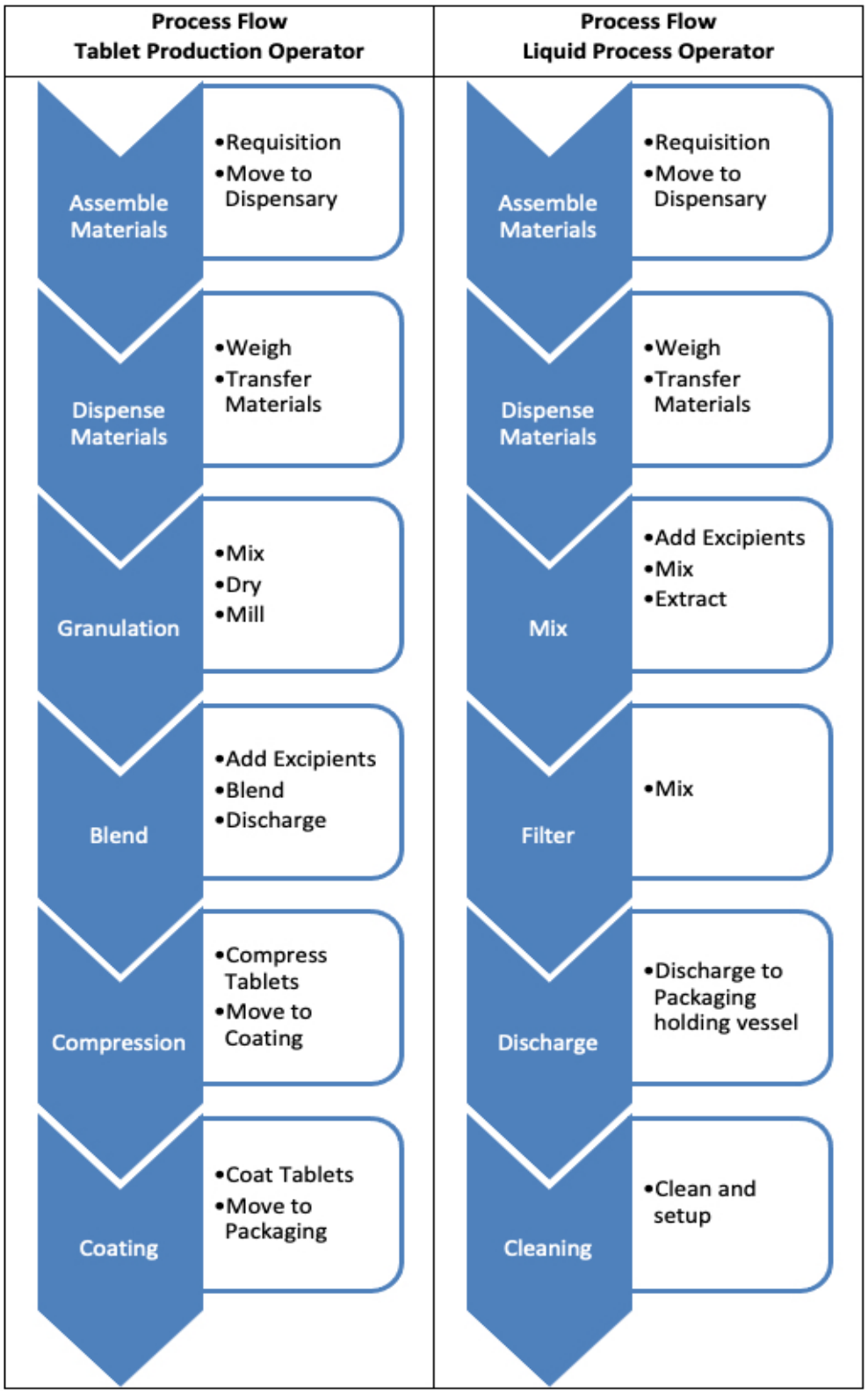
Common Workplace Signage

			
Danger Signs AS 1319 specifies that these signs are to be used where conditions are likely to be life threatening. The sign is to incorporate the word DANGER in white letters on a red oval shape inside a black rectangle.	**Warning Signs** AS 1319 specifies that these signs warn of conditions that are NOT likely to be life threatening if the message is ignored. The symbol used is a yellow equilateral triangle with a black enclosure.	**Prohibition Signs** AS 1319 specifies these signs are to have a red annulus and slash symbol on a white background. They indicate actions or activities that are not permitted.	**Mandatory Signs** AS 1319 specifies these signs shall be a blue disc with the symbol in white. The word MUST is usually contained in the message.
			

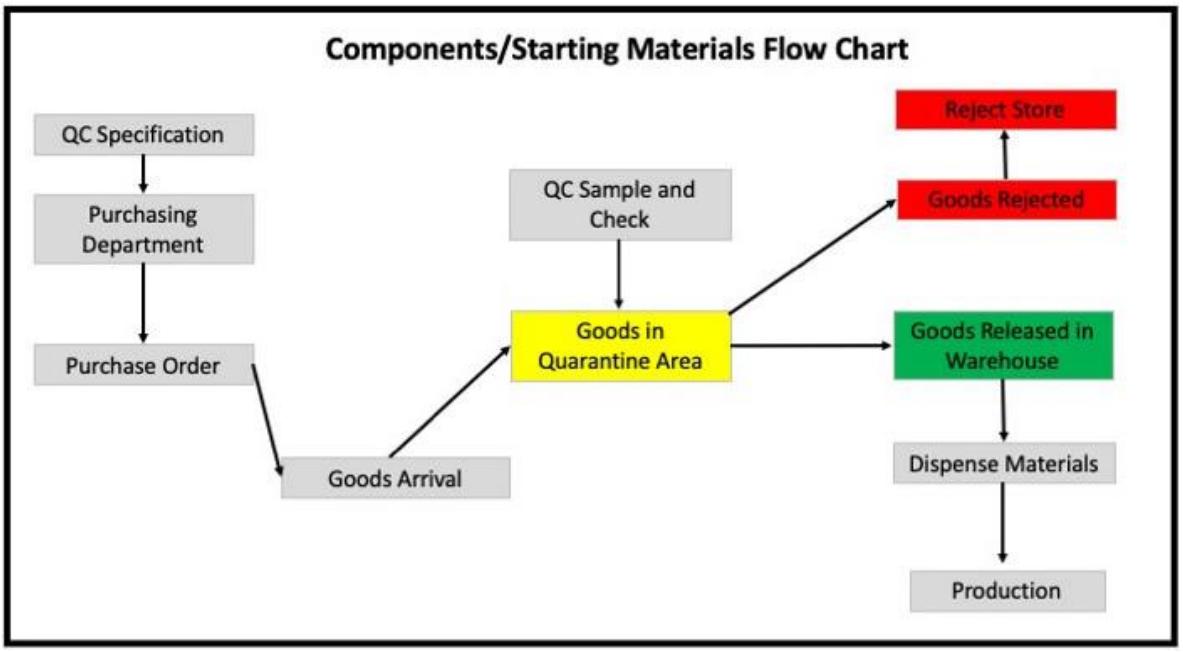
Site Safety, Directional, Traffic and Warning Signs and Symbols			
			
Emergency Signs AS 1319 specifies these signs shall comprise of a white symbol or text on a green rectangle with white enclosure. These signs indicate the location or direction to emergency related facilities and first aid or safety equipment.	**Fire Signs** AS 1319 – 1994 refers to fire signs which are covered in AS 2444 - 1995. These signs indicate the location of fire alarms and firefighting equipment. Signs shall comprise a red rectangle sign with a white legend and enclosure	**Hazchem Signs** AS 1216 – 1995 specifies the relevant 'designs, layout and size'. These signs are prescribed in the 'Australian Dangerous Goods Code' and various State Government 'Dangerous Goods, Storage and Handling Regulations'.	**Safety Tags & Lockout Systems** These are isolation systems that help to prevent incidents by making sure faulty equipment is not used. A lockout prevents operation of equipment by an unauthorised person. Only the person who placed a tag or lockout device can remove it.

Common Workplace Signage sourced from:
MTO Group, originally sourced from a free public SDS database, published with permission from MTO Group, 2021

Flow Chart – Process Flow for Liquid and Tablet Production Operators



Flow Chart – Flow of Components/Starting Materials



Permitted Standards for Controlled Environments

Permitted Airborne Particle Concentrations

Grade	Maximum permitted number of particles/m³ equal to or greater than the tabulated size			
	At rest		In operation	
	0.5µm	5.0µm	0.5µm	5.0µm
A	3,520	20	3,520	20
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	not defined	not defined

Microbial Contamination

	Controlled Environments		
Grade	**Air sample (CFU/m3)**	**Area**	**Example**
A	**< 3**	**Laminar flow (LAF)**	**LAF in Sterile area or Isolation technology**
B	**10**	**Cleanroom**	**Sterile production area**
C	**100**	**Controlled environment**	**Solution preparation area**
D	**200**	**Controlled environment**	**Packaging**
Uncontrolled		**Uncontrolled environment**	**Warehouse**

AS/ISO 14644-1 and U.S. Federal Standards

PIC/S GMP Guide	US Federal Standard 209E	AS/ISO 14644-1
Grade A	Class 100	ISO 5
Grade B	Class 100	ISO 5
Grade C	Class 10,000	ISO 7
Grade D	Class 100,000	ISO 8

Recommended Reading List

Reading recommended for this unit:

Print resources

- The Pharmaceutical Operator, by Dr Michael Kimber, published by HealthStar Training: healthstar.edu.au The Pharmaceutical Operator: https://pharmaceuticaloperator.com
- Good Pharmaceutical Manufacturing Practice: Rationale and Compliance, by John Sharp, ISBN 9780429205446. Publisher: CRC Press
- Aulton's Pharmaceutics: The Design and Manufacture of Medicines by Kevin M.G. Taylor and Michael E. Aulton, ISBN: 0-7020-7003-3. Publisher: Elsevier
- Work Health and Safety: A complete course for the CIV and Diploma Courses BSB41412 and BSB51312, by Michael Stol, Caroline McGill, James Ritchie, ISBN: 9781743077467, Publisher: McGraw-Hill Education

Online resources

- Therapeutic Goods Administration (TGA), Good manufacturing practice - an overview: https://www.tga.gov.au/good-manufacturing-practice-overview
- World Health Organization (WHO). Essential medicines and health products, Quality and Safety: Medicines teaching resources: https://www.who.int/medicines/training/qsm_training/en
- Pharmaceutical Inspection Co-operation Scheme (PIC/S), GMP Guide: https://picscheme.org/en/publications?tri=gmp#zone
- U.S. Food & Drug, Current Good Manufacturing Practice (CGMP) Regulations: https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations
- International Society for Pharmaceutical Engineering (ISPE): https://ispe.org
- International Pharmaceutical Federation (FIP): https://www.fip.org
- Medicines Australia: https://www.medicinesaustralia.com.au
- SeerPharma: https://www.seerpharma.com/about-us
- PharmOut: https://www.pharmout.net
- Safe Work Australia: https://www.safeworkaustralia.gov.au
- Normal body flora**:** https://www.scq.ubc.ca/microbes-and-you-normal-flora

Newsletters:

- Pharma in focus: https://www.pharmainfocus.com.au (signup for the free 2 week trial)
- Pharmaceutical Online (free newsletter): https://www.pharmaceuticalonline.com
- ISPE SmartBrief (free newsletter): https://ispe.org
- PharmTech (free newsletter): https://www.pharmtech.com

Please note that web addresses were checked and correct at the time of publication. Where URLs are not current, it is recommended to use the reference information provided to search for the source in an appropriate search engine.

Glossary of Terms

Aseptic technique – refers to procedures that are conducted under sterile conditions.

CIP – clean in place. This usually involves cleaning agents to be pumped through the machine as it runs normally. Rinsing and sanitising procedures also happen this way.

HEPA filter – high efficiency particulate air filter.

HVAC – Heating, Ventilation and Air Conditioning

Laminar flow (LAF) – fluid (gas or liquid) particles that travel along well-ordered, straight (non-intersecting) paths or layers. In true laminar flow, there is no mixing between the different layers.

Micrometer (µm) – a micrometer is one-millionth of a meter and can also be expressed as:

- 10^{-6} meter
- one thousandth of a millimetre
- one 25 thousandth of an inch

The term 'micron', now no longer used, also refers to a micrometer.

Particle – solid or liquid object generally between 0.001–1000 µm in size.

Particulate – substance that consists of particles (minute quantities of a solid or liquid).

Pass throughs – opening in a cleanroom wall with two doors where materials and objects are passed through.

PPE – Personal Protective Equipment

Sanitise – to clean an item to achieve minimal bacterial (microbial) load, can be done using heat, steam or chemical methods e.g. chlorine compounds, etc.

Sterilise – to make an item free from live bacteria or other microbes, usually using heat and/or steam.

Turbulence – an eddying (swirling) motion that interrupts the flow of a substance.

ULPA filter – ultra low penetration air filter.

Vortex – a spiral motion of a fluid (gas or liquid) within an area, often a swirling mass that sucks everything near it towards its centre e.g. a tornado or water going down a sink. A number of vortex (plural) is vortices.

WIP – wash in place (as for CIP)

Topic Mapping to Units

The following tables map the *Topics to Cover in Pharmaceutical Manufacturing Operator Induction Skill Set* to the 4 units in this Skill Set.

FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements

FBPPHM2001 Performance Criteria	Topic Number
1. Identify requirements of GMP related to own work	
1.1 Locate sources of information on GMP requirements in the workplace	Topic 1
1.2 Identify GMP requirements for pharmaceutical manufacture tasks	Topic 1
1.3 Confirm specific GMP requirements for own work	Topic 1
2. Prepare for work	
2.1 Ensure personal hygiene meets GMP requirements	Topic 3
2.2 Prepare, use, store and dispose of personal protective equipment and contamination prevention clothing according to GMP requirements and workplace procedures	Topic 3, 4, 5
2.3 Comply with area entry and exit procedures when moving around the workplace	Topic 3
3. Follow GMP requirements when carrying out work activities	
3.1 Routinely monitor work area, materials and equipment to ensure compliance with GMP requirements	Topic 4
3.2 Handle raw materials, product and packaging components according to GMP requirements and workplace procedures	Topic 4
3.3 Identify contamination and follow appropriate control measures relating to work responsibilities and GMP requirements	Topic 4, 6
3.4 Identify processes, practices or conditions which are inconsistent with GMP requirements and report according to workplace procedures	Topic 4, 6
3.5 Maintain workplace cleanliness and tidiness to meet GMP requirements	Topic 3
3.6 Conduct work according to workplace environmental procedures	Topic 4, 5
3.7 Complete documentation according to workplace procedures	Topic 1, 7

FBPPHM2001 Knowledge Evidence	Topic Number
Sources of advice on GMP requirements in relation to own work	Topic 1
The role of GMP in preventing contamination and potential implications of non-compliance	Topic 1, 3
The relationship between GMP and the quality system, including: • personnel responsible for designing and managing GMP • personal role to maintain GMP • the role of internal and external auditors	Topic 1, 7
Personal protective equipment and contamination prevention clothing requirements	Topic 3, 4, 5
Personal clothing and footwear use, storage and disposal requirements	Topic 3, 4, 5
Storage and handling requirements for raw materials, product and packaging components relevant to work role	Topic 4
Common types and sources of contamination in the work area including pest infestation	Topic 1, 3, 4, 6
Control methods and procedures used in the work area to maintain GMP, including: • the purpose of control • the consequences of lack of control • control monitoring	Topic 4, 6
Performance that is unacceptable or fails to meet specifications	Topic 4, 6
Actions required in response to non-conformance	Topic 6
Workplace environmental procedures	Topic 4, 5
Workplace procedures for reporting and recording information	Topic 1, 7

FBPWHS2001 Participate in work health and safety processes

FBPWHS2001 Performance Criteria	Topic Number
1. Plan and prepare to work safely	
1.1 Identify rights and responsibilities of self and others under applicable legislation for health and safety in the workplace	Topic 2
1.2 Obtain, fit and correctly use personal protective equipment	Topic 3, 4, 5
1.3 Confirm work requirements and control measures associated with activity	Topic 2, 3
1.4 Plan work activities to meet requirements	Topic 3, 4
1.5 Interpret work safety signage	Topic 2, 3
1.6 Carry out pre-start checks on equipment	Topic 2, 3
2. Conduct work safely	
2.1 Follow work procedures and workplace instructions to ensure safe work	Topic 2, 3, 4
2.2 Apply safe handling practices when moving materials and items	Topic 2, 3
2.3 Undertake housekeeping in work area according to health and safety requirements	Topic 3, 5
3. Respond to hazards	
3.1 Identify hazards in the work area and assess risk	Topic 2
3.2 Take action to control risks for hazards according to workplace procedures	Topic 2, 6
3.3 Report hazards and inadequacies in control measures in accordance with workplace procedures	Topic 2, 6
3.4 Report incidents and injuries to designated personnel	Topic 2, 6
4. Participate in work health and safety consultative activities	
4.1 Identify roles and responsibilities of health and safety representatives and committees in the workplace	Topic 2, 3
4.2 Participate constructively in workplace meetings, inspections or other consultative activities	Topic 2, 3
4.3 Raise health and safety issues with designated personnel	Topic 2, 3
4.4 Provide input to improve workplace health and safety systems and processes to eliminate hazards and reduce risks	Topic 2, 3
5. Follow emergency response procedures	
5.1 Identify emergency situations and procedures	Topic 2, 3
5.2 Follow reporting and communication procedures during emergency situations	Topic 2, 3
5.3 Follow organisation procedures for responding to emergencies	Topic 2, 3

FBPWHS2001 Knowledge Evidence	Topic Number
Legislation, regulations, standards, codes of practice and industry standards/guidance notes relevant to own work, role and responsibilities	Topic 2
Safety signs and their meanings, including signs for: • personal protective equipment • emergency equipment • dangerous goods class signs • specific hazards, such as sharps and radiation	Topic 2, 3
The difference between a hazard and a risk	Topic 2
Nature of common workplace hazards, including chemicals, bodily fluids, sharps, noise, manual handling, work postures, underfoot hazards and moving parts of machinery	Topic 2, 3
Potential consequences of not following safe work practices	Topic 2, 3
The elements within the hierarchy of control	Topic 2, 3
Safety measures for controlling common workplace hazards	Topic 2, 3
Sources of information about health and safety in the workplace	Topic 2, 3
The roles and responsibilities of employees for health and safety in the workplace	Topic 2, 3
Roles and responsibilities of health and safety representatives, committees, supervisors, managers and employers	Topic 2, 3
Workplace specific information, including: • hazards of the particular work environment • potential emergencies relevant to the workplace • designated person for raising issues about health and safety • organisation and work procedures particularly those related to performance of own work, specific hazards and risk control, reporting of hazards, incidents and injuries, consultation, use of personal protective equipment and emergency response	Topic 2, 3
Potential emergency situations, alarms and signals, and required responses	Topic 2, 3

FBPPHM3002 Operate a pharmaceutical production process

FBPPHM3002 Performance Criteria	Topic Number
1. Receipt materials and components	
1.1 Confirm incoming goods correspond to workplace documentation	Topic 1, 3, 4
1.2 Clean and label containers with prescribed data, according to workplace procedures	Topic 1, 4
1.3 Quarantine incoming goods including release and reject status according to Good Manufacturing Practice (GMP) requirements and workplace procedures	Topic 1, 4
1.4 Identify and report deviations, unusual events and non-conformances according to GMP and workplace procedures	Topic 1, 4, 6
2. Set up the production process for operation	
2.1 Confirm equipment and materials meet production requirements	Topic 1, 4
2.2 Confirm cleaning requirements and equipment status	Topic 3, 5
2.3 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures	Topic 3, 4, 5
2.4 Enter processing and operating parameters according to safety and production requirements	Topic 4
2.5 Check and adjust equipment performance	Topic 4
2.6 Conduct pre-start checks according to workplace procedures	Topic 4
3. Dispense materials	
3.1 Deliver materials in required quantities and sequence according to batch and production requirements	Topic 4
3.2 Record dispensed material, including weight or volume according to batch and production requirements	Topic 4
3.3 Label dispensed materials for each batch and stage according to production requirements	Topic 4

4. Operate and monitor the production process	
4.1 Start up, monitor and control production process to maintain process within required limits	Topic 4, 7
4.2 Identify and report out of limit products or processes according to workplace procedures	Topic 4
4.3 Maintain work area according to workplace cleaning standards	Topic 3, 5
4.4 Conduct production process according to safety and environmental requirements	Topic 4, 5
4.5 Complete documentation according to workplace procedures	Topic 1, 7
5. Hand over the production process	
5.1 Perform handover according to workplace procedures	Topic 7
5.2 Inform handover production team of process and related equipment status at completion of handover	Topic 7
6. Shut down the process	
6.1 Confirm the workplace procedures for shutting down the process	Topic 7
6.2 Complete end-of-batch procedures according to batch instructions and workplace procedures	Topic 7
6.3 Safely shut down the process	Topic 7
6.4 Complete records according to workplace procedures	Topic 7

FBPPHM3002 Knowledge Evidence	Topic Number
Stages of the pharmaceutical manufacturing process, including: • the purpose, methods and outcomes of each stage • control points • checking materials are suitable for use including release status • flow of materials, people and waste • flow of the manufacturing process and the effect of outputs on downstream processes	Topic 1, 3, 4, 7
Basic operating principles of equipment, requirements and parameters of pharmaceutical manufacturing equipment, including: • main equipment components, operating capacities and applications • typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems • status and purpose of guards • the purpose and location of sensors and related feedback instrumentation	Topic 3, 4
Processing equipment and utility systems and how product quality and Good Manufacturing Practice (GMP) compliance can be impacted by: • performance • functionality • construction • instrumentation	Topic 1, 3, 4
Common GMP non-conformances and unusual events found in a pharmaceutical production environment, including: • missing, illegible or inaccurate records • failure to follow workplace procedures • failure of cleaning regime • damaged goods, including; starting materials, components, intermediates and finished products • product diverted from normal course of process • loss of sterility or pressure • spills • out of limit situations including; yields, reconciliations, in process controls and in process checks • damage or poor maintenance of plant or equipment • signs of inadequate cleaning or pest infestation	Topic 1, 4
Terminology associated with control of GMP processes, including: • process variation • critical quality attribute • critical process parameter	Topic 6
Functions and limitations of personal protective equipment and contamination prevention clothing relevant to the work process	Topic 3, 5

Pre-start checks requirements, including: • carrying out required area or line clearances • carrying out differential pressure checks or room status checks • inspecting equipment condition to identify any signs of wear • confirming that equipment is clean or sanitised • confirming appropriate settings and/or related parameters • confirming product details and ingredients	Topic 4, 5
Methods used to monitor the production process, including: • inspecting • measuring • testing	Topic 4, 5
Items to monitor during the production process, including: • environment • product appearance • pH • volume or weight • temperature	Topic 4, 5
Product and process changeover procedures and responsibilities	Topic 7
End-of-batch procedures, including: • product sampling • environmental sampling • line clearances and cleaning (full or partial) • yield calculation • materials reconciliation • change equipment status (sterile/clean to dirty/clean)	Topic 2, 4, 7
Requirements of different shutdowns, including: • emergency and routine shutdowns • procedures to follow in the event of a power outage	Topic 7
Isolation, lock out and tag out procedures and responsibilities	Topic 2, 3
Operating principles of process control, including the relationship between control panels and systems and the physical equipment	Topic 2, 3
GMP requirements for production and process controls, including: • identification and traceability • yields and reconciliation • segregation and storage • status labels (physical and electronic)	Topic 4, 7
Environmental issues and controls relevant to the production environment, including waste collection and handling procedures	Topic 1, 4, 5
Requirements for completion of workplace documentation	Topic 1, 4, 7

FBPPHM3003 Work in a controlled environment

FBPPHM3003 Performance Criteria	Topic Number
1. Prepare to enter a controlled environment	
1.1 Obtain workplace information, including workplace procedures related to working in a controlled environment	Topic1, 2, 3
1.2 Remove jewellery and makeup according to workplace procedures	Topic 3, 5
1.3 Wash hands according to workplace procedures	Topic 3, 5
1.4 Source and fit personal protective equipment (PPE) and contamination prevention clothing prior to entering controlled environment	Topic 3, 5
1.5 Check controlled environment operating conditions prior to entry	Topic 5
2. Work in a controlled environment	
2.1 Enter controlled environment according to workplace procedures	Topic 5
2.2 Take commodity items into the controlled environment according to workplace procedures	Topic 5
2.3 Conduct work activities to minimise risk of contamination	Topic 5
3. Maintain a controlled environment	
3.1 Identify controlled environment contamination risks	Topic 5
3.2 Control environmental contamination according to GMP requirements and workplace procedures	Topic 5
3.3 Maintain controlled environment work area according to workplace cleaning standards and environmental requirements	Topic 5
4. Exit a controlled environment	
4.1 Follow workplace procedures to exit a controlled environment	Topic 5
4.2 Remove PPE and contamination prevention clothing according to workplace procedures	Topic 5
4.3 De-gown according to workplace procedures	Topic 5
4.4 Check, store and dispose of PPE according to manufacturer specifications, environmental and work health and safety requirements	Topic 5

FBPPHM3003 Knowledge Evidence	Topic Number
International nomenclature and classification of controlled environments and cleanrooms	Topic 5
GMP grades of cleanrooms and their relationship to the International Organization for Standardization (ISO) classification system	Topic 5
GMP requirements for the qualification of cleanrooms	Topic 5
Key design requirements for controlled environments and cleanroom for product protection: • layout and architecture • product and process requirements for clean air • filtration, including High Efficiency Particulate Air (HEPA) filters and the theory of particle filtration • airlocks for materials, equipment and people • turbulent and laminar air flows • pressure differentials • box-within-a-box principle • cleanability and maintainability	Topic 5
How controlled environments operate to control contamination, including: • clean rooms, including how they are certified • controlled, non-classified environments • clean zones • monitor and test systems • isolator technology • at rest and in operation • gowning and cleaning	Topic 5
GMP requirements and workplace procedures for working in controlled environments and cleanrooms, including: • requirements for approving and taking commodity items into the cleanroom • restrictions on movement of personnel to minimise cross-contamination • cleanroom garments, including types, materials, processing and reprocessing • personal hygiene requirements • clothing and footwear requirements for working in and moving between work areas • personal clothing use, storage and disposal requirements • workplace cleaning standards and environmental requirements relating to own work • responsibilities of general cleaning staff and how to work with a cleaning team	Topic 3, 4, 5

The role of cleaning and sanitising in preventing contamination of materials and products and protection of personnel, including: • how improper cleaning of a controlled environment or cleanroom can lead to product contamination • the need for proper selection of equipment and materials for proper cleaning	Topic 1, 3, 5
Controlled environment operating conditions, including: • differentials pressures • particle counts • microbial sampling • laminar air flow • humidity • temperature • room status • cleanliness status	Topic 5
Hygiene and basic elements of microbiology	Topic 1, 3, 5
Sources of contamination, including: • product • people • tools • facilities • equipment	Topic 1, 3, 4, 5
Risks associated with controlled environment and cleanroom operators: • physical behaviour, including how to walk and stand in a cleanroom • personal hygiene • psychological • workplace attitudes and habits • communications between workers • electrostatic discharge	Topic 1, 3, 5
Contamination risks associated with controlled environment and clean room operations, including: • number of personnel in the controlled environment • activities being undertaken • leaks • malfunctioning equipment • low differential pressures • high particle counts • incorrect air flow and velocity • humidity • temperature • room status inactive or in alarm • lack of cleanliness	Topic 1, 3, 4, 5

Common practices inconsistent with GMP found in controlled environment and clean room operations, including: • damage to plant or equipment • failure of cleaning regime • signs of pest infestation • missing or inaccurate records • failure to follow workplace procedures	Topic 1, 3, 4, 5, 7

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

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

Skillsimpact.com.au