22450VIC Course in Pharmaceutical Manufacturing Principles

This course has been accredited under Part 4.4 of the Education and Training Reform Act 2006.

Accreditation period: 1 October 2017 to 30 September 2022.

Contents

Section A: Copyright and course classification information

1. Copyright owner of the course	Copyright of this course is held by the Department of Education and Training, Victoria © State of Victoria (Department of Education and Training) 2017.
2. Address	Executive Director Industry Engagement and VET Systems Higher Education and Skills Group Department of Education and Training PO Box 4367 Melbourne, Victoria, 3001 **Organisational Contact:** Manager: Training Products Unit Higher Education and Skills Group Telephone: (03) 9637 3092 Email: course.enquiry@edumail.vic.gov.au **Day to day contact:** Curriculum Maintenance Manager Service - General Manufacturing Chisholm Institute 2 New Holland Drive Cranbourne VIC 3977 PO Box 684 Dandenong VIC 3175 T +61 3 9238 8448 Email: paul.saunders@chisholm.edu.au
3. Type of submission	This course is submitted for accreditation.
4. Copyright acknowledgement	Copyright of this material is reserved to the Crown in the right of the State of Victoria. © State of Victoria (Department of Education and Training) 2017 Copyright of the following unit of competency from nationally endorsed training packages is administered by the Commonwealth of Australia and can be accessed from Training.gov at www.training.gov.au Imported unit: *FDFOHS1001A Work safely* from the FDF10 Food Processing Training Package.

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6. Course accrediting body	Victorian Registration and Qualifications Authority: http://www.vrqa.vic.gov.au
7. AVETMISS information	**ANZSCO** (Australian and New Zealand Standard Classification of Occupations): 399999 Technicians And Trades Workers Nec **ASCED code – 4 digit** (Field of Education): 0303 Process and Resources Engineering National course code: 22450VIC
8. Period of accreditation	1 October 2017 to 30 September 2022.

Section B: Course information

1. Nomenclature	Standard 1 AQTF Standards for Accredited Courses
1.1 Name of the qualification	22450VIC Course in Pharmaceutical Manufacturing Principles
1.2 Nominal duration of the course	200 hours.
2. Vocational or educational outcomes	Standard 1 AQTF Standards for Accredited Courses
2.1 Purpose of the course	This course provides the skills and knowledge necessary to begin working in the pharmaceutical manufacturing sector. Pharmaceutical manufacturing takes many forms but has a range of common processes and procedures. This course enables learners to develop the skills and knowledge common to all pharmaceutical sectors prior to further process specific training. Graduates of this course may gain employment in any of the pharmaceutical sectors and will be able to readily move from one sector to another.
3. Development of the course	Standards 1 and 2 AQTF Standards for Accredited Courses
3.1 Industry / enterprise/ community needs	The Victorian Department of Economic Development, Jobs, Transport and Resources states that: *Medical Technologies and Pharmaceuticals is a priority growth sector for Victoria. The sector is supported by the Future Industries Medical Technologies and Pharmaceutical Sector Strategy which was developed following extensive sector consultation.* *The Sector Strategy specifically identified, based on consultations with pharmaceutical manufacturers and the Victorian Skills Commissioner, a lack of standardised training in current Good Manufacturing Practice (cGMP) and a lack of alignment between the training system and industry. This lack of alignment was identified as an area for action in order to support workers and assist the sector to grow.* *Victoria is home to over 22 pharmaceutical manufacturers and more than 40 Therapeutic Goods Administration (TGA) accredited production sites. Pharmaceutical manufacturing is growing in output and employment (employing ~6000) in the State with new companies investing, such as Korean manufacturer Komipharm currently building a new facility in Dandenong.* *Victoria's pharmaceutical manufacturers currently deliver training independently as there is no current accredited course which is recognised and endorsed across industry, meaning that even highly skilled and experienced pharmaceutical workers must repeat training with each new employer at considerable expense.* *A new industry-wide accredited course will provide more opportunity for workers from other advanced manufacturing industries such as automotive to transfer into the pharmaceuticals industry.* – Please see:

	Future Industries Medical Technologies and Pharmaceutical Sector Strategy) All pharmaceutical manufacturing must conform to stringent standards to ensure products are safe for the user. Victorian manufacturers are subject to requirements of one or all of the following bodies (depending on where the company has approval to market their products): the Australian Therapeutic Goods Administration (TGA), the American Food and Drugs Administration (FDA), the European Union, Health Canada, Medsafe, and ANVISA (this is not an exhaustive list). Irrespective of the particular products that are produced pharmaceutical manufacturers must all comply with current Good Manufacturing Processes (cGMP). All employees must have a clear understanding of cGMP and employers must demonstrate that employees have been trained in cGMP to ensure compliance. This course aims to provide a standardised, initial introduction to cGMP and its application in the pharmaceutical manufacturing environment. It is anticipated that the course will be utilised in three ways: • to train prospective employees of the sector, • as part of initial induction with a particular employer • to enable more efficient movement by employees between employers. Currently there are no acceptable accredited or endorsed training courses that enable employees to move to a new employer and have their existing skills and knowledge recognised. Each employer requires new employees to follow their full in-house training program regardless of prior experience or training. This is very inefficient and an unnecessary cost impost on the industry. Steering Committee: ▪ Felicity Harrison, Ego Pharmaceuticals ▪ Paul MacLeman (Chair), Danielle Savaglio: IDT Australia ▪ David Morton, Monash University ▪ Marita Counsel; Catalent Pharmaceuticals ▪ Anne Nicholls; Industry Consultant ▪ Ian Caddaye, Pfizer ▪ Vincent Chung, Seqirus (BioCSL) ▪ James Thomas, Sean Flannery: CSL Behring ▪ Melanie Thomson, MTP connect The FDF10 Food Processing Training Package includes five Pharmaceutical Manufacturing qualifications (Certificate I to Diploma). The Steering Committee indicated these qualifications do not meet the current requirements of the Victorian pharmaceutical industry. The skills and knowledge required for occupational health and safety has been provided for by the importation of the following unit of competency from the FDF10 Food Processing Training Package: FDFOHS1001A *Work safely*.

3.2 Review for re-accreditation	Not applicable
4. Course outcomes	Standards 1, 2, 3 and 4 AQTF Standards for Accredited Courses
4.1 Qualification level	This course does not align with any specific level of the Australian Qualifications Framework (AQF), but is consistent with the definition of a 'Course in …' It provides the skills and knowledge required for new entrants to the Victorian pharmaceutical manufacturing sector but does not have the breadth, depth or volume of learning of a qualification.
4.2 Employability skills	This course has been mapped to national employability skills. Refer to Section B, Appendix 1: Employability skills summary.
4.3 Recognition given to the course (if applicable)	*Standard 5 AQTF Standards for Accredited Courses* Not applicable
4.4 Licensing/ regulatory requirements (if applicable)	*Standard 5 AQTF Standards for Accredited Courses* At the time of accreditation no licensing or regulatory requirements apply.

5. Course rules	Standards 2, 6,7 and 9 AQTF Standards for Accredited Courses
5.1 Course structure	To be eligible for the **22450VIC Course in Pharmaceutical Manufacturing Principles**, learners must successfully complete a total of five (5) units. A Statement of Attainment will be issued for any unit of competency completed if the full course is not completed.

Unit of Competency/ Module Code	Field of Education Code (Six-digit)	Unit of Competency/Module title	Pre-requisite	Nominal Hours
Core Units				
VU22236	030199	Apply current Good Manufacturing Practice	Nil	60
VU22237	030199	Clean and sanitise facilities and equipment	Nil	30
VU22238	030199	Participate in a production process	Nil	30
VU22239	030199	Work in a controlled environment	Nil	50
FDFOHS1001A	061301	Work safely	Nil	30
		Total Nominal Hours	**200**	

5.2 Entry requirements	*Standard 9 AQTF Standards for Accredited Courses* Applicants for the **22450VIC Course in Pharmaceutical Manufacturing Principles** are to have achieved 'exit Level 3' for the core skills – reading, writing, oral communications and numeracy – as described in the Australian Core Skills Framework.

6. Assessment	Standards 10 and 12 AQTF Standards for Accredited Courses
6.1 Assessment strategy	All assessment will be consistent with the Australian Quality Training Framework Essential Conditions and Standards for Initial/Continuing Registration Standard 1.2 (Initial) and Standard 1.5 (Continuing). See: AQTF User guides to the Essential Conditions and Standards for Initial/Continuing Registration: OR Standard 1: Clauses 1.1 and 1.8 of the Standards for Registered Training Organisations (SRTOs) 2015 OR the relevant Standards for Registered Training Organisations in effect at the time of assessment. Assessment methods and collection of evidence will involve application of knowledge and skills to pharmaceutical manufacturing. A range of assessment methods will be used, such as but not limited to: • practical exercises • observation • direct questioning • presentation Assessment strategies must therefore ensure that: • all assessments are valid, reliable, flexible and fair • learners are informed of the context and purpose of the assessment and the assessment process • feedback is provided to learners about the outcomes of the assessment process and guidance given for future options • time allowance to complete a task is reasonable and specified to reflect the industry context in which the task takes place. A holistic approach to assessment may be used, by combining the assessment of more than one unit, where it better replicates working practice and reduces the potential for over assessment. RTOs must ensure that Recognition of Prior Learning (RPL) is offered to all applicants in determining competency for Credit. There is no mandatory workplace assessment.

6.2 Assessor competencies	*Standard 12 AQTF Standards for Accredited Courses* The Australian Quality Training Framework Essential Conditions and Standards for Initial/Continuing Registration, Standard 1.4 states the requirements for the competence of persons assessing the course See AQTF User guides to the Essential Conditions and Standards for Initial/Continuing Registration: OR Standard 1: Clauses 1.1 3,1.14, 1.15, 1.16,and 1.17 of the Standards for Registered Training Organisations (SRTOs) 2015 OR the relevant Standards for Registered Training Organisations in effect at the time of assessment. Assessment of the imported unit FDFOHS1001A *Work safely* must meet the assessor requirements for trainers specified in Training Package.
7. Delivery	Standards 11 and 12 AQTF Standards for Accredited Courses
7.1 Delivery modes	*Standard 11 AQTF Standards for Accredited Courses* Delivery of units of competency will take into consideration the individual needs of students and may involve: • workshops • individual assignments • team-based assignments • applied learning in the workplace or simulated pharmaceutical manufacturing environment Learners may be supported through: on-line (internet, social media, email and telephony); face-to-face conferencing, mentoring and interviews; ad hoc arrangements, and regular progress monitoring, particularly for practical work. There is no mandatory workplace delivery.

7.2 Resources	*Standard 12 AQTF Standards for Accredited Courses* Resources must include: - Equipment and materials relevant to the units of competency - Relevant range of texts, references and/or audio/visual material - Workplace documentation - Relevant organisational OHS/WHS policies and procedures • teachers/trainers who meet the Australian Quality Training Framework Essential Conditions and Standards for Initial/Continuing Registration Standard 1.4. See AQTF User guides to the Essential Conditions and Standards for Initial/Continuing Registration: OR • Standard 1: Clauses 1.1 3,1.14, 1.15, 1.16,and 1.17 of the Standards for Registered Training Organisations (SRTOs) 2015 OR the relevant Standards for Registered Training Organisations in effect at the time of assessment and, • access to computers and internet • access to workplace or simulated pharmaceutical manufacturing environment. • delivery of the imported unit FDFOHS1001A *Work safely* must meet any requirements for trainers as specified in the Training Package.
8. Pathways and articulation	Standard 8 AQTF Standards for Accredited Courses
	There are no formal articulation arrangements at present. Individuals will receive credit for any units completed as part of this course if they enrol in further training where the units are part of the qualification.
9. Ongoing monitoring and evaluation	Standard 13 AQTF Standards for Accredited Courses
	The Curriculum Maintenance Manager (CMM), General Manufacturing is responsible for monitoring and evaluation of the **22450VIC Course in Pharmaceutical Manufacturing Principles**. The **22450VIC Course in Pharmaceutical Manufacturing Principles** will be reviewed at mid-point in the accreditation period. Evaluations will involve consultation with: • course participants • pharmaceutical manufacturing industry representatives • teaching staff • assessors Any significant changes to the course resulting from course monitoring and evaluation procedures will be reported to the VRQA through a formal amendment process.

Appendix 1: Employability Skills Summary

Victorian Registration & Qualifications Authority	**Employability Skills Summary**
Qualification Code:	**22450VIC**
Qualification Title:	**Course in Pharmaceutical Manufacturing Principles**
The following table contains a summary of the employability skills required for this qualification. This table should be interpreted in conjunction with the detailed requirements of each unit of competency packaged in this qualification.	
Employability Skill	**Industry/enterprise requirements for this qualification include the following facets:**
Communication	• understand and follow instructions; oral, written, graphical, verbal • accurately complete documentation; manually and /or utilising ICT • ask questions to ensure full understanding • report issues verbally, in writing, and /or utilising ICT • use and apply relevant ratios, rates and proportions • calculate with fractions, decimals and percentages
Teamwork	• Contribute positively to team performance • Work as an individual and a team member • Work effectively with other team members • Work in a socially diverse environment • Negotiate outcomes where conflicting priorities exist • Work effectively when conflicts arise
Problem solving	• Identify, diagnose and rectify minor faults
Initiative and enterprise	• Adapt to new situations • Amend own work practices and behaviour to reflect performance feedback • Use analytical skills to identify improvement opportunities
Planning and organising	• Collect, analyse and organise information • Assist in prioritising and planning activities
Self-management	• Take responsibility for own work and performance • Access learning opportunities • Complete daily work activities

	• Contribute to personal skill development and learning • Identify opportunities for improvement
Learning	• Access learning opportunities to extend own personal work competencies • Be open to new ideas and techniques • Be prepared to invest time and effort in learning new skills • Be willing to learn in any setting – on or off the job • Undertake personal skill development
Technology	• Operate • systems, equipment and technology • Store or retrieve and process data / files

Section C: Units of Competency

The following VU units are contained in this document:

VU22236 Apply current Good Manufacturing Practice
VU22237 Clean and sanitise facilities and equipment
VU22238 Participate in a production process
VU22239 Work in a controlled environment

The following imported unit may be downloaded from
https://training.gov.au/Training/Details/FDFOHS1001A

FDFOHS1001A Work safely

VU22236 Apply current Good Manufacturing Practice

Unit Descriptor

This unit of competency covers the skills and knowledge required to comply with relevant current Good Manufacturing Practice (cGMP) codes through the implementation of workplace cGMP and quality procedures.

No licensing, legislative, regulatory or certification requirements apply to this unit at the time of publication.

Employability Skills

This unit contains Employability Skills.

Application of the Unit

This unit is intended for application as pre-employment training, retraining or during induction of new entrants to the pharmaceutical manufacturing workplace where workers require basic operational knowledge and skills for a limited range of tasks and problems.

It involves the application of policies and procedures to maintain cGMP awareness, compliance and continual improvement across a variety of operational roles, including quality, manufacturing and warehousing.

Application of this unit should be contextualised to reflect any specific workplace risks, and associated quality practices.

Competency Field

Pharmaceutical manufacturing, including biopharmaceuticals, complementary and veterinary medicines.

ELEMENT	PERFORMANCE CRITERIA
Elements describe the essential outcomes of a unit of competency.	*Performance criteria describe the required performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge and/or the range statement. Assessment of performance is to be consistent with the evidence guide.*
1 Maintain awareness of cGMP as a regulatory concept	1.1 Information appropriate to ***work role*** relating to current ***Australian and other applicable regulatory frameworks*** for manufacturing pharmaceuticals is identified and accessed.
	1.2 Information appropriate to work role relating to regulatory and industry initiatives for ***global harmonisation*** of ***current Good Manufacturing Practice (cGMP) compliance*** and product registrations is identified and accessed.
2 Identify requirements of cGMP related to own work	2.1 Workplace information on c***GMP requirements*** is located.
	2.2 cGMP procedures, instructions and labels related to work role are correctly identified.
	2.3 ***Relevant indications of a cGMP non-compliant situation*** and/or risks to product quality are recognised and appropriate action is taken to alert ***relevant personnel*** and/or take appropriate action in accordance with workplace procedures and applicable cGMP requirements.
3 Complete workplace documentation to support cGMP	3.1 ***cGMP documentation and recording requirements*** related to work role are correctly identified.
	3.2 Information, including calculations and test results, are recorded according to workplace reporting procedures to meet cGMP requirements
	3.3 Records, including electronic records, are certified according to cGMP requirements
4 Identify and follow biosecurity requirements	4.1 Information appropriate to work role relating to ***biosecurity requirements*** is identified and accessed
	4.2 All relevant biosecurity requirements and responsibilities related to work role are followed
5 Implement cGMP requirements when carrying out work activities	5.1 ***Common forms of contamination*** are identified and processes of contamination control followed
	5.2 Workplace procedures are followed to meet cGMP and environmental requirements

		5.3	The workplace is maintained in a clean and tidy manner to meet cGMP housekeeping standards
		5.4	Signs of unacceptable plant or equipment condition, including calibration status, are identified and reported
		5.5	cGMP requirements for routinely monitoring work area, materials, equipment and product are identified
		5.6	Records are completed in accordance with cGMP and workplace requirements
6	Ensure personal hygiene meets cGMP requirements	6.1	Personal hygiene requirements related to work role are identified.
		6.2	Hand washing is carried out according to best practice hygiene standards
		6.3	Protective gowns are donned, worn and maintained according to cGMP and workplace procedures
7	Participate in improving cGMP	7.1	Processes, practices or conditions which could result in non-compliance with cGMP are identified and reported according to workplace reporting requirements
		7.2	The ***elements of cGMP that help improve products and processes*** are identified.
		7.3	Corrective action is implemented within level of responsibility

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level, required for this unit.

Required Skills:

- maintain good personal hygiene
- maintain workplaces to meet cGMP housekeeping standards
- clean and sanitise hands using approved procedures.
- read and interpret relevant instructions and labels applicable to biopharmaceutical operations, including pictorial and written signs/instructions
- follow workplace information relating to cGMP responsibilities
- complete forms and deviation reports according to cGMP and workplace rules
- complete reconciliation calculations
- identify and give accurate verbal and/or written descriptions of incidents or situations that do or could compromise cGMP compliance and/ or product quality, and/or provide the potential for product contamination
- identify, and respond appropriately to, out-of-calibration equipment
- participate in procedures to support cGMP within level of responsibility
- identify and respond to out-of-specification or unacceptable raw materials, packaging components, final or part processed product within level of responsibility
- participate in failure investigations and in implementing improvement strategies
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor

Required Knowledge:

- cGMP as a regulatory concept, including regulatory obligations of employees, and the potential implications of non-compliance
- cGMP as a way of working to assure product quality as part of quality management systems.
- the historical development of cGMP and the applicable regulatory framework(s), including enforcement, for manufacturing pharmaceuticals
- drivers of global harmonisation initiatives, including risks in the supply chain when operating in a global environment
- basic principles of quality assurance, cGMP and quality control as currently defined for the industry sector
- cGMP arrangements in the workplace, including the Manufacturing Principles, relevant cGMP codes of practice and related workplace policies and procedures to implement these responsibilities

- the relationship between cGMP and the quality system, personnel responsible for designing and managing cGMP, personal role to maintain cGMP, and the role of internal and external auditors as appropriate
- the roles and responsibilities of employees, supervisors and managers in the workplace and the cGMP requirements for training
- personal hygiene, and the clothing and footwear requirements for working in and/or moving between work areas
- housekeeping requirements and responsibilities relating to own work, and use and storage of housekeeping/cleaning equipment where relevant
- awareness of common micro-biological, physical and chemical contaminants relevant to the work process
- awareness of control methods and procedures used in the work area to maintain cGMP, including an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant, as well as an understanding of the methods used to monitor process control
    - basic understanding of the standards, properties, handling and storage requirements of raw materials, packaging components and final product
    - cGMP requirements for maintaining plant and process equipment fit for use
- Documentation including recording requirements of cGMP, product and materials traceability procedures, and the legal significance of certifying and verifying cGMP records
- awareness of the controls and methods ~~for~~ to ensure electronic data integrity
- responsibilities for reporting and recording quality information
- the processes needed to investigate undesirable events and improve performance of processes
- procedures for responding to out-of-specification or unacceptable process performance/outcomes
- awareness of controls to protect personnel and the environment from contamination by products and materials
- awareness of how cGMP contributes to a safe workplace

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording in the Performance Criteria is detailed below. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Work role might include:

- manufacturing prescription or over the counter pharmaceuticals
- manufacturing biological or biotechnology pharmaceuticals
- manufacturing veterinary pharmaceuticals
- manufacturing complementary medicines including herbals and medicinal gases
- preparing solid or liquid dose
- sterile or non-sterile operations
- API manufacture
- finished dose manufacture
- quality Control
- warehousing
- inspection, labelling and packing including repacking

Australian and other applicable regulatory frameworks might include:

- National Medicines Policy
- Therapeutic Goods Act
- Therapeutic Goods Regulations
- Manufacturing Principles
- Therapeutic Goods Orders
- Pharmacopeias
- Code of cGMP
- other TGA guidelines relevant to product and market
- legislation relating to environmental manufacturing, Occupational Health & Safety
- US Food, Drug & Cosmetic Act and associated Codes of Federal Regulations and guidance
- European Directives and legislation of EU member states applicable to pharmaceutical manufacturing

Global harmonization might include:

- PIC/S background and guidance
- ICH background and guidance

Current Good Manufacturing Practice (cGMP) compliance includes:	• conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards
cGMP requirements might include:	• adherence to specific Quality, Quality Assurance, Quality Control, Quality Risk Management procedures
Relevant indications of a cGMP non-compliant situation might include:	• damage to plant or equipment • equipment or facility breakdown, malfunction or failure • breaches of regulations and procedures • poor housekeeping in the workplace • equipment exceeding nominated operating parameters and tolerances • not following procedures • operating processes without adequate training • documentation / data discrepancies • incorrect storage or labelling of materials, components or products
Relevant personnel might include:	• line operator • line / area supervisor • leading hand • unit / departmental manager • Quality Manager • Production Manager
cGMP documentation and recording requirements might include:	• policies, procedures, instructions • production data • in process or quality control test results • records of manufacturing and quality control • trend information • test reports • checklists • line clearances • validation reports • calculations • incident reports

Biosecurity requirements might include:	• The Gene Technology Act 2000 • Biosecurity Act 2015, Export Control Act 1982 and/or Imported Food Control Act 1992 • Regulatory requirements which apply to the supply of materials which are Genetically Modified Organisms (GMOs) • Regulatory requirements relating to quarantining and use of materials and products
Common forms of contamination might include:	• physical from equipment, environment or personnel • chemical from other products or materials, including cleaning agents • microbial from materials, equipment, environment or personnel
Elements of cGMP that help improve products and processes might include:	• customer complaint investigations • internal, external, customer and regulatory audits • deviation reports • out of specification reports • non-conforming products • product quality reviews • corrective / preventive action requests

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Overview of Assessment	The assessment environment must provide access to documentation related to cGMP together with a range of production/packaging activities typical of commercial manufacturing businesses.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	• To demonstrate competence in this unit, a candidate must provide evidence of the application of their knowledge of cGMP to: • identify the aspects of relevant regulatory frameworks that apply to work roles. • identify cGMP non-conformances, • follow required cGMP record keeping practices, • meet all cleaning and hygiene requirements, • use protective equipment in accordance with cGMP.
Context of and specific resources for assessment	Assessors must be satisfied that the person can consistently perform the unit including all elements and performance criteria, and can demonstrate the required skills and knowledge. Resources for assessment include: • a range of relevant exercises, case studies and/or other practical and knowledge assessment, and/or • access to an appropriate range of relevant operational situations • relevant and appropriate materials and equipment, and • applicable documentation including workplace procedures, regulations, codes of practice and operation manuals.
Method of assessment	As a minimum, assessment of knowledge must be conducted through appropriate written/oral tests. The following suggested methods are appropriate for this unit. • Practical activities such as problem solving, identifying cGMP non-conformances, good record keeping practices, cleaning, gowning, hand hygiene • observation

- direct questioning
- presentations
- third party reports

Guidance information for assessment

To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

VU22237 Clean and sanitise facilities and equipment

Unit Descriptor

This unit of competency covers cleaning, sanitation and related procedures for pharmaceutical processing facilities and equipment, as well as the skills and knowledge required to prepare process equipment for cleaning in place (CIP). It includes the rationale for, and science of, sanitisation.

No licensing, legislative, regulatory or certification requirements apply to this unit at the time of publication.

Employability Skills

This unit contains employability skills.

Application of the Unit

This unit is intended for application as pre-employment training, retraining, or during induction of new entrants to the pharmaceutical manufacturing workplace whose activities take them into production areas or control laboratories, and for other workers whose activities could impact on product quality e.g. maintenance personnel.

This unit supports the work of personnel who are, or will be, responsible for maintaining processing facilities and equipment in a validated clean and hygienic state.

It involves the application of policies and procedures to maintain cGMP awareness, compliance and continual improvement across a variety of operational roles, including quality, manufacturing and warehousing.

Application of this unit should be contextualised to reflect any specific workplace risks, and associated quality practices.

Competency Field

Pharmaceutical manufacturing, including biopharmaceuticals, complementary and veterinary medicines.

ELEMENT	PERFORMANCE CRITERIA
Elements describe the essential outcomes of a unit of competency.	*Performance criteria describe the required performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge and/or the range statement. Assessment of performance is to be consistent with the evidence guide.*
1 Plan and prepare to clean pharmaceutical processing areas and/or equipment	1.1 ***Workplace information*** applicable to the area and/or equipment, including sampling and testing, is accessed, interpreted and applied to planning.
	1.2 ***Surfaces,*** and ***soil and dirt types*** are identified by observation.
	1.3 Cleaning techniques and ***cleaning chemicals*** required for task are selected and prepared.
	1.4 ***Cleaning equipment*** is selected, checked for serviceability and compliance with cleaning and sanitation requirements of cGMP cleaning program.
	1.5 Cleaning equipment faults are rectified or reported before starting work.
	1.6 ***Services*** are confirmed as available and ready for operation.
	1.7 ***Personal protective equipment (PPE)*** is located according to health and safety requirements.
	1.8 ***Cleaning consumables*** are obtained to meet anticipated usage patterns according to company requirements.
	1.9 Cleaning chemicals are prepared to appropriate concentration according to workplace requirements/manufacturers' instructions
	1.10 Signs and barricades are selected and installed according to health and safety, and workplace requirements.
	1.11 The plant is set for the ***cleaning cycle***
2 Remove waste	2.1 ***Waste*** is collected and disposed of according to workplace specifications, and legislative, environmental, and health and safety requirements.
	2.2 Rubbish bins, where used, are cleaned and sanitised according to specified requirements, and new replacement bin liners are inserted.
3 Clean and sanitise pharmaceutical processing surfaces	3.1 Physical movement in pharmaceutical processing areas is conducted according to ***current Good Manufacturing Practice (cGMP)*** and workplace requirements.
	3.2 Loose dirt and debris are removed from pharmaceutical processing surfaces prior to applying cleaning treatment.
	3.3 ***Cleaning steps*** are followed according to workplace requirements.

		3.4	Cleaning chemicals, where used, are applied to pharmaceutical surfaces according to manufacturer specifications and workplace requirements.
		3.5	Surfaces are thoroughly rinsed and allowed to dry according to workplace requirements.
		3.6	***Chemical disinfectants and sanitisers***, where used, are applied to surfaces according to workplace requirements.
		3.7	***Practices inconsistent with*** c***GMP*** are reported according to company requirements.
4	Clean and sanitise to meet workplace requirements	4.1	***Processing equipment*** is cleaned, sanitized and drains are disinfected according to cGMP requirements and workplace information.
		4.2	Equipment is inspected to confirm cleanliness status, and non-conformance to acceptance criteria is identified and appropriate actions taken.
		4.3	Equipment is returned to operating order.
5	Monitor effectiveness of cleaning process	5.1	The ***sampling/test methods***, sampling/test points, types of samples and/or measurement requirements in accordance with relevant methods are confirmed.
		5.2	Samples are collected, stored and transported in accordance with sampling plan, and relevant methods and/or standards.
		5.3	***Data and information*** relating to equipment cleaning and sanitizing, including cleaning status and any sampling and testing, if required, is recorded, and certified, according to workplace reporting procedures to meet cGMP requirements.
6	Return plant to operating conditions, and clean and store cleaning equipment	6.1	Signs and barricades are removed according to health and safety, and workplace requirements.
		6.2	Room and/or equipment status is recorded according to workplace requirements.
		6.3	Cleaning equipment and PPE are cleaned, checked according to manufacturer specifications and environmental, health and safety requirements.
		6.4	Cleaning equipment and PPE is sanitised and stored so that it doesn't become a source of contamination.
		6.5	Unused chemicals are stored or disposed of according to manufacturer specifications, and health and safety and workplace requirements.

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level, required for this unit.

Required Skills:

- access workplace information, such as the cleaning schedule to identify cleaning requirements
- read and interpret relevant instructions and labels applicable to cleaning operations, including pictorial and written signs/instructions
- identify type of surfaces and soil typically present in the work area select cleaning equipment required for the task
- select and prepare cleaners and sanitisers as required according to typical workplace procedures
- select, fit and use personal protective equipment (PPE) as required by work tasks
- apply correct cleaning procedures to a range of surfaces (facilities) commonly encountered in pharmaceutical manufacturing sites
- apply correct cleaning and sanitizing procedures to a range of equipment commonly encountered in pharmaceutical manufacturing sites
- carry out typical cleaning checks and inspections
- take samples and conduct tests according to typical workplace procedures
- complete forms and deviation reports according to cGMP and workplace rules
- maintain housekeeping standards to meet cGMP requirements
- return equipment to operating order (this may involve basic assembly of equipment parts) inspect equipment to identify equipment condition and cleanliness
- store cleaners, sanitisers and related equipment as required

Required Knowledge:

- the importance of maintaining a tidy facility and how good housekeeping practices contribute to a safe and efficient workplace
- housekeeping requirements and responsibilities relating to own work
- responsibilities of general cleaning staff and how to work with a cleaning team
- common types of microbiological, physical and chemical contaminants relevant to the work process
- the role of cleaning and sanitising in preventing contamination of materials and products, and in the protection of personnel including, but not limited to, maintenance personnel and other external contractors
- the cGMP requirements for cleaning and sanitation of pharmaceutical processing facilities and equipment
- risks associated with cleaning and sanitising operations
- personal hygiene, and the clothing and footwear requirements for working in and/or moving between work areas

- personal clothing use, storage and disposal requirements
- use and storage of housekeeping/cleaning equipment where relevant
- terminology relating to the chemical cleaning and decontamination (cleaners, disinfectants, sanitisers, sterilants, fogging, fumigation)
- the different types of cleaning equipment suitable for use in a pharmaceutical processing environment
- hygienic vs unhygienic design features of facilities and equipment, including but not limited to, inserts and dead legs
- different cleaning methods: Clean-in-place (CIP) and Clean-out-of place (COP) methods, and the difference between cleaning, disinfecting, sanitising and sterilising
- different levels of cleaning requirements depending on the reason for cleaning, and whether equipment is dedicated or shared
- the influence of the time between manufacture and cleaning (dirty hold time), and the time between cleaning and use (clean hold time) on the cleaning process
- acceptance criteria (what is clean?), and how is clean measured (the sampling and testing commonly used)
- purpose of keeping records and the recording requirements of cGMP, including the legal significance of certifying and verifying cGMP records
- advantages and disadvantage of automated and semi-automated clean-in-place systems
- the different types and properties of cleaning and sanitising agents
- points to consider when choosing and using cleaning chemicals including:
    - the chemical and physical properties of the soils or residues to be removed,
    - the interactions between cleaning chemicals and the surfaces they may adhere to,
    - the solubility of the soil / residue in the cleaning solution, and
    - the need to rotate sanitisers
    - the frequency of cleaning and sanitising
- manual, and semi and fully automated cleaning methods
- purpose and basic principles of CIP, including the use and functions of caustic and acid solutions, and cleaning sequence and stages
- the variable factors that influence cleaning effectiveness and performance
- critical parameters in the cleaning and sanitising process(es) including, but not limited to, time, temperature, concentration
- cGMP requirements for the validation of cleaning processes
- procedures for responding to out-of-limits or unacceptable performance/outcomes
- waste collection, recycling and handling procedures relevant to own work responsibilities
- common cGMP deficiencies observed in cleaning and sanitising operations

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording in the Performance Criteria is detailed below. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Workplace Information might include:

- workplace quality policies, procedures and instructions
- safety and security policies, procedures and guidelines
- specifications and material safety data sheets (MSDS)
- signs and symbols
- workplace procedures and instructions and protocols
- production cleaning schedules
- approved workplace checklists standard forms

Surfaces might include:

- ceilings, walls, floors, windows, doors, ledges and all other structures
- benches
- outer surfaces of equipment
- door handles and door frames
- light switches
- lockers
- vents / grills
- pass-through cabinets

Soil and dirt types might include:

- physical (dust and fibre) particulates from equipment, environment or personnel
- chemicals from other products or ingredients, including decomposition products and preservatives
- microbial contamination from materials, equipment, environment or personnel
- difficult to remove residues including cleaning chemicals, and biological residues such as proteins, lipids, simple and complex sugars, salts and heat denatured residues

Cleaning chemicals might include:

- alkaline, neutral or acidic cleaners
- aerosol, gel, liquid, powder and tablet forms
- cleansers, strippers, degreasers, detergents, and abrasives
- emulsifiers and suspending agents
- ready-to-use, concentrates
- wetting agents

Cleaning equipment might include:	• wipes, including cleanroom wipes • mops, including cleanroom mops • buckets, including cleanroom mop bucket and wringer • vacuum cleaners, where allowed
Services might include:	• power • water: potable and/or purified • steam • compressed and instrumentation air • vacuum
Personal protective equipment (PPE) might include:	• gowns, scrubs, smocks and statcoats • cleanroom coveralls • cleanroom undergarments • head coverings • disposable coveralls • over boots and cleanroom boots • masks and googles
Cleaning consumables might include:	• cleaning and disinfecting solutions • wipes, including cleanroom wipes
Cleaning cycle might include:	• equipment shutdown and/or taken off line for cleaning • equipment and related valves and pipework are configured to confirm readiness for cleaning • pre-rinsing • cleaning • rinsing • sanitation • drying
Waste might include:	• biological waste • sharps • chemicals • general processing and laboratory wastes such as paper, glassware, consumables • protective clothing

Current Good Manufacturing Practice (cGMP) includes:	• conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards
Cleaning steps might include:	• cleaning of all work surfaces in the controlled environment. • vacuuming (if allowed) of the floors and work surfaces. • emptying of appropriate trash and waste. • cleaning of the doors, door frames and lockers in the pre-staging area and gowning areas • mop gowning and cleanroom floors • changing tacky mats
Chemical disinfectants and sanitisers might include:	• alcohol • aldehydes • hypochlorites • iodophors • quaternary ammonium compounds • acid-anionic surfactants • fogging agents • fumigants such as gases or hydrogen peroxide vapour
Practices inconsistent with cGMP might include:	• damage to plant or equipment • failure of cleaning regime • signs of pest infestation • missing or inaccurate records • failure to follow Standard Operating Procedures
Processing equipment might include:	• liquid mixing vessels and component parts such as blades, mixing shafts and/or impellors • solid blenders and component parts e.g. ribbon blenders, intensifiers • fluid bed driers • oven driers • freeze driers • bag filters • intermediate Bulks Container

	• ancillary equipment such as sampling tools • autoclaves • liquid fill/seal equipment
Monitoring of cleaning process might include:	• chemical strength • cycle time(s) • temperature • time of exposure • storage tank levels • rinse water quality • air and environmental monitoring
Sampling/test methods might include:	• visual checks • pH tests of final rinse water • swabbing of surfaces for presence of contamination
Data and information might include:	• cleaning status cards / logs completed • cleaning logs / records completed • incident reports

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Overview of Assessment

The assessment environment provides access to documentation related to cleaning together with a range of cleaning activities typical of commercial manufacturing operations, and that meet the requirements of the Australian Code of cGMP.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

To demonstrate competence in this unit, a candidate must provide evidence of the application of their knowledge of cleaning and sanitation processes under cGMP to:

- meet all cleaning and sanitisation requirements,
- follow manual and automated cleaning and sanitising processes and techniques,
- manage waste appropriately
- undertake monitoring
- collect and record all required data.

Context of and specific resources for assessment

Assessors must be satisfied that the person can consistently perform the unit including all elements and performance criteria, and can demonstrate the required skills and knowledge.

Resources for assessment include:

- a range of relevant exercises, case studies and/or other practical and knowledge assessment, and/or
- access to an appropriate range of relevant operational situations
- cleaning procedures and related advice on equipment operation, including advice on safe work practices and environmental requirements
- personal protective clothing and equipment
- equipment to be cleaned
- chemicals and/or automated chemical addition system services as required
- Material safety data sheets, as appropriate
- cleaning schedule and related standard operating procedures
- housekeeping standards and procedures
- advice on environmental management issues relevant to work responsibilities
- data collection forms and information recording systems, requirements and procedures.

Method of assessment

As a minimum, assessment of knowledge must be conducted through appropriate written/oral tests. The following suggested methods are appropriate for this unit:

- practical activities, including planning for cleaning, gowning, hand hygiene, identifying cGMP non-conformances, record keeping, problem solving
- review of records and reports generated during practical exercises
- determination of whether records have been correctly prepared and certified.
- observation
- direct questioning
- presentations
- third party reports

Guidance information for assessment

To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

VU22238 Participate in a production process

Unit Descriptor

This unit of competency covers the skills and knowledge required to set up, monitor and adjust a production process or sub-system in a pharmaceutical manufacturing environment. It includes the concept of criticality as applied to quality attributes and process parameters, and an understanding of the relationships between critical process parameters and product quality.

No licensing, legislative, regulatory or certification requirements apply to this unit at the time of publication.

Employability Skills

This unit contains employability skills.

Application of the Unit

This unit has application in a pharmaceutical production environment. It targets the production worker responsible for applying basic principles to the operation and/or monitoring of a production process and associated equipment according to Good Manufacturing Practices (cGMP).

It involves the application of policies and procedures to maintain cGMP awareness and compliance across a variety of pharmaceutical manufacturing processes.

This unit also supports the work of personnel who are, or will be, responsible for process validation as a means of assuring product quality throughout the product lifecycle

Application of this unit should be contextualised to reflect any specific workplace risks, and associated quality practices.

Competency Field

Pharmaceutical manufacturing, including biopharmaceuticals, complementary and veterinary medicines.

ELEMENT	PERFORMANCE CRITERIA
Elements describe the essential outcomes of a unit of competency.	*Performance criteria describe the required performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge and/or the range statement. Assessment of performance is to be consistent with the evidence guide.*
1 Receipt materials and components	1.1 ***Required batch materials*** are confirmed as compliant and corresponding to the ***workplace information***.
	1.2 Containers are cleaned, where necessary, and labelled with the ***prescribed data***, according to workplace information.
	1.3 Incoming goods are physically or administratively quarantined according to ***current Good Manufacturing Practices (cGMP)*** and workplace procedures.
	1.4 ***Deviations, unusual events*** and ***non-conformances*** are identified and reported according to cGMP and ***workplace procedures***.
2 Set up the production process for operation	2.1 ***Equipment, materials and services*** are confirmed to meet operating requirements.
	2.2 Line clearance requirements are completed as per documented procedures
	2.3 **Cleaning requirements** and **equipment status** are identified and confirmed.
	2.4 **Equipment settings** are selected or adjusted as required to meet operating requirements.
	2.5 Processing/operating parameters are entered as required to meet production requirements.
	2.6 **Pre-start checks** are carried out as required by cGMP and workplace requirements.
	2.7 Equipment performance is checked and adjusted as required
3 Dispense materials	3.1 ***Starting materials*** are dispensed according to cGMP and workplace procedures.
	3.2 Dispensed material, including weight or volume are checked and recorded according to cGMP and workplace procedures.
	3.3 Materials dispensed for each batch and stages are labelled according to cGMP and workplace procedures.
4 Operate and monitor the production process	4.1 The process is started up and operated according to workplace procedures.
	4.2 Equipment is ***monitored*** to identify variation in operating conditions.

		4.3	Variation in ***equipment operation*** is identified and maintenance requirements are reported according to workplace reporting requirements.
		4.4	The process is monitored to confirm that ***specifications*** are met.
		4.5	Deviations from standard procedures, out-of-specification product/process outcomes or any other unusual events are identified, rectified and/or reported, according to cGMP and workplace procedures, to maintain the process within specification.
		4.6	The work area is maintained according to housekeeping standards
		4.7	Work is conducted in accordance with workplace environmental guidelines
		4.8	***Workplace records*** are completed according to cGMP and workplace requirements.
5	Hand over the production process	5.1	***Handove***r is carried out according to workplace procedures
		5.2	Handover production team is made aware of process and related equipment status at completion of handover
6	Shut down the process	6.1	The appropriate ***shutdown procedure*** is identified
		6.2	The process is shut down according to workplace procedures
		6.3	Maintenance requirements are identified and reported according to workplace reporting requirements
		6.4	Checks on yields, and reconciliation of quantities performed according to workplace procedures.
		6.5	Yields and quantities performed outside acceptable limits are identified and rectified or reported
		6.6	Workplace records are maintained according to cGMP and workplace requirements.

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level, required for this unit.

Required Skills:

- access workplace information to identify processing requirements
- select, fit and use personal protective clothing and/or equipment
- confirm supply of necessary materials and services
- handle and store materials and products in a manner that prevents contamination and mix-ups
- perform area and/or line clearances
- identify pre-start checks, such as:
  - inspecting equipment condition to identify any signs of wear
  - selecting appropriate settings and/or related parameters
  - confirming that equipment is clean and ready for use
  - ensuring any scheduled maintenance has been carried out
  - confirm equipment is operating correctly
- monitor and adjust process equipment to achieve required outcomes, including monitoring control points, conducting inspections as required to confirm process remains within specification, and monitor supply and flow of materials to and from the process.
- take appropriate action in response to deviations, usually events and/or out-of-trend and out-of-specification results
- complete workplace records, as required, to maintain data integrity
- perform yield and reconciliation calculations
- maintain work area to meet housekeeping standards
- use process control systems according to workplace procedures
- collect samples and conduct tests according to workplace procedures
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor

Required Knowledge:

- purpose and basic principles of steps (unit operations) in pharmaceutical manufacturing processes
- typical processing equipment and utility systems, and how their attributes (performance, functionality, construction, instrumentation) can impact product quality and/or cGMP compliance
- basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications and the purpose and location of sensors and related feedback instrumentation
- services required and action to take if services are not available

- the flow of processes, the inputs and outputs of each step or unit operation, and the effect of outputs on downstream processes
- critical factors that impact product quality and the need for process control
- quality characteristics to be achieved by the process
- quality requirements of materials and effect of variation on process performance
- cGMP requirements for material handling, storage and preservation
- cGMP requirements for production and process controls, including but not limited to:
    - Identification and traceability
    - Yields and reconciliation
    - Segregation and storage
    - Status labels (physical and electronic)
- what validation is, and why it is legislated in the pharmaceutical industry
- types of process automation typically encountered in the pharmaceutical industry and typical controls
- intent and basic principles of cGMP requirements when processes are automated / semi-automated

  critical factors that affect the scale up processes, and their potential impact on product quality and the validated state
- operating requirements, parameters and corrective action required where operation is outside specified operating parameters
- typical equipment faults and failure modes, and related causes and potential effects on process control and product quality, including recognition of signs and symptoms of faulty equipment and early warning signs of potential problems
- cGMP requirements for record keeping and data integrity, including electronic data and information management systems
- inspection or test points (control points) in the process and the related procedures and recording requirements
- common causes of variation such as contamination and mix-up risks associated with the process and related control measures
- operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process
- requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage
- procedures and responsibility for reporting production and performance information
- environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process
- basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment
- product/process changeover procedures and responsibilities, where relevant
- routine maintenance procedures, where relevant
- cleaning and sanitation procedures, where relevant

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording in the Performance Criteria is detailed below. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Required batch materials might include:	• Raw materials • Packaging materials • Components
Workplace information might include:	• relevant clauses in the applicable current Good Manufacturing Practice (cGMP) codes • signs and symbols • workplace instructions • production schedules, including cleaning schedules • approved workplace checklists • room data sheets (specifications) • purchase orders • picking lists and bills of materials • change notes • deviation reports • material and product specifications • standard forms and reports
Prescribed data includes:	• Status labels • Identification labels
current Good Manufacturing Practices (cGMP) include	• conformance to site-wide manufacturing quality systems for ensuring that products are consistently produced and controlled according to quality standards
Deviations and unusual events might include:	• missing or inaccurate records • failure to follow Standard Operating Procedures • product diverted from normal course of process • spills & leaks • out of limit situations (yields, reconciliations, in process controls, in process checks) • damage to plant or equipment • signs of inadequate cleaning or pest infestation
Non-conformances might include:	• failure of cleaning regime • damaged goods: starting materials, components, intermediates or products
Workplace procedures might include:	• company quality policies, procedures, protocols and instructions • Master Processing Instructions • Master Packaging Instructions • safety and security policies, procedures and guidelines

Equipment might include:	• weighing instruments • mixing vessels and associated components • bioreactors and fermenters • filling machines and associated components • ancillary equipment such as sieves, filters
Materials might include**:**	• chemicals (raw materials) • intermediates • bulk product • packaging components: vials, ampoules, bottles • printed material: labels, cartons
Services might include:	• power • water: potable and/or purified • steam • compressed and instrumentation air • vacuum
Cleaning requirements might include:	• line clearance / area clearance • partial or full cleans • sanitation and/or sterilisation • automated, semi-automated, manual
Equipment status might include:	• clean • ready to use / In use • calibrated
Equipment settings might include:	• machine speed • mixing speed • pressure • chemical additive addition rates • time
Pre-start checks might include:	• area and/or line clearances • area / rooms checks such as differential pressures, room status • environmental sampling • cleaning • sanitation
Starting materials might include:	• Liquids • Powders
Monitored might include:	• the use of SCADA and process control systems • in process checks such as weights, pH • environmental monitoring • bioburden sampling • verification of checks performed by other operators

Equipment operation might include:	Operation of any equipment used in the dispensing manufacturing or packaging of pharmaceutical or biopharmaceuticals, including the use of automated equipment and process control systems.
Specifications include:	In the context of monitoring a production process, specifications refer to the acceptable range for each process variable e.g. a lower and upper limit for machine or mixing speed. Anything falling outside of the acceptable range may result in unacceptable product quality.
Workplace records might include:	• logs: cleaning, equipment, event • batch records • cleaning records • event report
Handover might include communication made:	• in person • using recorded information (records / reports) • via notice boards
Shutdown procedure might include:	• line clearances • environmental sampling • cleaning (in some cases cleaning might be carried out by a dedicated cleaning crew)

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Overview of Assessment

The assessment environment provides access to documentation related to pharmaceutical manufacturing together with a range of activities typical of commercial manufacturing operations, and that meet the requirements of the Australian Code of cGMP.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

To demonstrate competence in this unit, a candidate must provide evidence of the application of their knowledge of typical pharmaceutical and/or biopharmaceutical manufacturing processes to:

- receive, handle and store materials,
- operate a range of processes and/or process components,
- monitor and adjust processes to optimise production,
- collect and record required data.

Context of and specific resources for assessment

Assessors must be satisfied that the person can consistently perform the unit including all elements and performance criteria, and can demonstrate the required skills and knowledge.

Resources for assessment include:

- a range of relevant exercises, case studies and/or other practical and knowledge assessment, and/or
- access to an appropriate range of relevant operational situations.
- material handling and storage procedures
- pre-start checks on production system components and related advice on equipment operation, including advice on safe work practices and environmental requirements
- information relating to the operation, monitoring and typical adjustments of pharmaceutical and/or biopharmaceutical processes
- information and documentation relating to handover
- information relating to the regulatory and management of events or issues associated with production processes, relevant to work responsibilities
- examples of data collection forms and information recording systems, requirements, procedures and examples of data.

Method of assessment

As a minimum, assessment of knowledge must be conducted through appropriate written/oral tests. The following suggested methods are appropriate for this unit:

- practical activities, including planning for entry into the controlled environment, gowning, hand hygiene, identifying contamination risks and cGMP non-conformances, record keeping, problem solving
- observation
- direct questioning
- presentations
- third party reports

Guidance information for assessment

To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

VU22239 Work in a controlled environment

Unit Descriptor

This unit of competency covers the skills and knowledge required to work in a controlled environment within a pharmaceutical manufacturing facility. It provides for the procedures required to gown-up, enter and, and de-gown to minimise contamination risks.

No licensing, legislative, regulatory or certification requirements apply to this unit at the time of publication.

Employability Skills

This unit contains employability skills.

Application of the Unit

This unit has application in a pharmaceutical production environment. It targets the production worker responsible for conducting work according to cGMP and controlled environment standards.

This unit also supports the work of personnel who are, or will be responsible for maintaining processing facilities in a validated state.

It involves the application of policies and procedures to maintain cGMP awareness and compliance across a variety of operational roles, including quality, manufacturing and maintenance.

This unit does not meet the requirements to formally qualify 'cleanroom operators'.

Application of this unit should be contextualised to reflect any specific workplace risks, and associated quality practices.

Competency Field

Pharmaceutical manufacturing, including biopharmaceuticals, complementary and veterinary medicines.

ELEMENT	PERFORMANCE CRITERIA
Elements describe the essential outcomes of a unit of competency.	*Performance criteria describe the required performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge and/or the range statement. Assessment of performance is to be consistent with the evidence guide.*
1 Prepare to enter a controlled environment.	1.1 ***Workplace information*** relating to the ***controlled environment*** is identified and accessed.
	1.2 ***Hand washing and disinfecting procedures*** are followed according to workplace procedure.
	1.3 Appropriate ***protective clothing and footwear*** are identified and located.
	1.4 Protective clothing and footwear are correctly fitted and inspected prior to entering controlled environment.
	1.5 ***Operating conditions of controlled environment*** are checked prior to entry.
2 Work in a controlled environment.	2.1 ***Workplace procedures*** are followed to enter a controlled environment.
	2.2 Requirements for taking ***commodity items*** into the controlled environment are followed according to workplace procedures.
	2.3 ***Work activities*** are conducted to minimise risk of contamination.
3 Maintain a controlled environment	3.1 Controlled environment is monitored and ***contamination risks*** are identified.
	3.2 Contamination risks are assessed and risks from environmental contamination controlled according to workplace and cGMP requirements.
	3.3 ***Daily housekeeping and cleaning*** of controlled environments are followed according to workplace procedure.
	3.4 ***Practices inconsistent with*** c***GMP*** are reported according to workplace requirements.
4 Exit a controlled environment and de-gown	4.1 Workplace procedures are followed to exit a controlled environment.
	4.2 Protective clothing and footwear is removed according to workplace procedure.
	4.3 Protective clothing is checked, stored, or disposed of, according to manufacturer specifications and environmental, health and safety, and workplace requirements.

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level, required for this unit.

Required Skills:

- check operating conditions of the controlled environment according to workplace and cGMP requirements
- maintain high standards of personal hygiene, health and cleanliness appropriate to the operating environment
- identify and report any condition that may cause shedding of abnormal numbers or types of contaminants
- follow changing and washing procedures to prevent carry-through of contaminants to the clean areas
- don and wear facility suits / cleanroom apparel appropriately for the grade of cleanroom and in a manner that does not generate additional contaminants
- enter cleanrooms in a manner to minimise contamination
- maintain housekeeping standards to meet cGMP requirements
- follow controlled environment / cleanroom protocols
- exit and degown according to workplace instructions, and in a manner that does not generate additional contaminants which can later be shed
- read and interpret relevant instructions and labels applicable to controlled environments and cleanrooms, including pictorial and written signs/instructions
- identify contamination hazards typically encountered in pharmaceutical manufacturing environments and take steps to prevent identified hazards
- complete forms and incident reports according to cGMP and workplace rules
- use oral communication skills/language competence to fulfil the job role, including questioning, active listening, asking for clarification and seeking advice from supervisor

Required Knowledge:

- product and process requirements for “clean” air
- sources of contamination generated by product, people, tools, the facilities, equipment
- what is a cleanroom / controlled zone?
- international nomenclature and classification of cleanrooms
- cleanroom terminology including at rest and in operation
- cGMP grades of cleanrooms and their relationship to the ISO classification system

- controlled, non-classified environments: similarities and differences to cleanroom
- key design requirements for controlled environments and cleanroom for product protection:
  - layout and architecture
  - filtration, including HEPA filters: the theory of particle filtration
  - airlocks: materials, equipment and people
  - airflows: turbulent versus laminar air flows
  - pressure differentials
  - box-within-a-box principle
  - cleanability and maintainability
  - temperature and humidity
- how cleanrooms / controlled zones operate to control contamination, including gowning and cleaning requirements
- cleaning key design requirements for containment facilities for personal and environmental protection
- the principles of, and terminology for, isolator technology
- monitoring and test systems (instruments and measurement) used for cleanroom operations:
- how cleanrooms are certified: test methods, sampling sites
- cGMP requirements for the qualification of cleanrooms
- cGMP rules and requirements for working in controlled environments and cleanrooms including personal actions prohibited in cleanrooms including:
  - requirements for approving and taking commodity items into the cleanroom
  - restrictions on movement of personnel, including QC, maintenance and cleaning staff to minimise cross-contamination
  - cleanroom garments: types, materials, processing and reprocessing, where allowed
  - personal hygiene, and the clothing and footwear requirements for working in and/or moving between work areas
  - personal clothing use, storage and disposal requirements
  - housekeeping requirements and responsibilities relating to own work
- responsibilities of general cleaning staff and how to work with a cleaning team, including knowledge of when cleanrooms can be cleaned
- the role of cleaning and sanitising in preventing contamination of materials and products, and in the protection of personnel including maintenance personnel and other external contractors e.g.
  - how improper cleaning of the cleanroom can lead to product contamination
  - the need for proper selection of equipment and materials for proper cleaning

- risks associated with cleanroom operators:
  - physical behaviour
  - personal hygiene risks-- Skin flakes, oils, perspiration, use of cosmetics, hair
  - psychological concerns associated with working in cleanrooms e.g. room temperature, humidity, claustrophobia
  - workplace attitudes and habits
  - communications between workers
  - electrostatic discharge
- common cGMP deficiencies observed in cleanroom operations
- procedures for responding to out-of-specification or unacceptable performance/outcomes
- purpose of keeping records and the recording requirements of cGMP, including the legal significance of certifying and verifying cGMP records

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording in the Performance Criteria is detailed below. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Workplace information might include:

- signs and symbols
- workplace instructions
- production schedules, including cleaning schedules
- approved workplace checklists
- room data sheets (specifications)
- material and product specifications
- standard forms and reports
- licensing and legislative requirements
- relevant clauses in the applicable Good Manufacturing Practice (cGMP) codes

Controlled environment might include:

- environmentally graded work areas that have controls over their use.
- Cleanrooms that are controlled environments that have been certified as meeting an internationally recognized standard

Hand washing and disinfecting procedures might include:

- correct handwashing technique with liquid soap
- correct hand washing technique for cleanroom
- correct use of alcohol hand disinfectants

Protective clothing and footwear might include:

- a variety of facility suits for controlled, non-classified operating environments
- a variety of types and styles of cleanroom garments including disposable and reusable garments, gloves, face masks, head covers, shoes, over boots, goggles
- personnel protective clothing and footwear appropriate to the activities being undertaken

Operating conditions of controlled environment might include measurements such as:

- differentials pressures
- particle counts
- air flow & velocity
- humidity
- temperature
- room status
- cleanliness status

Workplace procedures include:	• workplace quality policies, procedures, protocols and instructions • safety and security policies, procedures and guidelines
Commodity items might include:	• wipers / wipes • cleanroom paper and indelible ink pens • cleaning agents • other supplies that service the cleanroom
Work activities might include:	• manufacturing • filling • cleaning • maintenance • quality control (sampling and testing of controlled and cleanroom environments) • monitoring cleanrooms and associated plant and services
Contamination risks might include:	• number of personnel in the controlled environment • activities being undertaken • leaks • malfunctioning equipment • low differentials pressures • high particle counts • incorrect air flow & velocity, • humidity • temperature • room status inactive or in alarm • lack of cleanliness
Daily housekeeping and cleaning might include:	• waste removal • wipe down benches • facility cleaning • equipment cleaning
Practices inconsistent with c**GMP** might include:	• damage to plant or equipment • failure of cleaning regime or pest control program • missing or inaccurate records • failure to follow Standard Operating Procedures

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Overview of Assessment

The assessment environment provides access to documentation related to controlled environments together with a range of activities typical of commercial manufacturing operations, and that meet the requirements of the Australian Code of current GMP.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

To demonstrate competence in this unit, a candidate must provide evidence of the application of their knowledge to:

- describe the characteristics of controlled environments,
- describe the operating parameters of controlled environments,
- follow pre-entry requirements,
- follow required work practices appropriate to controlled environments,
- follow exit procedures

Context of and specific resources for assessment

Assessors must be satisfied that the person can consistently perform the unit including all elements and performance criteria, and can demonstrate the required skills and knowledge.

Resources for assessment include:

- a range of relevant exercises, case studies and/or other practical and knowledge assessment, and/or
- access to an appropriate range of relevant operational situations
- gowning/degowning procedures and related advice on equipment operation, including advice on safe work practices and environmental requirements
- personal protective clothing and equipment
- information relating to the design, operation, testing and monitoring of Air Handling Units / Heating Ventilations and Air Conditioning (HVAC)
- information relating to the regulatory and management issues associated with controlled environments, relevant to work responsibilities
- examples of data collection forms and information recording systems, requirements, procedures and examples of data.

Method of assessment	As a minimum, assessment of knowledge must be conducted through appropriate written/oral tests. The following suggested methods are appropriate for this unit: • practical activities, including planning for entry into the controlled environment, gowning, hand hygiene, identifying contamination risks and cGMP non-conformances, record keeping, problem solving • observation • direct questioning • presentations • third party reports
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.