



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH3001A Monitor and maintain Good Manufacturing Practice procedures

Revision Number: 1

FDFPH3001A Monitor and maintain Good Manufacturing Practice procedures

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to provide a leadership role in supporting day-to-day implementation of Good Manufacturing Practices (GMP) in a work area. It also involves supporting others to implement the requirements of GMP.
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Application of the Unit

Application of the unit	This unit applies to those with formal responsibility for others and to those required to model workplace policies and procedures but who have no formal management role.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
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Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Ensure others in the work area are able to meet GMP requirements	1.1.Relevant clothing and equipment appropriate to work requirements is available, functional and correctly fitted 1.2.Advice on GMP responsibilities and procedures is accessible and clearly explained 1.3.GMP control measures used in the work area can be identified by those in the work area 1.4.Mentoring and coaching support is available to support individuals/groups to implement GMP and related procedures 1.5.Training needs are identified and addressed within level of responsibility
2. Monitor personal hygiene and conduct of team members in the work area	2.1.Personal hygiene of work team meets GMP requirements 2.2.Clothing is prepared, used, stored and disposed of according to GMP and workplace procedures 2.3.Personal movement around the workplace complies with area entry and exit procedures
3. Monitor implementation of GMP requirements in the work area	3.1.GMP procedures in the work area are clearly defined, documented and followed 3.2.Non-compliance from identified procedures is reported and addressed within level of responsibility 3.3.Signs of unacceptable plant or equipment condition are identified and reported 3.4.Personal behaviour provides a role model to others to support implementation of GMP workplace policies and procedures 3.5.Workplace procedures to control resource allocation are followed to meet GMP requirements 3.6.GMP non-conformance is identified and reported according to workplace procedure 3.7.GMP information is recorded to meet workplace reporting requirements 3.8.The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards
4. Participate in validation processes	4.1.Validation procedures are followed to GMP requirements 4.2.Issues arising from validation are raised with designated personnel 4.3.Validation procedures are documented to meet GMP

ELEMENT	PERFORMANCE CRITERIA
	requirements
5. Take corrective action in response to GMP non-compliance	5.1. Processes, practices or conditions which could result in non-compliance with GMP are identified and reported according to workplace reporting requirements 5.2. Corrective action is taken in accordance within level of responsibility 5.3. GMP issues are raised with designated personnel
6. Maintain and improve GMP in the work area	6.1. Processes or conditions which could result in non-conformance with GMP are identified, reported and corrected within level of responsibility 6.2. Matters raised relating to GMP are promptly resolved and/or referred to appropriate personnel 6.3. Effectiveness of control measures are monitored within level of responsibility 6.4. Others in the work area are advised of GMP matters relevant to work role 6.5. Workplace records and documents are maintained in accordance with workplace procedures and GMP requirements

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- communicate information on GMP requirements to others in the work area, including demonstration of two-way communication, such as active listening and constructive response to feedback
- access and use document management systems
- model personal conduct and work activities to meet requirements of GMP
- monitor that data is recorded to meet GMP recording requirements within level of responsibility
- provide guidance and support to others in the work area to implement GMP responsibilities within level of responsibility
- determine action required to respond to GMP non-compliance within level of responsibility
- participate in improvement processes, such as investigating actual and potential GMP non-compliance
- participate in and/or review practices and procedures to prevent or minimise the likelihood of unacceptable performance
- work cooperatively within a culturally diverse workforce

Required knowledge

Knowledge of:

- the role of GMP in preventing contamination, its relationship to legal requirements of pharmaceutical manufacturers and potential implications of non-compliance
- GMP arrangements in the workplace, including relevant GMP codes of practice and related workplace policies and procedures to implement these responsibilities
- role of effective communication and consultation processes
- workplace training and development system and responsibilities
- role of quality assurance and related system components and activities in GMP
- procedures followed to investigate contamination events and performance improvement processes
- personal clothing and footwear requirements for working in and/or moving between work areas
- personal clothing use, storage and disposal requirements
- current technical and process knowledge required to monitor GMP and participate in investigating GMP non-compliance within level of responsibility, including common microbiological, physical and chemical contaminants, conditions under which types of contamination, e.g. cross-contamination, are likely to occur, related

REQUIRED SKILLS AND KNOWLEDGE

- control methods and validation procedures and responsibilities
- control methods and procedures used in the work area to maintain GMP, including the purpose of control, the consequences if not controlled and the method of control where relevant
- methods used to monitor process control, purpose and requirements of validation procedures and purpose of equipment calibration
- recall and traceability procedures relevant to work area
- line clearance procedures and responsibilities
- properties, handling and storage requirements of raw materials, packaging components and final product handled and used in the work area
- standards for materials, equipment and utensils used in the work area
- procedures for responding to out-of-specification or unacceptable performance/outcomes, including procedures for identifying and isolating or quarantining materials or product of unacceptable quality within level of responsibility
- documentation system and procedures, including record keeping to meet both company and legal requirements, procedures for developing and/or reviewing workplace procedures and document control systems used in the workplace and responsibilities for reporting and recording information
- housekeeping requirements and responsibilities relating to own work, and where relevant, use and storage of housekeeping/cleaning equipment
- waste collection, recycling, handling and disposal, including handling/disposal requirements for different types of waste, such as hazardous waste where relevant

Evidence Guide

EVIDENCE GUIDE	
The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.	
Overview of assessment	Assessment may occur in a real or simulated workplace context. A simulated environment must provide access to a typical range of production equipment, procedures and related documentation, records and related resources to meet the requirements of the Therapeutic Goods Act.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	GMP is an ongoing and routine aspect of work responsibilities. Assessors should collect sufficient evidence that the skills and knowledge of this unit are routinely applied to the work environment. Evidence of ability to: • identify the components of GMP and related roles and responsibilities as they relate to work role • provide a role model to others in the workplace to support implementation of GMP • participate in GMP processes within level of responsibility. Examples of these processes include validation, line clearance, equipment calibration, change management, maintenance of documentation. This would typically be undertaken in a team context.
Context of and specific resources for assessment	Assessors must be satisfied that the person can consistently perform the unit as a whole, including all elements, performance criteria, and required skills and knowledge. A holistic approach should be taken to the assessment. Assessment of this unit would typically involve questioning and workplace observation. It may involve additional collection of evidence from a range of sources, such as third party reports, workplace documentation relating to GMP, and real or simulated workplace contexts.
Method of assessment	This unit is a core requirement for all pharmaceutical operators at AQF 3 and could be assessed concurrently with other units relating to process improvement and supporting others, such as: • FDFPPL3001A Participate in improvement processes • FDFPPL3003A Support and mentor individuals and

EVIDENCE GUIDE	
	groups • FDFPPL3005A Participate in an audit process • FDFTEC3001A Participate in a HACCP team.
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.

Range Statement

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, if used in the performance criteria, is detailed below. 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) may also be included.	
Work activities	Work activities are carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements
Unacceptable plant or equipment condition	Unacceptable plant or equipment condition can include: • damage to plant or equipment • failure of cleaning regime • equipment requiring calibration • signs of pest infestation
Validation	Typically validation is the responsibility of the quality department. A person at this level would be expected to understand the purpose and responsibilities for validation and may be required to participate in validation processes as part of a team
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant, Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and other legislation and codes relevant to product and market • legislation relating to environmental management, occupational health and safety (OHS), anti-discrimination and equal opportunity
Quality assurance and related system components and activities	Quality assurance and related system components and activities can include but is not limited to: • process control • deviation investigation and analysis

RANGE STATEMENT

	• corrective and preventative action systems • sampling plans • change control • validation procedures • line clearance • system documentation requirements • audit processes
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Unit Sector(s)

Unit sector	Pharmaceutical manufacturing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		