



**Australian Government**

**Department of Education, Employment and Workplace Relations**

# **FDFPH1001A Follow work procedures to maintain Good Manufacturing Practice**

**Revision Number: 1**

## FDFPH1001A Follow work procedures to maintain Good Manufacturing Practice

### Modification History

Not applicable.

### Unit Descriptor

|                        |   |
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| <b>Unit descriptor</b> | This unit of competency covers the skills and knowledge required to comply with relevant Good Manufacturing Practice (GMP) codes and workplace quality standards. |
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### Application of the Unit

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| <b>Application of the unit</b> | This unit has application in a pharmaceutical manufacturing environment. Responsibility for applying GMP relates to the person's work area. |
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### Licensing/Regulatory Information

Not applicable.

### Pre-Requisites

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| <b>Prerequisite units</b> |  |
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### Employability Skills Information

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| <b>Employability skills</b> | This unit contains employability skills. |
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## Elements and Performance Criteria Pre-Content

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| 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. Identify requirements of GMP related to own work              | 1.1. Sources of information on GMP requirements are located<br>1.2. GMP requirements and responsibilities related to own work are identified   |
| 2. Observe personal hygiene and conduct to meet GMP requirements | 2.1. Personal hygiene meets GMP requirements<br>2.2. Clothing is prepared, used, stored and disposed of according to GMP and workplace procedures<br>2.3. Personal movement around the workplace complies with area entry and exit procedures  |
| 3. Follow GMP requirements when carrying out work activities     | 3.1. GMP requirements are identified<br>3.2. Work area, materials, equipment and product are routinely monitored to ensure compliance with GMP requirements<br>3.3. Raw materials, product and packaging components are handled according to GMP and workplace procedures<br>3.4. Contamination is identified and appropriate control measures are followed relating to work responsibilities and according to GMP requirements<br>3.5. Processes, practices or conditions which are not consistent with GMP are identified and reported according to workplace reporting procedure<br>3.6. The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards<br>3.7. Work is conducted in accordance with workplace environmental guidelines |
| 4. Complete workplace documentation to support GMP               | 4.1. Documentation and recording requirements are identified<br>4.2. Information is recorded according to workplace reporting procedures to meet 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:*

- locate and follow workplace information relating to GMP responsibilities
- maintain personal hygiene consistent with GMP
- follow workplace procedures when moving around the workplace and/or from one task to another to maintain GMP
- use, store and dispose of appropriate clothing/footwear as required by work tasks and consistent with GMP
- carry out relevant checks and inspections as required, such as visual checks and inspections on equipment and/or raw materials, product, packaging components and processing conditions relevant to own work
- identify and respond to out-of-specification or unacceptable conditions or performance, such as making adjustments within level of responsibility and/or reporting
- follow GMP when carrying out work functions
- identify and report situations that do or could compromise GMP
- handle and/or dispose of out-of-specification or contaminated materials, packaging components/consumables and product, waste and recyclable material according to GMP as required by work responsibilities
- maintain the work area in a clean and tidy state
- identify and report signs of pest infestation
- 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
- work cooperatively within a culturally diverse workforce

#### Required knowledge

##### *Knowledge of:*

- the role of GMP in preventing contamination, its relationship to legislative responsibilities and potential implications of non-compliance
- the relationship between the Code of GMP and workplace procedures, systems and processes
- GMP personnel and their respective responsibilities
- personal role, responsibility and accountability for implementing GMP
- sources of advice on GMP requirements for own work
- personal clothing and footwear requirements for working in and/or moving between work areas

**REQUIRED SKILLS AND KNOWLEDGE**

- personal clothing use, storage and disposal requirements
- common types and sources of contamination that occur in the work area
- control methods and procedures used in the work area to maintain GMP, including an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant
- monitoring, inspection and checking procedures relating to process control requirements
- standards for materials, equipment and utensils used in the work area
- evidence of out-of-standard or unacceptable performance
- action required in the event of non-compliance
- storage and handling requirements for raw materials, packaging components and product relevant to work role
- housekeeping requirements and responsibilities relating to own work, where relevant this includes use and storage of housekeeping/cleaning equipment
- waste collection, recycling and handling procedures relevant to own work responsibilities
- responsibilities for reporting and recording quality information

## Evidence Guide

| <b>EVIDENCE GUIDE</b>   |  |
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| <p>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.</p> |  |
| <p><b>Overview of assessment</b></p>  | <p>Assessment must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.</p>  |
| <p><b>Critical aspects for assessment and evidence required to demonstrate competency in this unit</b></p>  | <p>Evidence of ability to:</p> <ul style="list-style-type: none"> <li>• identify requirements of GMP</li> <li>• apply GMP procedures to own work</li> <li>• identify and report non-compliances</li> <li>• complete required documentation.</li> </ul>   |
| <p><b>Context of and specific resources for assessment</b></p>  | <p>Assessment must occur in a real or simulated workplace where the assessee has access to:</p> <ul style="list-style-type: none"> <li>• GMP information relating to the workplace</li> <li>• related work instructions and procedures</li> <li>• work tasks and responsibilities</li> <li>• appropriate protective clothing</li> <li>• reporting and monitoring systems.</li> </ul> |
| <p><b>Method of assessment</b></p>  | <p>This unit should be assessed together with other units of competency relevant to the work role. An example could be:</p> <ul style="list-style-type: none"> <li>• FDFOP1009A Follow work procedures to maintain quality.</li> </ul>   |
| <p><b>Guidance information for assessment</b></p>   | <p>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.</p>   |

## Range Statement

| <b>RANGE STATEMENT</b>   |   |
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| <p>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.</p> |   |
| <b>Policies and procedures</b>   | Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements  |
| <b>Legislative requirements</b>  | <p>Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes:</p> <ul style="list-style-type: none"> <li>• relevant GMP codes</li> <li>• the Therapeutic Goods Act</li> <li>• the Food Standards Code, including labelling, weights and measures legislation</li> <li>• legislation covering environmental management, occupational health and safety (OHS), anti-discrimination and equal opportunity</li> </ul> |
| <b>Reporting systems</b>   | <p>Reporting systems may include:</p> <ul style="list-style-type: none"> <li>• electronic and manual data recording and storage systems</li> </ul>  |

## Unit Sector(s)

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| <b>Unit sector</b> | Pharmaceutical manufacturing |
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## Competency field

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| <b>Competency field</b> |  |
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## Co-requisite units

| Co-requisite units |  |  |
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