



**Australian Government**

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

# **FDFPHGMP1A Follow work procedures to maintain Good Manufacturing Practice**

**Release: 1**

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### **Modification History**

Not applicable.

### **Unit Descriptor**

This is a Core unit for pharmaceutical processing. It 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**

Not applicable.

### **Licensing/Regulatory Information**

Not applicable.

### **Pre-Requisites**

Not applicable.

### **Employability Skills Information**

Not applicable.

### **Elements and Performance Criteria Pre-Content**

Not applicable.

# Elements and Performance Criteria

## Elements and Performance Criteria

<b>Element</b>	<b>Performance Criteria</b>
1 Identify requirements of GMP related to own work	1.1 Sources of information on GMP requirements are located
	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
	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 Follow GMP requirements when carrying out work activities	3.1 GMP requirements are identified
	3.2 Work area, materials, equipment and product are routinely monitored to ensure compliance with GMP requirements
	3.3 Raw materials, product and packaging components are handled according to GMP and workplace procedures
	3.4 Contamination is identified and appropriate control measures are followed relating to work responsibilities and according to GMP requirements
	3.5 Processes, practices or conditions which are not consistent with GMP are identified and reported according to workplace reporting procedure
	3.6 The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards
4 Complete workplace documentation to support GMP	4.1 Documentation and recording requirements are identified
	4.2 Information is recorded according to workplace reporting procedures to meet GMP requirements

## **Required Skills and Knowledge**

Not applicable.

## Evidence Guide

The assessment process must address all of the following items of evidence.

Ability to:

1. Locate and follow workplace information relating to GMP responsibilities
2. Maintain personal hygiene consistent with GMP
3. Follow workplace procedures when moving around the workplace and/or from one task to another to maintain GMP
4. Use, store and dispose of appropriate clothing / footwear as required by work tasks and consistent with GMP
5. Carry out relevant checks and inspections as required. This may include visual checks and inspections on equipment and/or raw materials, product, packaging components and processing conditions relevant to own work
6. Identify and respond to out-of-specification or unacceptable conditions or performance. This may include making adjustments within level of responsibility and/or reporting
7. Follow GMP when carrying out work functions
8. Identify and report situations that do or could compromise GMP
9. 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
10. Maintain the work area in a clean and tidy state
11. Identify and report signs of pest infestation

Knowledge of:

12. The role of GMP in preventing contamination, its relationship to legislative responsibilities and potential implications of non-compliance
13. The relationship between the Code of Good Manufacturing Practice and workplace procedures, systems and processes
14. GMP personnel and their respective responsibilities
15. Personal role, responsibility and accountability for implementing GMP
16. Sources of advice on GMP requirements for own work
17. Personal clothing and footwear requirements for working in and/or moving between work areas
18. Personal clothing use, storage and disposal requirements
19. Common types and sources of contamination that occurs in the work area
20. Control methods and procedures used in the work area to maintain GMP. This includes an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant
21. Monitoring, inspection and checking procedures relating to process control requirements
22. Standards for materials, equipment and utensils used in the work area
23. Evidence of out-of-standard or unacceptable performance
24. Action required in the event of non-compliance
25. Storage and handling requirements for raw materials, packaging components and product relevant to work role
26. Housekeeping requirements and responsibilities relating to own work. Where relevant this includes use and storage of housekeeping/cleaning equipment
27. Waste collection, recycling and handling procedures relevant to own work responsibilities
28. Responsibilities for reporting and recording quality information

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## Range Statement

The range statement indicates the context for demonstrating competence. This statement is a guide and unless otherwise indicated, items may or may not apply as required by the work context.

- Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements
  - 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, labelling, weights and measures legislation and legislation covering environmental management, occupational health and safety, anti-discrimination and equal opportunity
  - Responsibility for applying good manufacturing practice relates to the person's work area
  - Reporting systems may include electronic and manual data recording and storage systems
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## Unit Sector(s)

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