Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2001A Apply Good Manufacturing Practice procedures

Revision Number: 1

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Modification History

Not applicable.

Unit Descriptor

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

Application of the Unit

Application of the unit	This unit applies to all production and packaging operators working in the pharmaceutical sector.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.

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.

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 1.2. GMP requirements and responsibilities related to own work are identified
2. Ensure that personal hygiene and conduct meets 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. Implement GMP requirements when carrying out work activities	3.1. Work area, materials, equipment and product are routinely monitored to ensure compliance with GMP requirements 3.2. Raw materials, packaging components and product are handled/stored according to GMP and workplace procedures 3.3. Workplace procedures to control resource allocation are followed to meet GMP requirements 3.4. Common forms of contamination are identified and appropriate control measures are followed according to GMP requirements 3.5. The workplace is maintained in a clean and tidy order to meet GMP housekeeping standards 3.6. Work is conducted in accordance with workplace environmental guidelines 3.7. Out-of-specification or contaminated materials, packaging components/consumables and product, waste and recyclable materials are handled and disposed of according to GMP requirements and workplace procedures 3.8. Signs of unacceptable plant or equipment condition are identified and reported
4. Participate in improving GMP	4.1. Processes, practices or conditions which could result in non-compliance with GMP are identified and reported according to workplace reporting requirements 4.2. Corrective action is implemented within level of responsibility 4.3. GMP issues are raised with designated personnel
5. Complete workplace documentation to	5.1. Documentation and recording requirements are identified

ELEMENT	PERFORMANCE CRITERIA
support GMP	5.2. 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
- identify and report situations that do or could compromise GMP
- participate in procedures to support GMP 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
- 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 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
- the relationship between GMP and the quality system, personnel responsible for designing and managing GMP, personal role to maintain GMP, and the role of internal and external auditors as appropriate
- 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
- awareness of common micro-biological, physical and chemical contaminants relevant to the work process, including the types of contamination likely to occur, such as cross-contamination, the conditions under which they occur, possible consequences and control methods to prevent occurrence
- basic concepts of quality assurance, including quality specifications, operating parameters, validation procedures and control methods, and related documentation, including standard operating procedures (SOPs) and/or batch instructions
- 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, as well as an understanding of the methods used to monitor process control

REQUIRED SKILLS AND KNOWLEDGE

- basic understanding of the properties, handling and storage requirements of raw materials, packaging components and final product handled and used
- standards for materials, equipment and utensils used in the work area
- procedures for responding to out-of-specification or unacceptable performance/outcomes
- purpose of keeping records and the recording requirements of GMP, including product and materials traceability procedures
- housekeeping requirements and responsibilities relating to own work, and use and storage of housekeeping/cleaning equipment where relevant
- waste collection, recycling and handling procedures relevant to own work responsibilities
- responsibilities for reporting and recording quality information

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 pharmaceutical or complementary medicine manufacturing workplace where the assessment environment provides access to workplace documentation related to GMP together with a range of commercial production/packaging equipment and activities typical of commercial manufacturing businesses and that 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 to ensure that the skills and knowledge of this unit are routinely applied to the work environment. Assessment must require the candidate to identify and demonstrate responsibilities for implementation of GMP in the workplace.
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 2 and could be assessed concurrently with other operational units.
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.	
Policies and procedures	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 • signs of pest infestation
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant GMP codes • the Therapeutic Goods Act • other legislation and codes relevant to product and market • legislation relating to environmental management, occupational health and safety (OHS), anti-discrimination and equal opportunity

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing

Competency field

Competency field	

Co-requisite units

Co-requisite units		