Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice

Release: 1

FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required by production/packaging line managers or supervisors to develop, review and manage workplace documentation to support Good Manufacturing Practice (GMP). This units targets content outlined in Chapter 4 of the Australian Code of Good Manufacturing Practice for Medicinal Products and should be read in conjunction with this document.

Application of the Unit

Application of the unit	This unit applies to people working in a supervisory or line management production/packaging role. Their responsibilities for document design, review and maintenance would typically require them to work in close consultation with others and focus on documentation relevant to their work area.

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. Develop and/or review workplace documentation to meet GMP requirements	1.1. Policies and master plans are identified to determine work area requirements 1.2. Workplace documentation is identified and reviewed to confirm GMP requirements are met 1.3. Procedures and records are developed and/or reviewed to confirm GMP requirements are met 1.4. Improvements to workplace documentation are identified and reported 1.5. Procedures to alter workplace documents are followed
2. Facilitate development and communication of workplace documentation	2.1. Workplace documentation is developed in consultation with relevant stakeholders to support GMP 2.2. Documentation is made available and clearly explained to relevant stakeholders 2.3. Training requirements are identified and addressed within level of responsibility

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Ability to:

- use workplace documentation, recording and reporting formats and software
- prepare workplace documentation inplain English and suited to purpose and audience
- use communication skills to interpret and complete work information to support operations of work team or area
- demonstrate and support cooperative work practices within a culturally diverse workforce

Required knowledge

Knowledge of:

- documentation requirements (as outlined in Chapter 4 of the Australian Code of Good Manufacturing Practice for Medicinal Products)
- document authorisation requirements and procedures and legal responsibilities of signatory
- document types to support workplace systems and related development and control systems, roles and responsibilities, including an understanding of system security and access levels
- procedures and responsibilities for altering documents and managing version control
- systems, methods and procedures for recording and storing data and authorised levels of access (to electronic systems)
- use of documentation including an understanding of the documents that can be used as evidence in audit processes
- recording and reporting requirements
- training and assessment arrangements and responsibilities

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 and related document control and management systems that are typical of commercial manufacturing businesses and meet the requirements of the Therapeutic Goods Act. It will also provide a range of commercial manufacturing packaging equipment and activities typically used in a commercial manufacturing environment.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Evidence of ability to: • review workplace documentation to confirm that it meets GMP requirements. Documentation may relate to a specific work area (rather than the whole plant). The candidate is required to document their findings • develop, design or amend documentation to support GMP. For example, this could require the development of operating procedures. It may include reviewing and updating existing documentation or developing new documentation within required formats. The candidate must demonstrate application of document control procedures to submit or amend documents. They must also demonstrate that appropriate consultation was undertaken in the development process and the document changes are effectively communicated. This includes demonstrating an awareness of the link to related documents. Where training needs arise from the change, these must be identified together with recommendations for how they can be addressed • review completed GMP-related documents and records to ensure that GMP requirements are met.
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.

EVIDENCE GUIDE	
	Assessment of this unit would typically involve responding to 'what if' scenarios, answering questions and conducting workplace projects. Resources for assessment include: • Australian Code of Good Manufacturing Practice for Medicinal Products • workplace documentation and related document control and management system • workplace personnel • real or simulated workplace context.
Method of assessment	This unit is a core requirement for all pharmaceutical operators at AQF 4 and 5. This unit could be assessed concurrently with other units relating to problem solving and process improvement. Examples could be: • FDFPH4002A Facilitate and monitor Good Manufacturing Practice • FDFPH4004A Participate in change control procedures • FDFPH4005A Participate in validation processes.
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.	
Workplace documentation	Workplace documentation may include but is not limited to: • policies and master plans • quality manual • specifications • certificates • manufacturing formula • processing and packaging instructions • procedures • records • protocols (validation) • reports Documentation typically includes: • written descriptions • graphic display of information, including diagrams and photos • flow charts Information is typically stored and accessed electronically
Procedures and records	Information covered by procedures includes but is not limited to: • receipt of starting and packaging material • sampling • testing • release and rejection procedures • validation • equipment assembly and calibration • maintenance, cleaning and sanitation • personnel matters, including training and personal hygiene • environmental monitoring

RANGE STATEMENT	
	• pest control • complaints • recalls • returns • equipment operation Records should include but are not limited to: • batch records • equipment recording (as appropriate) • validations • calibrations • maintenance • cleaning or repair work, including details of when/who • operating log sheets • complaints
Stakeholders	Stakeholders refer to process and technical experts and may include but are not limited to: • operators • engineering department • quality assurance • area managers • related functions/personnel
Version control	Version control includes: • the maintenance of workplace documents to meet company and regulatory requirements

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing

Competency field

Competency field	

Co-requisite units

Co-requisite units		