



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4004A Participate in change control procedures

Revision Number: 1

FDFPH4004A Participate in change control procedures

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency 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. It covers the skills and knowledge required to participate in change control procedures.
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Application of the Unit

Application of the unit	This unit provides an overview of the change management and validation procedures that form part of Good Manufacturing Practice (GMP). This unit applies to people working in supervisory or line management production/packaging roles. This person would typically work within defined change management and validation programs and procedures. They contribute to the development of these procedures as a team member and are responsible to ensure procedures are supported in the work area.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

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. Participate in planning change	1.1.Regulations, codes and guides relevant to the work area are identified 1.2.Procedures, roles and responsibilities for managing change are identified 1.3.Risk assessment is conducted 1.4.Planning of change management is undertaken within level of responsibility 1.5.Workplace documentation affected by the change is identified and responsibilities for review are allocated within level of responsibility 1.6.Any training needs arising from change are identified and delivery method/s and responsibilities are determined 1.7.Validation and/or other relevant authorisation requirements and procedures are identified and followed
2. Participate in implementing change	2.1.Change is implemented according to the change management plan and occupational health and safety (OHS) procedures 2.2.Advice on change is communicated to all affected personnel 2.3.Relevant training is sourced 2.4.Workplace documentation is revised to reflect change requirements 2.5.Change is monitored and evaluated against established evaluation criteria 2.6.Any further adjustments or modifications are identified and implemented or reported according to change control procedure 2.7.Outcomes are documented and reported to meet change control 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 regulations, codes, guides and internal company documentation relevant to GMP and products/processes used in the work area
- participate in change control procedures
- apply communication and consultation skills to engage and consult with work areas and personnel affected by change
- ensure that related skills and knowledge requirements are addressed by the training system
- apply negotiation/issue resolution skills
- prepare workplace documentation in plain English and suited to purpose and audience
- demonstrate and support cooperative work practices within a culturally diverse workforce

Required knowledge

Knowledge of:

- types of change that come within the scope of change control procedures
- change classification procedures and responsibilities
- principles of risk management and related procedures
- documentary evidence required to support change request
- change control procedures, roles and responsibilities
- workplace documentation including procedures for review, authorisation and control of documents
- training system including assessment methods and documentation
- validation system, procedures 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 document management systems related to change control 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 participation in a project team to control change in a work area. This includes providing evidence that the candidate:

- identifies situations requiring change control for a given set of change scenarios
- participates in developing a change management plan
- develops a documented implementation plan to introduce change into a work area. This may be a sub-set of a larger change management plan
- leads the implementation of change in a work area. This includes reviewing relevant workplace documentation, ensuring that required training occurs, consulting with parties affected by change and negotiating any issues raised, monitoring and reporting on change and liaising with relevant departments/ personnel to ensure that authorisation and validation processes occur as required.

Context of and specific resources for assessment

Resources for assessment

- change request
- workplace documentation including procedures relating to change control
- real or simulated workplace context.

Method of assessment

This unit could be assessed concurrently with other units relating to problem solving and process improvement. Examples could be:

EVIDENCE GUIDE	
	• FDFOP2015A Apply principles of statistical process control • FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice • FDFPH4002A Facilitate and monitor Good Manufacturing Practice • FDFPH4003A Facilitate contamination control • FDFPH4005A Participate in validation processes • MSACMT450A Undertake process capability improvements.
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.

Regulations, codes and guides

Relevant regulations, codes and guides include:

- Therapeutic Goods Act
- Therapeutic Goods Regulations
- Australian Code of Good Manufacturing Practice for Medicinal Products
- Therapeutic Goods Act guides to interpretation of legal requirements
- regulations, codes and guides related to other relevant international legislation (appropriate to product and market)
- company policies and guidelines

Change

Change that must be controlled refers to any change that may affect product quality or reproducibility of the process. This may include but is not limited to change in:

- formulation
- product component
- method of production or testing
- process environment (or site)
- batch size
- equipment

Change management

Change management procedures and data requirements must meet the requirements of Change Management as outlined in Annex 15 of the Australian Code of Good Manufacturing Practice for Medicinal Products

Workplace documentation

Workplace documentation relevant to work area activities includes:

- company policies and procedures
- specifications
- manufacturing formulae
- processing and packaging instructions

RANGE STATEMENT	
	• scaling batch size up or down • batch production and packaging records • standard operating procedures (SOPs) • operating manuals • OHS information, including material safety data sheets (MSDS)
Authorisation requirements	Authorisation requirements reflect regulatory requirements and internal authorisation processes
Change management plan	A change management plan includes steps or activities required to approve and implement the proposed change. Typically these steps will be described in a change control SOP. Depending on the significance/level of the change, this could include: • process capability assessment • test methods • validation • liaison with regulator It also includes: • timelines • responsibilities, including sign-off/approval • verification of the effectiveness of change • OHS implications

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		