



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4003A Facilitate contamination control

Revision Number: 1

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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 facilitate contamination control in a work area.
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Application of the Unit

Application of the unit	This unit provides an overview of the cleaning and sanitation systems, equipment and procedures used in a pharmaceutical workplace. This unit applies to people working in supervisory or line management production/packaging roles. This person would typically work within defined cleaning, sanitation, change control and validation programs and procedures. They need to be aware of the systems, equipment and procedures used and are responsible to oversee implementation in their 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. Contamination risks and related control measures are identified and implemented to meet GMP requirements	1.1. Hazards that could present a contamination risk are identified by type, origin and product association 1.2. Hazards and related control measures, critical limits, monitoring and recording requirements are reviewed and meet GMP requirements 1.3. Control measures are verified or validated
2. Review systems and procedures used to control risk of cross contamination	2.1. Effective barriers and control systems to minimise risk of cross contamination are identified and meet GMP requirements 2.2. In-process and environmental monitoring occurs and is recorded as required by GMP 2.3. Cleaning procedures are validated according to validation procedures, roles and responsibilities 2.4. Line clearance checklists and procedures are followed in the work area 2.5. Personal hygiene and conduct of personnel in the work area meets GMP requirements 2.6. Operators have the required skills and knowledge required to support cleaning and sanitation and personal hygiene policies and procedures

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Ability to:

- interpret and apply relevant legislation, codes, guidelines and technical standards
- use management systems to ensure that procedures are understood and implemented
- monitor that data is recorded to meet GMP recording requirements
- read and interpret equipment drawings, piping and instrumentation diagrams (P&IDs) and process flow charting
- read and interpret typical test results for in-process and environmental monitoring
- use communication and document management systems to access and review relevant documents
- 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:

- principles of workflow design to minimise risk of contamination
- facility and segregation requirements relevant to products produced

Basic microbiology

- microbiological limits, monitoring methods and reporting and recording formats and requirements

Sources of technical advice

- ventilation system requirements
- personal hygiene and clothing requirements including decontamination and laundering
- cleaning records and logs
- line clearance procedures, roles and responsibilities
- equipment status labelling
- cleaning requirements and levels related to dedicated production, campaign processing and multiple product processing

Storage requirements

- storage requirements of raw materials prior to use in manufacture, time limits and conditions of storage of finished product prior to packaging, and other

REQUIRED SKILLS AND KNOWLEDGE

requirements relevant to product range

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 controlling contamination 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:

- identify legal, company and audit requirements of contamination control systems and conduct a system review to support audit readiness
- demonstrate methods used to monitor consistent observance of contamination control.

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 responding to 'what if' scenarios, answering questions and conducting workplace projects.

Resources for assessment:

- copies of the relevant Act, regulations, codes and guides
- workplace documentation relating to cleaning and sanitation
- real or simulated workplace context.

Method of assessment

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

- FDFOP2015A Apply principles of statistical process

EVIDENCE GUIDE	
	control • FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice • FDFPH4002A Facilitate and monitor Good Manufacturing Practice • FDFPH4004A Participate in change control procedures • 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.

Barriers and control systems

Barriers and control systems include but are not limited to:

- ventilation systems
- appropriate clothing
- area access restrictions and procedures
- cleaning and sanitation procedures
- environmental monitoring
- line clearance checklists
- personal hygiene and conduct
- pest prevention

Refer to the Australian Code of Good Manufacturing Practice for Medicinal Products

Codes, guidelines and technical standards

Codes, guidelines and technical standards includes:

- the Australian Code of Good Manufacturing Practice for Medicinal Products, Chapter 3 which outlines minimum requirements for design of pharmaceutical production facilities and equipment

Basic microbiology

Basic microbiology covers the ability to source information on:

- likely microbiological contaminants given product/packaging used
- origins
- growth rates
- transmission routes
- likely carriers
- control limits
- control methods

Sources of technical advice

Sources of technical advice include but are not limited to:

RANGE STATEMENT	
	• Therapeutic Goods Administration • British Pharmacopeia • European Pharmacopeia • US Pharmacopeia
Storage requirements	Storage requirements may include but are not limited to: • storage requirements of raw materials prior to use in manufacture • time limits and storage conditions for finished product prior to packaging • other requirements relevant to product range

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		