



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4006A Respond to non-conformance

Revision Number: 1

FDFPH4006A Respond to non-conformance

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to respond to non-conformance within level of authority and consistent with legal requirements within the pharmaceutical sector.
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Application of the Unit

Application of the unit	This unit can apply to people working in a supervisory or line management production role. They would typically work as part of a team responsible for investigating causes and controls to prevent recurrence of non-conformance. Typical applications of this unit would include responding to deviation and incident reporting results and may include participation in responding to customer complaints, product recalls and audit findings. Responding to non-conformance is typically within the parameters of established policies, plans and procedures.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

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. Identify non-conformance	1.1. Workplace systems, reports and operating parameters are monitored to identify non-conformance 1.2. Nature of non-conformance is identified and described 1.3. Corrective and preventative action and reporting procedures appropriate to nature of non-conformance are followed
2. Identify causes of non-conformance	2.1. Workplace systems are used to investigate possible causes of non-conformance 2.2. Risk assessment is conducted
3. Review processes to minimise the risk of recurrence	3.1. Solutions are identified and assessed to eliminate or minimise the risk of recurrence 3.2. An implementation plan is developed 3.3. Workplace documentation is developed or reviewed to support implementation 3.4. Consultative mechanisms are established and/or reviewed to support continuous improvement and communicate information

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Ability to:

- identify systems under which non-conformance may be raised, including the provisions of the Therapeutic Goods Act as it relates to systems (e.g. customer complaints, product recalls and auditing)
- identify relevant company policies and procedures relating to responding to non-conformance and confirm level of authority and responsibility for participating in these procedures
- identify the components of the management system, including information recording systems (such as those to support traceability), identification of personnel responsible for assessing information and determining appropriate action, procedures to be followed in the event of a non-conformance, change management requirements and definitions of roles and levels of responsibility
- participate in the investigation of causes and review of arrangements and procedures in response to a non-conformance, such as reviewing responses to previous incidents to assess effectiveness and/or developing recommendations on appropriate procedures
- identify and/or develop the appropriate communication systems and channels for consulting with people affected by any proposed changes
- 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:

- legal requirements relating to management of non-conformance
- systems and responsibilities for identifying, investigating and responding to non-conformance
- consultation and communication methods required to investigate possible causes and communicate changed practices and procedures
- change management procedures and responsibilities, including the role of corrective and preventative actions
- procedures for reviewing, amending and validation
- information systems, technologies and software to access and analyse information
- problem solving methods

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 including production records and data management systems related to managing non-conformance that are typical of commercial manufacturing businesses and meet the requirements of the Therapeutic Goods Act. It will also provide access to workplace policies and procedures to support the management of non-conformance to meet the requirements of the Therapeutic Goods Act.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of participation in a team responsible for responding to deviation and non-conformance. This includes providing evidence developed by the candidate to:

- identify deviation
- identify and determine the nature of non-conformance
- implement required corrective action and reporting
- investigate the causes of a non-conformance
- identify changes to company systems and procedures required to minimise the risk of recurrence
- follow procedures to participate in proposing changes
- develop and implement required preventative action.

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

EVIDENCE GUIDE	
	• workplace documentation relating to responding to non-conformance • 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: • FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice • FDFPPL4004A Optimise a work process • MSACMC410A Lead change in a manufacturing environment • 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.	
Non-conformance	Non-conformance may be assessed against policies, procedures, specifications and audit requirements
Implementation plan	An implementation plan includes but is not limited to: • allocation of responsibilities and roles • establishing and negotiating timelines and resources • documentation review • appropriate authorisation • identification of training/skill development requirements
Legal requirements	Legal requirements are those prescribed in the Therapeutic Goods Act and other relevant legislation, regulations and codes (relating to product and markets)
Systems	Systems and responsibilities for identifying, investigating and responding to non-conformance can include but are not limited to: • corrective and preventative action • customer complaints • product recall • audits (internal and external)

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		