



Australian Government

FBPPHM4006 Respond to non-conformance

Release: 1

FBPPHM4006 Respond to non-conformance

Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Application

This unit of competency describes the skills and knowledge required to identify and respond to non-conformance and review processes to minimise risk of recurrence to meet Good Manufacturing Practice (GMP) requirements in a pharmaceutical manufacturing facility.

The unit applies to individuals with specialised skills and knowledge of GMP requirements who respond to non-conformance relevant to pharmaceutical manufacturing operations and have responsibility for the output of others. This includes applying and communicating non-routine technical solutions to predictable and unpredictable problems.

No occupational licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
1. Identify non-conformance	1.1 Interpret workplace procedures and documentation relevant to non-conformance 1.2 Identify nature of non-conformance 1.3 Follow non-conformance corrective and preventive action (CAPA) according to GMP requirements and workplace procedures

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
2. Identify causes of non-conformance	2.1 Investigate possible causes of non-conformance 2.2 Conduct root cause analysis (RCA) to determine cause of non-conformance 2.3 Conduct non-conformance risk assessment on current and previous material according to workplace procedures
3. Review processes to minimise risk of recurrence	3.1 Assess and select solutions to eliminate or minimise the risk of recurrence 3.2 Develop an implementation plan for risk minimisation solutions 3.3 Conduct CAPA effectiveness checks according to GMP requirements and workplace procedures 3.4 Establish consultative mechanisms and communicate implementation plan to support continuous improvement according to GMP requirements and workplace procedures

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria.

Skill	Description
Reading	- Interpret key information in workplace documentation and CAPA relevant to non-conformance - Interpret key information in GMP requirements and workplace procedures relevant to non-conformance
Writing	Prepare RCA documentation
Oral Communication	- Demonstrate two-way communication including active listening and confirming instructions when explaining implementation plan to team members - Use appropriate vocabulary, including technical language, to explain requirements
Get the work done	Access and use electronic document management systems

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM4006 Respond to non-conformance	FDFPH4006A Respond to non-conformance	Updated to meet Standards for Training Packages Changes to performance criteria for clarity	Equivalent unit

Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>

Assessment Requirements for FBPPHM4006 Respond to non-conformance

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Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has responded to at least one non-conformance, including:

- identified workplace procedures and documentation relating to non-conformance
- interpreted Good Manufacturing Practice (GMP) requirements and workplace procedures related to non-conformance
- identified workplace non-conformance change management procedures and responsibilities, including:
 - corrective and preventive actions (CAPA)
 - investigating possible causes of non-conformance
 - root cause analysis (RCA)
 - risk assessment
 - repeat incident
 - isolated incident
 - impact assessment
 - recording requirements
- reviewed responses to previous incidents to assess effectiveness and developed recommendations on appropriate workplace procedures
- communicated implementation plan requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - constructive responses to feedback.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- workplace non-conformance change management procedures and responsibilities, including:
 - CAPA
 - investigating possible causes of non-conformance
 - RCA
 - risk assessment
 - repeat incident
 - isolated incident
 - impact assessment
 - recording requirements
- the provisions of the Therapeutic Goods Act relating to identifying non-conformance, including customer complaints, product recalls and auditing
- consultation and communication methods used to communicate implementation plan requirements to others in the work area, including demonstrating:
 - two-way communication
 - active listening
 - providing constructive responses to feedback
- GMP requirements and workplace procedures relevant to responding to non-conformance
- documentation systems and procedures, including:
 - record keeping to meet both company and legal requirements
 - processes for developing or reviewing workplace procedures
 - document control systems used in the workplace
 - responsibilities for reporting and recording information.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
 - a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - workplace procedures and documentation relating to non-conformance
- specifications:
 - CAPA documentation
 - workplace procedures relating to responding to non-conformance
 - GMP requirements related to responding to non-conformance
 - provisions of the Therapeutic Goods Act relating to identifying non-conformance

- relationships:
 - team members.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

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