



Australian Government

Assessment Requirements for FBPPHM4006 Respond to non-conformance

Release: 1

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Modification History

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

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.

Links

Companion Volume Implementation Guides are found in VETNet: -

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