



Australian Government

**Assessment Requirements for
FBPPHM4002 Prepare and review
workplace documentation to support Good
Manufacturing Practice requirements**

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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 must satisfy all of the elements and performance criteria in this unit.

There must be evidence that the individual has reviewed and developed workplace documentation to support the Good Manufacturing Practice (GMP) requirement of at least one workplace, including:

- identified workplace documentation requiring development or review using workplace documentation management process
- reviewed and developed workplace documentation, suitable for purpose and audience, including:
 - ensuring compliance with workplace procedures and GMP requirements
 - reporting improvements
 - reviewing and updating existing documentation
 - developing new documentation
 - applying documentation control procedures when submitting or amending documents
- accessed and used document management systems
- consulted with relevant stakeholders in the preparation and review process and ensured changes are effectively communicated
- communicated information on documentation 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 procedures and GMP requirements
- types of documentation requiring development or review, including:
 - procedures
 - instructions
 - records
- situations requiring documentation development or review, including:
 - general review
 - process change
 - inspection findings
 - deviations
- procedures and responsibilities for developing and altering documents, including:
 - version control
 - good documentation design and the use of templates
 - an understanding of system security and access levels
 - controls systems, including individual roles and responsibilities
 - document authorisation requirements and responsibilities of signatories
 - systems for recording and storing data and authorised levels of access to electronic systems
- use of documentation, including documents that can be used as evidence during audit processes
- requirements for completion of workplace documentation.

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:
 - document management system
- specifications:
 - information about GMP requirements
 - workplace procedures related to GMP.

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>