Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.0 and meets the Standards for Training Packages 2012. |

| FDFPHM4006 | Respond to non-conformance |
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| Application | This unit of competency describes the skills and knowledge required to respond to non-conformance according to legal requirements and individual level of authority.  The unit applies to individuals who are responsible for investigating causes and controls to prevent the recurrence of non-conformance. They typically work as part of a team in a team leader, supervisory or line management production role in the pharmaceutical sector.  No occupational licensing, legislative or certification requirements apply to this unit at the time of publication. |
| Prerequisite Unit | Nil |
| Unit Sector | Pharmaceutical (PHM) |

| Elements | Performance Criteria |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Identify non-conformance | 1.1 Identify workplace systems, reports and operating parameters to identify non-conformance  1.2 Identify and describe nature of non-conformance  1.3 Follow corrective and preventative action and workplace reporting procedures appropriate to nature of non-conformance |
| 2. Identify causes of non-conformance | 2.1 Use workplace systems to investigate possible causes of non-conformance  2.2 Conduct risk assessment of non-conformance issues for a pharmaceutical operation |
| 3. Review processes to minimise risk of recurrence | 3.1 Identify and assess solutions to eliminate or minimise the risk of recurrence  3.2 Develop an implementation plan  3.3 Develop or review workplace procedures to support implementation  3.4 Establish or review consultative mechanisms to support continuous improvement and communicate information |

| 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. | |
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| Skill | Description |
| Reading | * Access, interpret and extract key information from relevant workplace procedures relating to non-conformance * Collate and interpret non-conformance information recorded in various workplace procedures and documents |
| Writing | * Prepare documentation relating to non-conformance according to workplace procedures |
| Oral Communication | * Use correct technical language and appropriate oral communication skills for the audience to disseminate information about non-conformance within work teams |
| Numeracy | * Monitor non-conformance data and identify deviations |
| Navigate the world of work | * Identify and describe own skills, knowledge and experience within context of job role * Monitor adherence to regulatory standards and responsibilities for self and others |
| Interact with others | * Communicate changes to workplace systems and procedures required to minimise the risk of recurrence * Report non-conformance information to relevant personnel using required communication method |
| Get the work done | * Use problem solving strategies to identify, determine and investigate the causes of a non-conformances * Assess effectiveness of current procedures and develop continuous improvement recommendations to minimise non-conformances |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4006 Respond to non-conformance | FDFPH4006A Respond to non-conformance | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | Equivalent unit |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet <https://vetnet.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4> |

| TITLE | Assessment requirements for 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, on at least one occasion, the individual has responded to non-conformance, including:   * identified workplace procedures and documents relating to non-conformance and confirmed level of authority and responsibility for participating in these practices * identified workplace systems under which non-conformance is raised or identified * identified components of the workplace system to identify roles and responsibilities of personnel, traceability of non-conformance incidents or issues, and actions taken * identified personnel responsible for assessing information and determining appropriate action * participated in the investigation of causes, and the review of arrangements and procedures, in response to a non-conformance * reviewed responses to previous incidents to assess effectiveness or develop recommendations on appropriate workplace procedures * identified and developed the appropriate communication systems and channels for consulting with people affected by proposed changes * communicated information to support the operations of workplace personnel. | |

| Knowledge Evidence |
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| 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:   * legislative requirements related to managing non-conformance * the provisions of the Therapeutic Goods Act as it relates to systems for identifying non-conformance, including customer complaints, product recalls and auditing * workplace systems for raising and recording non-conformances * responsibilities for identifying, investigating and responding to non-conformance in the workplace * consultation and communication methods required to investigate possible causes of non-conformance and to communicate changed practices and procedures * workplace procedures to be followed in the event of non-conformance including change management requirements, definitions of roles and levels of responsibility * workplace change management procedures and responsibilities, including the role of corrective and preventative actions * workplace procedures for reviewing, amending and validation * information systems, technologies and software used to access and analyse information * problem solving methods. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * a workplace setting or an environment that accurately represents workplace conditions * resources, equipment and materials: * workplace procedures relating to responding to non-conformance * specifications: * workplace procedures relating to responding to non-conformance * relationships: * interactions with team members and supervisors or realistic scenarios or roleplays.   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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