Modification history

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

| FDFPHM4003 | Facilitate contamination control |
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| Application | This unit of competency describes the skills and knowledge required to control cross contamination in a work area to meet Good Manufacturing Practice (GMP)  This unit applies to individuals who are responsible for overseeing the implementation of cleaning, sanitation, change control and validation programs within their work area. It applies to individuals working in supervisory and line management, production or packaging roles in a pharmaceutical manufacturing environment.  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 and implement contamination risks and related control measures to meet GMP requirements | 1.1 Identify hazards that could present contamination risks by type, origin and product association  1.2 Review hazards, related control measures, critical limits and monitoring and recording requirements to confirm they meet GMP requirements  1.3 Verify or validate control measures |
| 2. Review systems and procedures used to control risk of cross contamination | 2.1 Identify effective barriers and control systems to minimise risk of cross-contamination and to meet GMP requirements  2.2 Carry out and record in-process and environmental monitoring according to GMP requirements and workplace procedures  2.3 Validate cleaning processes according to workplace validation procedures, roles and responsibilities  2.4 Follow line clearance checklists and procedures in work area  2.5 Ensure personal hygiene and conduct of personnel in work area meets GMP requirements  2.6 Ensure operators have the skills and knowledge required to support cleaning, sanitation and personal hygiene policies and 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. | |
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| Skill | Description |
| Reading | * Read and interpret typical test results for in-process and environmental monitoring * Interpret key information in relevant legislation, codes, guidelines and technical standards relevant to managing cross contamination in the workplace |
| Writing | * Access and record cross contamination information in document management systems |
| Numeracy | * Monitor data to determine instances of non-conformance or cross contamination according to GMP requirements |
| Navigate the world of work | * Identify and describe own skills, knowledge and experience within context of job role * Monitor adherence to legal and regulatory standards and responsibilities for self and others |
| Interact with others | * Use appropriate vocabulary, including technical language directly relevant to role * Use appropriate language and communication skills to ensure that contamination management procedures are understood and implemented within the work area * Report GMP requirements for contamination management to relevant personnel using required communication method |
| Get the work done | * Provide a role model to others in the workplace to support consistent observance of contamination control |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM4003 Facilitate contamination control | FDFPH4003A Facilitate contamination control | 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 Facilitate contamination control |
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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 facilitated contamination control, including:   * identified hazards that could present contamination risks by type, origin and product association * reviewed hazards, related control measures, critical limits and monitoring and recording requirements to confirm they meet GMP requirements * verified or validated contamination control measures * interpreted and applied relevant legislation, codes, guidelines and technical standards for contamination control in the workplace * used management systems to ensure that procedures are understood and implemented * monitored the recording of data according to GMP requirements * read and interpreted equipment drawings, piping and instrumentation diagrams (P&IDs) and process flow charting * used communication management systems to access and review documents regarding cross-contamination * used communication skills for interpreting and completing work information to support work area operations. | |

| 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:   * the principles of workflow design to minimise risk of contamination * facility and segregation requirements relevant to the products produced * hazards that could present contamination risks in the workplace * basic microbiology * microbiological limits, monitoring methods and reporting and recording formats and requirements * sources of technical advice * ventilation system requirements * personal hygiene and clothing requirements, including decontamination and laundering * cleaning records and logs * line clearance procedures, roles and responsibilities * equipment status labelling * cleaning requirements and levels related to dedicated production, campaign processing and multiple product processing * storage requirements of raw materials prior to their use in manufacture, time limits and conditions of for storing finished products prior to packaging, and other requirements relevant to product range. |

| 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: * personal protective clothing and equipment * copies of the relevant Act, regulations, codes and guides * specifications: * workplace procedures relating to cleaning and sanitation * document control and management system * 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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