Modification history

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

| FDFPHM3XXX | Work in a controlled environment |
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| Application | This unit of competency describes the skills and knowledge required to prepare to enter, work and exit a controlled environment within a pharmaceutical manufacturing facility.  The unit applies to individuals who work in a pharmaceutical manufacturing facility controlled environment, under broad direction and taking responsibility for their own work.  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. Prepare to enter a controlled environment | 1.1 Identify and access Workplace information relating to the controlled environment  1.2 Follow Hand washing and disinfecting procedures according to workplace procedure  1.3 Identify and locate protective clothing and footwear  1.4 Fit and inspect protective clothing and footwear prior to entering controlled environment  1.5 Check controlled environment operating conditions prior to entry. |
| 2. Work in a controlled environment | 2.1 Follow Workplace procedures related to entering the controlled environment  2.2 Follow requirements for taking commodity items into the controlled environment according to workplace procedures  2.3 Conduct Work activities to minimise risk of contamination. |
| 3. Maintain a controlled environment | 3.1 Monitor controlled environment and identify contamination risks  3.2 Assess contamination risks and control environmental contamination according to workplace and Good Manufacturing Practice (GMP) requirements  3.3 Follow daily housekeeping and cleaning of controlled environments according to workplace procedure  3.4 Report practices inconsistent with GMP according to workplace requirements. |
| 4. Exit a controlled environment and de- gown | 4.1 Follow workplace procedures to exit a controlled environment  4.2 Remove protective clothing and footwear according to workplace procedure  4.3 Check, store and dispose protective clothing according to manufacturer specifications and environmental, health and safety, 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. | |
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| Skill | Description |
| Reading | * Identify and follow signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to controlled environments * Identify and follow workplace information, procedures and manufacturer specifications * Identify and interpret Good Manufacturing Practice codes relevant to controlled environments |
| Writing | * Complete checklists, standard forms and reports relating to practices inconsistent with Good Manufacturing Practice |
| Oral communication | * Use clear language to report contamination risks, and practices inconsistent with Good Manufacturing Practice * Participate in verbal exchanges to respond to questions and clarify information |
| Numeracy | * Interpret room data sheets and controlled environment operating condition data |
| Navigate the world of work | * Recognise and follow workplace requirements, including safety requirements and Good Manufacturing Practice, associated with own role and area of responsibility |

| Range Of Conditions  This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included. | |
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| Workplace information must include at least one of the following: | * signs and symbols * workplace instructions * production schedules, including cleaning schedules * approved workplace checklists * room data sheets (specifications) * material and product specifications * standard forms and reports * licensing and legislative requirements * relevant clauses in the applicable Good Manufacturing Practice (GMP) codes. |
| Controlled environment must include at least one of the following: | * environmentally graded work areas that have controls over their use * cleanrooms that are controlled environments that have been certified as meeting an internationally recognised standard. |
| Hand washing and disinfecting procedures must include at least one of the following: | * correct handwashing technique with liquid soap * correct hand washing technique for cleanroom * correct use of alcohol hand disinfectants. |
| Protective clothing and footwear must include at least one of the following: | * a variety of facility suits for controlled, non-classified operating environments * a variety of types and styles of cleanroom garments, including disposable and reusable: * surgical gloves * surgical masks * hair nets * shoes * disposable overshoes * goggles * personnel protective clothing and footwear appropriate to the activities being undertaken. |
| Controlled environment operating conditions must include at least one of the following: | * differentials pressures * particle counts * air flow & velocity * humidity * temperature * room status * cleanliness status. |
| Workplace procedures must include at least one of the following: | * workplace quality policies, procedures, protocols and instructions * safety and security policies, procedures and guidelines. |
| Commodity items must include at least one of the following: | * wipers * wipes * cleanroom paper * cleanroom pencils * cleaning agents * other supplies that service the cleanroom. |
| Work activities must include at least one of the following: | * manufacturing * filling * cleaning * maintenance * quality control (sampling and testing of controlled and cleanroom environments). |
| Daily housekeeping and cleaning must include at least one the following: | * waste removal * wipe down benches * facility cleaning * equipment cleaning. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Work in a controlled environment | Not applicable | New unit | No 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 FDFPHM3XXX Work in a controlled environment |
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| Performance Evidence | |
| An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.  There must be evidence that, on at least one occasion, the individual has worked in a controlled environment, including:   * checked operating conditions of the controlled environment according to workplace and GMP requirements * maintained high standards of health, personal hygiene and cleanliness appropriate to the operating environment * identified and reported any condition that may cause shedding of abnormal numbers or types of contaminants * followed changing and washing procedures to prevent carry-through of contaminants to the clean areas * donned and wore facility suits, controlled environment and cleanroom apparel appropriate for the grade of controlled environment or cleanroom and in a manner that does not generate additional contaminants * entered controlled environments or cleanrooms in a manner to minimise contamination * maintained housekeeping standards to meet GMP requirements * followed controlled environment and cleanroom protocols * exited and degowned according to workplace instructions, and in a manner that does not generate additional contaminants which can later be shed * read and interpreted relevant instructions and labels applicable to controlled environments and cleanrooms, including pictorial and written signs/instructions * identified contamination hazards typically encountered in pharmaceutical manufacturing environments and took steps to prevent identified hazards * completed forms and incident reports according to GMP and workplace rules. | |

| 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:   * product and process requirements for “clean” air * sources of contamination generated by product, people, tools, the facilities, equipment * what is a cleanroom and clean zone * international nomenclature and classification of controlled environments and cleanrooms * controlled environment and cleanroom terminology including at rest and in operation * GMP grades of cleanrooms and their relationship to the ISO classification system * controlled, non-classified environments: similarities and differences to cleanroom * key design requirements for controlled environments and cleanroom for product protection: * layout and architecture * filtration, including HEPA filters: the theory of particle filtration * airlocks: materials, equipment and people * airflows: turbulent versus laminar air flows * pressure differentials * box-within-a-box principle * cleanability and maintainability * how controlled environments, cleanrooms and clean zones operate to control contamination, including gowning and cleaning requirements * cleaning key design requirements for containment facilities for personal and environmental protection * the principles of, and terminology for, isolator technology * monitoring and test systems (instruments and measurement) used for controlled environment and cleanroom operations * how cleanrooms are certified: test methods, sampling sites * GMP requirements for the qualification of cleanrooms * GMP rules and requirements for working in controlled environments and cleanrooms including personal actions prohibited in cleanrooms including: * requirements for approving and taking commodity items into the cleanroom * restrictions on movement of personnel, including QC, maintenance and cleaning staff to minimise cross-contamination * cleanroom garments: types, materials, processing and reprocessing, where allowed * personal hygiene, and the clothing and footwear requirements for working in and moving between work areas * personal clothing use, storage and disposal requirements * housekeeping requirements and responsibilities relating to own work * responsibilities of general cleaning staff and how to work with a cleaning team, including knowledge of when cleanrooms can be cleaned * the role of cleaning and sanitising in preventing contamination of materials and products, and in the protection of personnel including maintenance personnel and other external contractors, including: * how improper cleaning of a controlled environment or cleanroom can lead to product contamination * the need for proper selection of equipment and materials for proper cleaning * risks associated with controlled environment and cleanroom operators: * physical behaviour * personal hygiene risks, such as; skin flakes, oils, perspiration, use of cosmetics, hair * psychological concerns associated with working in cleanrooms, such as; room temperature, humidity, claustrophobia * workplace attitudes and habits * communications between workers * electrostatic discharge * contamination risks associated with controlled environment and clean room operations, including: * number of personnel in the controlled environment * activities being undertaken * leaks * malfunctioning equipment * low differential pressures * high particle counts * incorrect air flow and velocity * humidity * temperature * room status inactive or in alarm * lack of cleanliness * common GMP deficiencies observed in controlled environment and clean room operations, including: * damage to plant or equipment * failure of cleaning regime or pest control program * missing or inaccurate records * failure to follow workplace procedures * procedures for responding to out-of-specification or unacceptable performance/outcomes * purpose of keeping records and the recording requirements of GMP, including the legal significance of certifying and verifying GMP records. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * skills must be demonstrated in a controlled environment of a commercial pharmaceutical or complementary medicine manufacturing workplace setting or an environment that accurately represents workplace conditions * resources, equipment and materials: * controlled environment or cleanroom environment * protective clothing, footwear and equipment * data collection forms and information recording systems * specifications: * gowning/degowning procedures and related advice on equipment operation, including advice on safe work practices and environmental requirements * information relating to the design, operation, testing and monitoring of Air Handling Units or Heating Ventilation and Air Conditioning systems (HVAC) * GMP information relating to controlled environments and work responsibilities * data collection and information recording requirements and procedures * relationships: * team member(s)/supervisors or realistic scenarios or role plays * timeframes: * according to the job requirements.   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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