Modification history

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

| FBPPHM3013 | Operate a granulation process |
| --- | --- |
| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a granulation process in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) and operating principles to the granulation process under broad direction, and take 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 |
| --- | --- |
| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Prepare granulation process for operation | 1.1 Confirm materials and equipment are available and meet production requirements  1.2 Select and fit personal protective clothing and equipment according to workplace procedures  1.3 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual  1.4 Enter processing and operating parameters according to safety and production requirements  1.5 Conduct pre-start checks according to workplace requirements |
| 2. Operate and monitor granulation process | 2.1 Start up and monitor granulation process to confirm specifications are within required limits  2.2 Rectify, identify and report out-of-specification granulated products or processes to maintain process within specifications  2.3 Maintain work area according to workplace cleaning standards  2.4 Conduct process according to safety and environmental requirements  2.5 Contain, remove and report spillages according to workplace procedures  2.6 Complete documentation according to workplace requirements |
| 3. Shut down the granulation process | 3.1 Confirm the workplace procedures for shutting down the process  3.2 Complete end-of-batch procedures according to batch instructions and workplace procedures  3.3 Safely shut down the process  3.4 Complete records according to 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. | |
| --- | --- |
| Skill | Description |
| Reading | * Identify relevant information from workplace documentation and interpret requirements for the granulation process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Interpret specifications for flow rates and product quantity |
| Navigate the world of work | * Identify workplace procedures relevant to own role |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Plan, organise and implement tasks required to achieve production outcomes * Use problem-solving skills to analyse product and process faults and decide on appropriate action |

| 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. | |
| --- | --- |
| Pre-start checks must include at least five of the following: | * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * cancelling isolation or lock outs * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational. |

|  |  |  |  |
| --- | --- | --- | --- |
| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3013 Operate a granulation process | FDFPH2011A Operate a granulation process | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | Equivalent unit |

|  |  |
| --- | --- |
| 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 FBPPHM3013 Operate a granulation process |
| --- | --- |
| 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 safely operated at least one granulation process, including:   * accessed workplace information to confirm production requirements for the granulation process * confirmed supply of necessary materials and services, including checking raw materials meet batch requirements * selected, fitted and used one of the following: * protective gown * scrubs * smock * statcoat * disposable coverall * selected, fitted and used personal protective clothing and equipment, including: * surgical mask * surgical gloves * disposable overshoes * hair net * conducted pre-start checks required for the safe operation of the granulation process, including five of the following: * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * cancelling isolation or lock outs * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational * started, operated, monitored and adjusted a granulation process to achieve required outcomes, including: * interpreting and implementing batch instructions * supply and flow of materials to and from the granulation process * checked control points and conducted inspections to confirm the process remains within specification, including: * granule size * moisture content * taken corrective action in response to out-of-specification results * located emergency stop functions on equipment * followed isolation and lock out and tag out procedures to take granulation process and related equipment off-line in preparation for cleaning and maintenance * followed end-of-batch procedures, including: * line clearance and cleaning * yield calculation * materials reconciliation * product labelling * used process control systems according to workplace procedures * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements. | |

| 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:   * stages of the granulation process, including: * the purpose, methods and outcomes of each stage * control points * quality characteristics to be met by the granulation process * stages and changes which occur during granulation * types of raw materials used in the granulation process and related handling and segregation requirements, including handling hazardous goods * flow of the granulation process and the effect of outputs on downstream pharmaceutical processes * basic operating principles of equipment, requirements and parameters of granulation equipment, including: * main equipment components, operating capacities and applications * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * status and purpose of guards * the purpose and location of sensors and related feedback instrumentation * corrective actions required where operation is outside specified parameters * functions and limitations of personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats, or disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair nets * pre-start checks requirements, including: * inspecting equipment condition to identify signs of wear * selecting appropriate settings and/or related parameters * cancelling isolation or lock outs * confirming line clearance and cleaning status * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * confirming that all safety guards are in place and operational * methods used to monitor granulation process, including: * inspecting * measuring * testing * product and process changeover procedures and responsibilities * end-of-batch procedures, including: * calculating yield * materials reconciliation * product labelling responsibilities and procedures * requirements of different shutdowns, including: * emergency and routine shutdowns * procedures to follow in the event of a power outage * line clearance procedures, including cleaning and sanitation procedures * isolation, lock out and tag out procedures and responsibilities * operating principles of process control, including the relationship between control panels and systems and physical equipment * GMP requirements associated with a granulation process and related control measures * environmental issues and controls relevant to the granulation process, including waste collection and handling procedures * 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: * personal protective clothing and equipment * granulation process equipment * materials required for the granulation process * test equipment * cleaning materials and equipment associated with granulation process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to granulation process and procedures * GMP requirements relating to granulation process * production schedule/batch instructions * sampling schedules and test procedures * cleaning procedures associated with granulation process.   Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards. |

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