Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2010A Operate an encapsulation process

Revision Number: 1

FDFPH2010A Operate an encapsulation process

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down the encapsulation process.

Application of the Unit

Application of the unit	This unit has application in a pharmaceutical manufacturing environment. It typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of an encapsulation process and equipment. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures. When batch or product changeover procedures are part of this work process, the procedures should be used to customise the application of this unit. Where more detailed changeovers are carried out, FDFOP2011A Conduct routine maintenance, should be considered.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare the encapsulation process for operation	1.1. Materials are confirmed and available to meet operating requirements 1.2. Cleaning and maintenance requirements and status are identified and confirmed 1.3. Machine components and related attachments are fitted and adjusted to meet operating requirements 1.4. Processing/operating parameters are entered as required to meet safety and production requirements 1.5. Equipment performance is checked and adjusted as required 1.6. Pre-start checks are carried out as required by workplace requirements
2. Operate and monitor the encapsulation process	2.1. The encapsulation process is started and operated according to workplace procedures 2.2. Equipment is monitored to identify variation in operating conditions 2.3. Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements 2.4. The process is monitored to confirm that capsules meet specifications 2.5. Out-of-specification product/process outcomes are identified, rectified and/or reported to maintain the process within specification 2.6. The work area is maintained according to housekeeping standards 2.7. Work is conducted according to environmental standards 2.8. Spillages are reported and removed according to standard operating procedures 2.9. Workplace records are maintained according to workplace recording requirements
3. Shut down the encapsulation process	3.1. End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures (SOPs) 3.2. The process is shut down according to workplace procedures 3.3. Maintenance requirements are identified and reported according to workplace reporting requirements

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- access workplace information to identify production requirements for the encapsulation process
- select, fit and use personal protective clothing and/or equipment
- confirm supply of necessary materials and services to the encapsulation process
- conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming line clearance and cleaning status and that equipment is correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational
- verify raw materials with batch instructions
- start, operate, monitor and adjust encapsulation process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as:
  - flow rates/quantity
  - product quality
- take corrective action in response to out-of-specification results, such as adjusting the flow rates
- monitor supply and flow of materials to and from the encapsulation process
- respond to and/or report equipment failure within level of responsibility
- locate emergency stop functions on equipment
- follow isolation and lock out/tag out procedures as required to take encapsulation process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility
- demonstrate batch/product changeovers
- follow end-of-batch procedures, including line clearance and cleaning, yield calculation, materials reconciliation and product labelling
- complete workplace records as required
- maintain work area to meet housekeeping standards
- use process control systems according to enterprise procedures
- collect samples and conduct tests according to enterprise procedures
- conduct routine maintenance according to enterprise procedures
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor
- work cooperatively within a culturally diverse workforce

REQUIRED SKILLS AND KNOWLEDGE

Required knowledge

Knowledge of:

- purpose and basic principles of the encapsulation process
- basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation
- services required and action to take if services are not available
- types of raw materials used in the encapsulation process and related handling/segregation requirements, such as handling hazardous goods
- stages and changes which occur during encapsulation
- quality characteristics and legal requirements to be achieved by the encapsulation process
- the flow of the encapsulation process and the effect of outputs on downstream pharmaceutical processes
- operating requirements and parameters and corrective action required where operation is outside specified operating parameters
- typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
- methods used to monitor the encapsulation process, such as inspecting, measuring and testing as required by the process
- inspection or test points (control points) in the encapsulation process and the related procedures and recording requirements
- GMP requirements associated with the encapsulation process and related control measures
- common causes of variation and corrective action required
- product/process changeover procedures and responsibilities
- occupational health and safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process
- end-of-batch procedures including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labelling responsibilities and procedures
- requirements of different shutdowns as appropriate to the encapsulation process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage
- line clearance, cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- procedures and responsibility for reporting production and performance information
- environmental issues and controls relevant to the encapsulation process, including waste collection and handling procedures related to the process
- basic operating principles of process control, where relevant, including the

REQUIRED SKILLS AND KNOWLEDGE
relationship between control panels and systems and the physical equipment • sampling and testing associated with process monitoring and control where relevant • routine maintenance procedures where relevant

Evidence Guide

EVIDENCE GUIDE	
The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.	
Overview of assessment	Assessment must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Evidence of ability to: • conduct pre-start checks on equipment used for encapsulation • start, operate, monitor and adjust process equipment to achieve required quality outcomes • take corrective action in response to typical faults and inconsistencies • complete workplace records as required • apply safe work practices and identify OHS hazards and controls • safely shut down equipment • apply food safety procedures to work practices.
Context of and specific resources for assessment	Assessment must occur in a real or simulated workplace where assessee has access to: • personal protective clothing and equipment • work procedures, including advice on safe work practices, GMP, quality and environmental requirements • information on equipment capacity and operating parameters • production schedule/batch instructions • specifications, control points and processing parameters • encapsulation process and related equipment and services • materials required for the encapsulation process • sampling schedules and test procedures and equipment as required • documentation and recording requirements and procedures • cleaning procedures, materials and equipment as

EVIDENCE GUIDE	
	required.
Method of assessment	This unit should be assessed together with core units and other units of competency relevant to the function or work role. Examples could be: • FDFOP2003A Clean equipment in place • FDFOP2004A Clean and sanitise equipment • FDFOP2011A Conduct routine maintenance • FDFOP2013A Apply sampling procedures • FDFOP2030A Operate a process control interface • MSL973001A Perform basic tests.
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity
Workplace information	Workplace information may include: • SOPs • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Encapsulation equipment and accessories	Encapsulation equipment and accessories may include: • semi-automatic filling machines • intermittent filling machines • continuous filling machines • augers • stirrers • hoppers • post-ejection accessories
Encapsulation filling methods	Encapsulation filling methods may include: • powder filling

RANGE STATEMENT	
	• pellet filling • solid filling • liquid filling
Stock	Stock for the encapsulation process: • is supplied from the granulation process and ingredients/raw materials from the dispensing process
Capsule defects	Capsule defects may include: • short body • short cap • rough cut, • collet pinches • punched ends • long body or cap • split • wrinkles • specks • star ends • dirt • strings • bubbles • print errors/defects
Work	Work may involve: • exposure to dangerous and hazardous substances
Operation of equipment and processes	Operation of equipment and processes may require: • the use of process control panels and systems
Shutdown procedures	Shutdown procedures may include: • cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)
Services	Services may need to be confirmed. These depend on the nature of the process. Typical examples include: • power • steam • water

RANGE STATEMENT	
	• vacuum • gases • compressed and instrumentation air

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing

Competency field

Competency field	

Co-requisite units

Co-requisite units		