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Food Processing Industry

FDF 98

Pharmaceutical Competency Units

NATIONAL FOOD INDUSTRY TRAINING COUNCIL

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INDEX TO: Pharmaceutical Units

FDF CORGMP1 A	Apply basic good manufacturing practice
Descriptor	This core unit has been developed for the pharmaceutical manufacturing sector. It involves applying the relevant sections of the Code of Good Manufacturing Practice (GMP).

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out within company policy and procedures, good manufacturing practice and legislative requirements
- Responsibility for applying good manufacturing practice relates to the person's work area
- Stock handled by the operator may include raw materials, ingredients, consumable products, finished product
- Reporting systems may include electronic and manual data recording and storage systems.

Element	Performance criteria	Evidence guide – Part A
Apply the GMP requirements in immediate work area	Personal hygiene complies with good manufacturing practice Personal movement around the workplace complies with work area standards Clothing is prepared, used, stored and disposed according to good manufacturing practice Stock and equipment is handled and used according to good manufacturing practice GMP non-compliance is identified, rectified and/or reported	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – apply GMP provisions for personal hygiene – apply GMP provisions for movement about the workplace – identify GMP non-compliance – comply with entry and exit requirements for moving through designated work areas/sections – implement GMP provisions regarding control of contamination – identify documentation in person's work area which contains GMP provisions – implement GMP provisions related resources and process control – implement documentation as specified – report/record GMP non-compliance **Underpinning knowledge:** – purpose and significance of compliance with the Code of Good Manufacturing Practice – the relationship between the Code of Good Manufacturing Practice and standard operating procedures, instructions, processes and procedures *(cont.)*
Control contamination	Pharmaceutical products are free of contamination The risk of contamination is minimised by the application of good manufacturing practice Contamination is detected and reported within standard procedures	

Element	Performance criteria	Evidence guide – Part A
Implement GMP documentation	Documentation supporting GMP requirements is used as specified	*Underpinning knowledge: (continued)* – role/responsibility/accountability of operator in implementing GMP – the quality characteristics in pharmaceutical manufacturing – the relationship between quality and good manufacturing practice – the purpose of documentation systems and processes – clothing requirements – actual/potential implications of breaching GMP requirements – systems and processes for reporting non-compliance with GMP – roles and responsibilities of external audit groups in monitoring and reporting GMP compliance – types of contamination – causes of contamination – methods of preventing contamination – reporting/recording systems and processes

Evidence guide – Part B

Assessment guide

- Assessment must take into account the food industry's endorsed assessment guidelines and may use the non-endorsed Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995.
- The competencies described in this unit need to be performed over time and events under normal workplace conditions, giving due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can consistently achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The procedures and documentation should be that actually used in a workplace. Compliance with statutory OHS, hygiene and sanitation and environmental provisions relevant to the food processing industry should be emphasised.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level with this unit.

Assessment context

Assessment of this unit must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to apply good manufacturing practice in a pharmaceutical manufacturing enterprise given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements

– Code of Good Manufacturing Practice

– quality standards
– work instructions and procedures
– appropriate clothing
– cleaning and sanitation policies and procedures
– reporting/recording systems and processes.

Relationship to other units

Co-requisites:
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Apply safe work practices
– Communicate in the workplace

Relationship to learning resources

Main learning resource:
– Good Manufacturing Practice A and Applied Good Manufacturing Practice

Related learning resources:
– Calculations A
– Industrial Communication A
– Occupational Health and Safety A
– Quality Assurance A

FDF PHDC1 A	Locate industry and company products and processes (Pharmaceutical Manufacturing)

Descriptor This is a specialist unit that has been customised for the pharmaceutical manufacturing sector. It covers the products and processes used in their workplace.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Processes and procedures are carried out within company policy and procedures and legislative requirements
- Pharmaceutical manufacturing processes typically include dispensing, product production, packaging, and warehousing
- Stages refer to functions or activities in the production, packaging and despatch processes. Examples of typical stages are dispensing, granulating, compressing, encapsulating, tablet coating, packing, storing and despatching

Element	Performance criteria	Evidence guide – Part A
Identify products and quality products	Company product range is identified Quality requirements of final products are identified in accord with company standards	Part A of the Evidence guide identifies the knowledge to be demonstrated to confirm competence for this unit. Part B of the Evidence guide outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify materials and production requirements – identify and locate materials used in the work process – identify and locate production and/or packaging stages and processes in the workplace – comply with OHS and food safety requirements when moving around the workplace **Underpinning knowledge:** – range of final products produced by the company – basic understanding of brand image, company goals and philosophy – quality requirements/specifications for final products – consequences of product failing to meet quality requirements – stages and processes used to manufacture product *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Identify and locate production and packaging processes	Raw materials and related handling systems are located and operated as required Production and packaging stages and processes are identified Equipment used for each stage is located	*Underpinning knowledge: (continued)* – basic purpose of equipment used at each stage – raw materials/consumables used – preparation, packaging, handling and storage of finished product prior to sale – OHS, quality, food safety and environmental requirements relating to own work

Evidence guide – Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995***.**
- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to describe pharmaceutical manufacturing products and processes given:

– work procedures including advice on safe work practices, food safety and environmental requirements
– production systems, stages and processes
– raw materials, in-process and finished product requirements and/or specifications

Relationship to other units

Co-requisites:

– Communicate in the workplace
– Apply basic mathematical concepts
– Apply safe work procedures
– Apply basic quality assurance practices
– Apply basic good manufacturing practice

Relationship to learning resources

Main learning resources:

– Production Processes 1A

Related learning resources:

– Industrial Communication A
– Calculations A
– Occupational Health and Safety A
– Quality Assurance A
– Good Manufacturing Practice A and Applied Good Manufacturing Practice

FDF CORGMP2 A Implement good manufacturing practice

Descriptor This is a core unit that has been developed for the pharmaceutical manufacturing sector. It involves applying the Code of Good Manufacturing Practice (GMP) to prevent physical, chemical and biological contamination and control waste and pests.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out within company policy and procedures, food safety, good manufacturing practice and legislative requirements
- The process used may be computer controlled or manually controlled or a combination
- Stock handled by the operator may include raw materials, ingredients, consumables, in-process product, finished product
- Contaminants may be classified as physical, chemical, biological
- Control points, inspection and tests requirements are contained in company plans/procedures
- Equipment is available to detect contaminants
- Reporting systems may include electronic and manual data recording and storage systems.

Element	Performance criteria	Evidence guide – Part A
Prevent physical contamination	Good manufacturing practice is applied to prevent physical contamination Critical points which impact on physical contamination are monitored to ensure appropriate control of contaminants Physical contamination is identified, rectified and/or reported Potential sources of physical contamination are identified and reported	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – monitor control points to identify risk of contaminants – locate contamination – follow GMP to remove/isolate problem – take action to prevent contamination occurring or recurring – sort and dispose waste materials – identify presence of pests – record workplace information **Underpinning knowledge:** – purpose and significance of compliance with the Code of Good Manufacturing Practice in preventing contamination – the relationship between the Code of Good Manufacturing Practice and standard operating procedures, instructions, processes and procedures – common types of physical, chemical and biological contaminants *(cont.)*
Prevent chemical contamination	Good manufacturing practice is applied to prevent chemical contamination Critical points which impact on chemical contamination are monitored to ensure appropriate control of contaminants	

Element	Performance criteria	Evidence guide – Part A
Prevent chemical contamination *(continued)*	Chemical contamination is identified, rectified and/or reported Potential sources of chemical contamination are identified and reported	*Underpinning knowledge: (continued)* – conditions which cause physical, chemical and biological contamination – procedures for preventing contamination – procedures for investigating contamination – the effect of contamination on products, consumers and the company – control points in the management of contamination – common methods used to prevent contamination – types of waste and the handling methods – requirements for classifying and handling solid and liquid waste – pest prevention and control methods and procedures – reporting/recording systems and processes
Prevent biological contamination	Good manufacturing practice is applied to prevent biological contamination Critical points which impact on biological contamination are monitored to ensure appropriate control of contaminants Biological contamination is identified, rectified and/or reported Potential sources of biological contamination are identified and reported	
Control waste and pests	Waste is classified and disposed according to good manufacturing practice Potential waste and pest problems are identified and reported	

Evidence guide – Part B

Assessment guide

- Assessment must take into account the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.
- The competencies described in this unit need to be performed over time and events under normal workplace conditions, giving due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can consistently achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The procedures and documentation should be that actually used in a workplace. Compliance with statutory OHS, hygiene and sanitation and environmental provisions relevant to the food processing industry should be emphasised.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level with this unit.

Assessment context

Assessment of this unit must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to implement good manufacturing practice given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– Code of Good Manufacturing Practice
– product safety policy, system and procedures
– quality standards
– control points, inspection and test requirements
– monitoring systems
– equipment to detect contamination
– pest control plan and procedures
– waste handling policy, systems and processes
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Apply safe work practices
– Communicate in the workplace

Co-requisites:

– Apply occupational health and safety principles and procedures
– Implement the quality system
– Collect, present and apply workplace information

Relationship to learning resources

Main learning resource:

– Good Manufacturing Practice B

Related learning resources:

– Industrial Communication B
– Occupational Health and Safety B
– Quality Assurance

FDF PHDP2 A	Operate a dispensing process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up the dispensing section and preparing and dispensing raw materials for the manufacturing process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Dispensing equipment may include measuring instruments, containers, scoops, labeller
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Dispensing documentation may include good manufacturing practice, Standard Operating Procedures (SOPs), dispensing schedules, batch instructions
- Stock for the process is supplied from bulk and packaged solids and liquids materials
- Services may include power, instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the dispensing process for operation	Materials are confirmed and available to meet batch requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for use The dispensing process is set to meet batch requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify requirements for the dispensing process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the dispensing process – confirm equipment status and condition – implement batch instructions – set up and start up the dispensing process – interpret the coding system for identifying raw materials – calculate assay/potency adjustment – weigh materials – segregate raw materials *(cont.)*
Operate and monitor the dispensing process	The dispensing process is started up according to company procedures Control points are monitored to confirm that performance is maintained within specification	

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the dispensing process *(continued)*	Raw materials are dispensed according to batch instructions and standard operating procedures Equipment is monitored to confirm operating condition Stock flow to and from dispensing process is maintained within production requirements Out-of-specification product, process and equipment performance is identified, rectified and/or reported	*Demonstrated ability to: (continued)* – verify accuracy of raw materials dispensed with information in the documentation/ systems – pack and label dispensed materials – stack dispensed product for transfer to designated location – handle containers within SOP requirements – monitor the dispensing process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ labelling ➢ stock flow/quantity ➢ measuring devices ➢ materials faults ➢ equipment faults ➢ service faults – monitor supply and flow of materials to and from the dispensing process – take corrective action in response to out-of-specification results or non-compliance – report and/or record corrective action as required – sort, collect, treat, recycle or dispose of waste – shut down dispensing equipment – prepare dispensing equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance **Underpinning knowledge:** – purpose and basic principles of the dispensing process – relationship between the dispensing process and other pharmaceutical manufacturing processes – identification and application of good manufacturing practice and standard operating procedures – types and characteristics of raw materials – legislative requirements in dispensing pharmaceutical products – dangerous goods handling requirements – raw materials segregation purpose and requirements *(cont.)*
Shut down the dispensing process	End of batch procedures are completed in accordance with batch instructions and standard operating procedures Dispensing process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – raw materials reconciliation purpose and procedures – raw materials coding system purpose and application – effect of dispensing process on the end product – quality characteristics to be achieved – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the dispensing process – services used in dispensing process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdowns and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995.*
- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.

- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a dispensing process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– dispensing schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– dispensing equipment
– services as required
– materials required for the dispensing process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:

– Implement occupational health and safety principles and procedures
– Collect, present and apply workplace information
– Implement good manufacturing practice
– Implement the quality system

Related units:

– Clean and sanitise equipment
– Apply sampling techniques
– Conduct routine tests
– Conduct routine preventative maintenance

Where related units form an integral part of operating a dispensing process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:

– Production Processes 2G (Dispensing)

Related learning resources:

– Cleaning and Sanitation
– Good Manufacturing Practice B
– Industrial Communication B
– Occupational Health and Safety B
– Quality Assurance B

FDF PHGP2 A	Operate a granulation process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the granulation process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Granulation may be a dry process or wet process or a combination
- Granulation equipment may include granulators, mixers, blenders, dryers, oscillators, mills, sieves, depending on whether it is wet or dry granulation system
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Stock for the process is supplied from dispensing process and from bulk containers
- Supplies may include deionised/purified water
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the granulation process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for use The granulation process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the granulation process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the granulation process – confirm equipment status and condition *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the granulation process	The granulation process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Granulated product is meets specifications Equipment is monitored to confirm operating condition Stock flow to and from granulation process is maintained within production requirements Out-of-specification product, process and equipment performance is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (continued)* – set up and start up the process. This can involve the use of process control systems – interpret and implement batch instructions – verify raw materials with batch instructions – monitor the granulation process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ service faults – monitor supply and flow of materials to and from the granulation process – take corrective action in response to out-of-specification results or non-compliance. – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down granulation equipment in response to emergency situation – shut down granulation equipment in response to routine shutdown requirements – prepare granulation equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement granulation instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance **Underpinning knowledge:** – purpose and basic principles of the granulation process – relationship between the granulation process and other pharmaceutical processes – identification and application of good manufacturing practice and standard operating procedures – stages and changes which occur during granulation *(cont.)*
Shut down the granulation process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Granulation process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – types of additives and ingredients – legislative requirements in granulation of pharmaceutical products – characteristics of raw materials and their chemical reactions – effect of granulation process on the end product – quality characteristics to be achieved – dangerous goods handling requirements – ingredient/raw material segregation requirements – purpose and characteristics of ingredients/raw materials used in granulation and their chemical reactions – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the granulation process – services used in granulation process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.

- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a granulation process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– granulation equipment
– services as required
– materials required for the granulation process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:

– Implement occupational health and safety principles and procedures
– Collect, present and apply workplace information
– Implement good manufacturing practice
– Implement the quality system

Related units:
- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating a granulation process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Production Processes 2F (Granulation)
- Production Processes 3F (Granulation)

Related learning resources:
- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF PHCP2 A	Operate a compressing process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the compressing process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Compressing equipment and accessories may include single punch compressors, rotary compressors, punches, dies
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Stock for the process is supplied from the granulation process and the dispensing process
- Raw materials/ingredients which are added to the granulated product may include diluents, adhesives/binders, disintegrants, glidants, lubricants, fillers, colourants, flavouring agents
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- In-process tests may include appearance, hardness, friability, disintegration, weight, dimensions
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the compressing process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for use The compressing process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the compressing process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the compressing process – confirm equipment status and condition – confirm line clearance *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the compressing process	The compressing process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Tablet product meets specifications Equipment is monitored to confirm operating condition Stock flow to and from compressing process is maintained within production requirements Out-of-specification product, process and equipment is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (continued)* – set up and start up the process. This can involve the use of process control systems – verify granules/powder blends with batch instructions – install punches and dies – monitor the compressing process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ flow rates/quantity ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ services faults – monitor supply and flow of materials to and from the compressing process – take corrective action in response to out-of-specification results or non-compliance. – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down compressing equipment in response to emergency situation – shut down compressing equipment in response to routine shutdown requirements – prepare compressing equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement compressing instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance
Shut down the compressing process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Compressing process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	**Underpinning knowledge:** – purpose and basic principles of the compressing process – relationship between the compressing process and other pharmaceutical processes – identification and application of good manufacturing practice and standard operating procedures *(cont.)*

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – stages and changes which occur during compressing – types of additives and ingredients – dangerous goods handling requirements – ingredient/raw material segregation requirements – purpose and characteristics of ingredients/raw materials used in compressing and their chemical reactions – quality characteristics to be achieved – legislative requirements in compressing pharmaceutical products – effect of compressing process on the end product – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the compressing process – services used in compressing process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.

- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a compressing process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– compressing equipment
– services as required
– materials required for the compressing process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:

– Implement occupational health and safety principles and procedures
– Collect, present and apply workplace information
– Implement good manufacturing practice
– Implement the quality system

Related units:
- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating a compressing process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Production Processes 2C (Compressing)
- Production Processes 3C (Compressing)

Related learning resources:
- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF PHEP2 A	Operate an encapsulation process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the encapsulation process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Encapsulation equipment and accessories may include semi-automatic filling machines, intermittent filling machines, continuous filling machines, augers, stirrers, hoppers, post ejection accessories
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Encapsulation filling methods may include powder filling, pellet filling, solid filling, liquid filling
- Stock for the process is supplied from the granulation process and ingredients/raw materials from the dispensing process
- 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
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the encapsulation process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for use The encapsulation process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the encapsulation process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the encapsulation process *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the encapsulation process	The encapsulation process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Capsules meet specifications Equipment is monitored to confirm operating condition Stock flow to and from encapsulation process is maintained within production requirements Out-of-specification product, process and equipment is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (continued)* – confirm equipment status and condition – set up and start up the process. This can involve the use of process control systems – verify raw materials with batch instructions – monitor the encapsulation process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ flow rates/quantity ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ services faults – monitor supply and flow of materials to and from the encapsulation process – take corrective action in response to out-of-specification results or non-compliance. This can involve adjusting the flow rates – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down encapsulation equipment in response to emergency situation – shut down encapsulation equipment in response to routine shutdown requirements – prepare encapsulation equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement encapsulation instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance
Shut down the encapsulation process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Encapsulation process is shut down according company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	**Underpinning knowledge:** – purpose and basic principles of the encapsulation process – relationship between the encapsulation process and other pharmaceutical processes – identification and application of good manufacturing practice and standard operating procedures *(cont.)*

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – stages and changes which occur during encapsulation – types of additives and ingredients – legislative requirements in encapsulation of pharmaceutical products – effect of encapsulation process on the end product – quality characteristics to be achieved – dangerous goods handling requirements – ingredient/raw material segregation requirements – purpose and characteristics of ingredients/raw materials used in encapsulation and their chemical reactions – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the encapsulation process – services used in encapsulation process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.

- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate an encapsulation process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– encapsulation equipment
– services as required
– materials required for the encapsulation process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:

– Implement occupational health and safety principles and procedures
– Collect, present and apply workplace information
– Implement good manufacturing practice
– Implement the quality system

Related units:
- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating an encapsulation process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Production Processes 2E (Encapsulation)
- Production Processes 3E (Encapsulation)

Related learning resources:
- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF PHTC2 A	Operate a tablet coating process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the tablet coating process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Tablet coating equipment may include spray guns, coating pan, polishing pans, solution tanks, blenders and mixers, homogenisers, mills, pumps, steam jackets, exhaust and heating pipes, scales
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Tablet coating processes may include sugar coating, film coating
- Stock for the process is supplied from the dispensing process and from bulk containers of tablets
- Materials used in the sugar coating process include purified water, cellulose derivatives, polyvinal, gums, sugar
- Materials used in film coating include purified water, cellulose derivatives
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the tablet coating process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for operation The tablet coating process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the tablet coating process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the tablet coating process *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the tablet coating process	The tablet coating process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Coated tablets meet specifications Equipment is monitored to confirm operating condition Stock flow to and from tablet coating process is maintained within production requirements Out-of-specification product, process and equipment performance is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (contributed)* – confirm equipment status and condition – set up and start up the process. This can involve the use of process control systems – implement batch instructions – verify raw materials with batch instructions – prepare tablet coating solutions – monitor the tablet coating process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ flow rates/quantity ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ services faults – monitor supply and flow of materials to and from the tablet coating process – take corrective action in response to out-of-specification results or non-compliance. – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down tablet coating equipment in response to emergency situation – shut down tablet coating equipment in response to routine shutdown requirements – prepare tablet coating equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement tablet coating instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance
Shut down the tablet coating process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Tablet coating process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	**Underpinning knowledge:** – purpose and basic principles of the tablet coating process – relationship between the tablet coating process and other pharmaceutical processes *(cont.)*

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – identification and application of good manufacturing practice and standard operating procedures – stages and changes which occur during tablet coating – types of additives and ingredients – legislative requirements of tablet coating – dangerous goods handling requirements – validation processes used in tablet coating – labelling requirements – characteristics of raw materials and their chemical reactions – effect of tablet coating process on the end product – quality characteristics to be achieved – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the tablet coating process – services used in tablet coating process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.

- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a tablet coating process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– tablet coating equipment
– services as required
– materials required for the tablet coating process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:

– Implement occupational health and safety principles and procedures
– Collect, present and apply workplace information
– Implement good manufacturing practice
– Implement the quality system

Related units:
- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating a tablet coating process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Production Processes 2D (Tablet coating)
- Production Processes 3D (Tablet coating)

Related learning resources:
- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF PHLM2 A	Operate a liquid manufacturing process

Descriptor This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the liquid manufacturing process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Liquid manufacturing equipment may include tanks, mixers, homogenisers, thermal jackets, mills, filters, vacuum systems, pumps, stirrers and impellers, purified water systems
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Stock for the process is supplied from the dispensing process and from bulk containers
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the liquid manufacturing process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for operation The liquid manufacturing process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the liquid manufacturing process – select, fit and use personal protective clothing and equipment – confirm supply of necessary materials and services to the liquid manufacturing process – confirm equipment status and condition – set up and start up the process. This can involve the use of process control systems *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the liquid manufacturing process	The liquid manufacturing process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Liquid product meets specifications Equipment is monitored to confirm operating condition Stock flow to and from liquid manufacturing process is maintained within production requirements Out-of-specification product, process and equipment performance is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (continued)* – implement batch instructions – verify raw materials with batch instructions – introduce raw materials to liquid manufacturing process – monitor the liquid manufacturing process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ flow rates/quantity ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ services faults – monitor supply and flow of materials to and from the liquid manufacturing process – take corrective action in response to out-of-specification results or non-compliance. – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down liquid manufacturing equipment in response to emergency situation – shut down liquid manufacturing equipment in response to routine shutdown requirements – prepare liquid manufacturing equipment for cleaning – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement liquid manufacturing instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment – take samples and conduct tests – carry out routine maintenance **Underpinning knowledge:** – purpose and basic principles of the liquid manufacturing process – relationship between the liquid manufacturing process and other pharmaceutical processes – identification and application of good manufacturing practice and standard operating procedures *(cont.)*
Shut down the liquid manufacturing process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Liquid manufacturing process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Recording information	Workplace information is recorded in the appropriate format	

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – stages and changes which occur during liquid manufacturing – types of liquid products – types of additives and ingredients – legislative requirements in liquid manufacturing of pharmaceutical products – the purpose of validating processes – effect of liquid manufacturing process on the end product – quality characteristics to be achieved – dangerous goods handling requirements – ingredient/raw material segregation requirements – purpose and characteristics of ingredients/raw materials used in liquid manufacturing and their chemical reactions – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the liquid manufacturing process – services used in liquid manufacturing process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.
- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a liquid manufacturing process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– liquid manufacturing equipment
– services as required
– materials required for the liquid manufacturing process
– stock flow system
– related work areas and communication system
– relevant OHS clothing and equipment
– routine preventative maintenance schedule as required
– cleaning schedule as required
– sampling and testing schedules as required
– documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

– Apply basic good manufacturing practices
– Apply basic mathematical concepts
– Apply basic quality assurance practices
– Communicate in the workplace
– Apply safe work procedures

Co-requisites:
- Implement occupational health and safety principles and procedures
- Collect, present and apply workplace information
- Implement good manufacturing practice
- Implement the quality system

Related units:
- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating a liquid manufacturing process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Production Processes 2B (Liquid manufacturing)
- Production Processes 3B (Liquid manufacturing)

Related learning resources:
- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF PHSM2 A	Operate a sterile manufacturing process
Descriptor	This is a specialist unit that has been developed for the pharmaceutical manufacturing sector. It involves setting up, operating and shutting down the sterile manufacturing process within quality requirements and standard operating procedures.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial arrangements
- Workplace information can include Standard Operating Procedures (SOPs), specifications and production schedules
- Sterile manufacturing may be a dry process or wet process or a combination
- Sterile manufacturing equipment may include air filters, UV light cabinets, laminar flow work stations
- Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place and equipment is operational
- Aseptic techniques and procedures to prevent contamination include gowning, personal hygiene and sanitation, personal conduct
- Sterilisation may involve use of heat (dry and steam), chemicals (gases and liquids), gamma irradiation, filtration, removal of disinfecting agents
- Stock for the process is supplied from the dispensing process and from bulk containers
- Services may include power, steam, water, vacuum, gases and compressed and instrumentation air
- Monitoring the process may involve the use of production data such as performance control charts
- Process operation and monitoring functions may be manual or involve the use of a process control system
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical) and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Work may involve exposure to dangerous and hazardous substances

Element	Performance criteria	Evidence guide – Part A
Prepare the sterile manufacturing process for operation	Materials are confirmed and available to meet production requirements Services are confirmed as being ready for operation Equipment and work area is checked to confirm readiness for use The sterile manufacturing process is set to meet production requirements	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – access workplace information to identify production requirements for the sterile manufacturing process – select, fit and use personal protective clothing and equipment – disinfect equipment and surfaces – sterilise equipment and surfaces *(cont.)*

Element	Performance criteria	Evidence guide – Part A
Operate and monitor the sterile manufacturing process	The sterile manufacturing process is started up according to company specifications Control points are monitored to confirm that performance is maintained within specification Sterile product meets specifications Equipment is monitored to confirm operating condition Stock flow to and from sterile manufacturing process is maintained within production requirements Out-of-specification process, equipment and product is identified, rectified and/or reported Spillages are reported and removed according to standard operating procedures Waste generated by the process is monitored and cleared according to company procedures	*Demonstrated ability to: (continued)* – maintain cleanrooms – confirm supply of necessary materials and services to the sterile manufacturing process – confirm equipment status and condition – interpret and implement batch instructions – verify raw materials with batch instructions – set up and start up the process. This can involve the use of process control systems – monitor the sterile manufacturing process and equipment operation to identify out-of-specification results or non-compliance. This may include: ➢ sterility problems ➢ flow rates/quantity ➢ product defects ➢ materials faults ➢ process faults ➢ equipment faults ➢ service faults – monitor supply and flow of materials to and from the sterile manufacturing process – take corrective action in response to out-of-specification results or non-compliance. – report and/or record corrective action as required – conduct product/batch changeover – sort, collect, treat, recycle or dispose of waste – shut down sterile manufacturing equipment in response to emergency situation – shut down sterile manufacturing equipment in response to routine shutdown requirements – prepare sterile manufacturing equipment for cleaning, disinfecting and sterilising – maintain work area to meet housekeeping standards – verify clearance and cleanliness – interpret and implement sterile manufacturing instructions – label product – calculate yield – prepare materials reconciliation – record workplace information May include the ability to: – clean and sanitise equipment
Shut down the sterile manufacturing process	End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures Sterile manufacturing process is shut down according to company procedures Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	

Recording information	Workplace information is recorded in the appropriate format	– take samples and conduct tests – carry out routine maintenance **Underpinning knowledge:** – purpose and basic principles of the sterile manufacturing process *(cont.)*

Element	Performance criteria	Evidence guide – Part A

		Underpinning knowledge: (continued) – distinction between cleaning, disinfecting and sterilising – relationship between the sterile manufacturing process and other pharmaceutical processes – identification and application of good manufacturing practice and standard operating procedures – stages and changes which occur during sterile manufacturing – legislative requirements in the sterile manufacturing of pharmaceutical products – basic principles of contamination identification and control – basic principles of contamination identification and control including: ➢ causes of contamination ➢ consequences of contamination ➢ detection and monitoring of contamination – dress and movement requirements for sterile manufacturing including: – consequences if aseptic techniques are not followed – action required if there is a breach of aseptic procedures – use of air filters and air locks to control contamination – quality parameters to be achieved – effect of sterile manufacturing process on the end product – process specifications, procedures and operating parameters – equipment and instrumentation components, purpose and operation – significance and methods of monitoring control points within the sterile manufacturing process – services used in sterile manufacturing process – common causes of variation and corrective action required – OHS hazards and controls – lock out and tag out procedures – procedures and responsibility for reporting problems – environmental issues and controls – shutdown and cleaning requirements associated with changeovers and types of shutdowns – waste handling requirements and procedures – dangerous goods handling requirements *(cont.)*

Element	Performance criteria	Evidence guide – Part A
		Underpinning knowledge: (continued) – purpose and characteristics of ingredients/raw materials used in sterile manufacturing and their chemical reactions – yield and reconciliation purpose and application – implications if yield/reconciliation are not within prescribed limits – end of batch procedures – recording requirements and procedures May include: – cleaning and sanitation procedures – sampling and testing procedures – routine maintenance procedures

Evidence guide - Part B

Assessment guide

- Assessment must take account of the food industry's endorsed assessment guidelines and may use the non-endorsed *Assessment Framework for the Food and Beverage Processing Industry NFITC June 1995*.
- The competencies described in this unit need to be performed over a specified time and events, under normal workplace conditions, having due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, food safety, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.

Assessment context

Assessment must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to operate a sterile manufacturing process given:

– work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
– production schedule, batch instructions
– material data safety sheets where appropriate
– specifications, control points and processing parameters
– sterile manufacturing equipment

- services as required
- materials required for the sterile manufacturing process
- stock flow system
- related work areas and communication system
- relevant OHS clothing and equipment
- routine preventative maintenance schedule as required
- cleaning schedule as required
- sampling and testing schedules as required
- documentation and recording requirements and procedures

Relationship to other units

Pre-requisites (or equivalent):

- Apply basic good manufacturing practices
- Apply basic mathematical concepts
- Apply basic quality assurance practices
- Communicate in the workplace
- Apply safe work procedures

Co-requisites:

- Implement occupational health and safety principles and procedures
- Collect, present and apply workplace information
- Implement good manufacturing practice
- Implement the quality system

Related units:

- Clean and sanitise equipment
- Apply sampling techniques
- Conduct routine tests
- Conduct routine preventative maintenance

Where related units form an integral part of operating a sterile manufacturing process in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:

- Production Processes 2H (Sterile manufacturing)

Related learning resources:

- Cleaning and Sanitation
- Good Manufacturing Practice B
- Industrial Communication B
- Occupational Health and Safety B
- Quality Assurance B

FDF CORGMP3 A	Monitor the implementation of good manufacturing practice

Descriptor This is a core unit that has been developed for the pharmaceutical manufacturing sector. It involves monitoring the implementation of good manufacturing practice and developing arrangements that will improve GMP compliance.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out within company policy and procedures, food safety, good manufacturing practice and legislative requirements
- Stock handled by the operator may include raw materials, ingredients, consumables, in-process product, finished product
- Contaminants may be classified as physical, chemical, biological
- Control points, inspection and tests requirements are contained in company plans/procedures
- Monitoring may involve the use of checklists, inspection lists, control charts, equipment
- Equipment is available to detect contaminants
- Reporting systems may include electronic and manual data recording and storage systems.

Element	Performance criteria	Evidence guide – Part A
Monitor good manufacturing practice	GMP requirements and procedures are communicated to work team Work processes and procedures are monitored to confirm compliance with GMP requirements Mentoring and coaching is provided to support individuals/groups to implement GMP Procedures describing improved GMP requirements are drafted and recommended to designated persons/groups	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B outlines how this guide is to be applied. It should be read in conjunction with the Range of variables. **Demonstrated ability to:** – implement work processes and procedures consistent with GMP requirements – monitor control points to identify GMP compliance – diagnose GMP non-compliance – participate in investigating non-compliance problems – remove/isolate/rectify the non-compliance – take action to prevent non-compliance occurring/recurring – draft procedures to improve GMP arrangements – communicate information about GMP to others – provide mentoring/coaching support – plan the conduct of an internal GMP audit – conduct/participate in GMP audit *(cont.)*
Respond to non-compliance	GMP non-compliance is identified, rectified and/or reported	

Element	Performance criteria	Evidence guide – Part A
Respond to non-compliance *(continued)*	Process and procedures for dealing with GMP non-compliance are implemented according to agreed arrangements GMP procedures are reviewed and measures are implemented to prevent recurrence	*Demonstrated ability to: (continued)* – report/record information in the company system **Underpinning knowledge:** – purpose and significance of compliance with the Code of Good Manufacturing Practice – the relationship between the Code of Good Manufacturing Practice and standard operating procedures, instructions, and work processes and procedures – factors which affect implementation of GMP – risk assessment processes and procedures – problem solving techniques to identify and rectify GMP non-compliance – consultative processes to negotiate GMP improvement – traceability and recall procedures – mentoring and coaching techniques – purpose and significance of GMP audits – purpose and types of GMP audits – audit responsibilities – internal audit processes and procedures – follow-up systems and processes – reporting/recording systems and processes
Conduct and participate in GMP audit	GMP audit is conducted according to company and legislative requirements Audit outcomes/ recommendations are reported and followed up as part of the company's continuous improvement system/ processes	

Evidence guide – Part B

Assessment guide

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- The competencies described in this unit need to be performed over time and events under normal workplace conditions, giving due regard for the key assessment principles of validity, reliability, fairness and flexibility.
- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can consistently achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The procedures and documentation should be that actually used in a workplace. Compliance with statutory OHS, hygiene and sanitation and environmental provisions relevant to the food processing industry should be emphasised.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level with this unit.

Assessment context

Assessment of this unit must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to monitor the implement good manufacturing practice in a pharmaceutical manufacturing enterprise given:

- work procedures including advice on safe work practices, good manufacturing practice, standard operating procedures and environmental requirements
- Code of Good Manufacturing Practice
- product safety policy, system and procedures
- quality standards
- control points, inspection and test requirements
- monitoring systems and processes
- traceability and recall systems and procedures
- equipment to detect contamination
- pest control plan and procedures
- waste handling policy, systems and processes
- GMP review/audit arrangements
- communication system
- reporting/recording systems and processes.

Relationship to other units

Pre-requisites (or equivalent):

- Apply occupational health and safety principles and procedures
- Implement good manufacturing practice
- Implement the quality system
- Collect, present and apply workplace information

Co-requisites:

- Analyse and convey workplace information
- Monitor the implementation of occupational health and safety
- Monitor the implementation of the quality system

Relationship to learning resources

Main learning resource:

- Good Manufacturing Practice C

Related learning resources:

- Industrial Communication C
- Occupational Health and Safety C
- Quality Assurance C

FDF PHOS3 A Operate a system (Pharmaceutical Manufacturing)

Descriptor

This is a specialist unit that has been customised for the pharmaceutical manufacturing sector. It covers the preparation and operation of a production or packaging system.

A system typically describes the operation of an entire process which may comprise a number of sub-systems. System operation requires higher level planning and problem solving skills than are necessary when operating an individual sub-system or piece of equipment. It can also involve facilitating the work of others.

Range of variables

The range of variables provides further advice to interpret the scope and context of this unit of competence. It assumes:

- Work is carried out in accordance with company procedures, licensing requirements, legislative requirements and industrial awards and agreements
- System operation typically involves planning, co-ordination and troubleshooting within their level of authority
- Pharmaceutical manufacturing processes include dispensing, product production, packaging and warehousing
- Control points refer to those key points in a work process which must be monitored and controlled. This includes good manufacturing practice (critical), quality and regulatory control points as well as inspection points
- Information systems may be print or screen based
- Co-ordination, planning and troubleshooting is undertaken with assistance from others
- Workplace systems are in place to support production/packaging processes. These include quality, good manufacturing practice, occupational health and safety and environmental management

Element	Performance criteria	Evidence guide – Part A
Prepare the system for operation	Supply of materials is confirmed to meet production/packaging requirements Work area is prepared for operation Services are confirmed as available and ready for operation Equipment and work area is checked to confirm readiness for use	Part A of the Evidence guide identifies the skills and knowledge to be demonstrated to confirm competence for this unit. Part B of the Evidence guide outlines how this guide is to be applied. Both parts should be read in conjunction with the Range of variables. **Demonstrated ability to:** – liaise with relevant work areas to confirm or secure necessary materials, services, equipment and labour to meet production/packaging requirements *(cont.)*

Element	Performance criteria	Evidence guide –Part A
Operate and monitor the system	The pharmaceutical manufacturing system is set to meet specifications The system is started up according to company procedures Control points are monitored to confirm performance is maintained within specification System outputs meet specification Equipment is monitored to confirm operating condition Out-of-specification product, process and equipment performance is identified, rectified and/or reported	*Demonstrated ability to: (continued)* – confirm that all equipment within the system meets hygiene and sanitation standards, all safety guards are in place and equipment is ready for operation – monitor implementation of set up and start up procedures. This may involve monitoring the use of checksheets by others – monitor observance of work procedures and systems – monitor materials flow and work-in-progress through the system – confirm that the system operates within specified parameters and control points are monitored – determine responses to out-of-specification results or non-conformance within level of responsibility – co-ordinate batch/product changeovers – communicate information effectively – plan maintenance and cleaning procedures to minimise disruption – monitor operating efficiencies of the system and investigate, resolve and/or report problems – review and maintain procedures to support system improvements **Underpinning knowledge:** – purpose and principles of the pharmaceutical production/packaging system – equipment purpose and operation including an understanding of process control systems where used – technical knowledge of product characteristics and processing requirements – codes and legislation relating to product and packaging requirements – equipment calibration schedule and responsibilities – type and purpose of tests conducted – related work areas and departments – relevant procedures, specifications and operating parameters – relevant systems and legislative requirements *(cont.)*
Shut down the system	The system is shut down according to company procedures Cleaning and sanitising requirements for equipment and work area are identified Equipment is cleaned and maintained to meet production/packaging and hygiene requirements Waste generated by both the process and cleaning procedures is collected, treated and disposed or recycled according to company procedures	
Record information	Workplace information is recorded and reported in required format	

Element	Performance criteria	Evidence guide –Part A
Contribute to continuous improvement of the system	Quality of process outputs is assessed against specifications Opportunities for improvement are identified and investigated Proposals for improvements are developed and implemented within company planning arrangements and according to company procedures	*Underpinning knowledge: (continued)* – responsibilities in areas such as human resources, good manufacturing practice, quality, occupational health and safety and environmental management – industrial awards and agreements relating to system operation – hazards, risks, controls and methods for monitoring processes within the system – maintenance and cleaning requirements of equipment in production/packaging system – end of batch procedures – yield and reconciliation requirements – process improvement procedures and related consultative arrangements – troubleshooting procedures and problem solving techniques – recording and reporting requirements

Evidence guide – Part B

Assessment guide

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- Assessment should be structured on whole of work activities giving emphasis to confirming that the assessee can achieve the workplace outcomes described in the Performance criteria, including demonstration of the underpinning knowledge and skills contained in the Evidence guide.
- The equipment used should be the actual items described in the Range of variables and Assessment context.
- The procedures and documentation should be those typically used in a workplace. Compliance with statutory occupational health and safety, good manufacturing practice, hygiene and environmental requirements relevant to the food processing industry should be emphasised.
- Assessment should reinforce the integration of the key competencies and the food industry's core competencies for the particular AQF level.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.
- Assessment should not require a higher level of communication competency than that specified in the core competencies for the particular AQF level.

Assessment context

Assessment of this unit must occur in a real or simulated workplace. Such an environment must provide an opportunity for the assessee to prepare and operate a production or packaging system given:

– work procedures including advice on safe work practices, good manufacturing practice and environmental requirements for processes within the production/packaging system

– company policies and workplace systems including human resources, OHS, quality, good manufacturing practice and environmental management

– production/packaging schedule, batch instructions

– sampling and testing schedules as required

- specifications, control points and processing parameters for processes within the production/ packaging system
- production/packaging system equipment
- personnel operating the production/packaging system
- services
- related work areas and communication system
- relevant OHS clothing and equipment
- cleaning, calibration and maintenance schedules as required
- troubleshooting advice where available
- documentation and record keeping system
- planning, resources management and training arrangements

Relationship to other units

Pre-requisites or equivalent:
- Collect, present and apply workplace information
- Implement occupational health and safety principles and procedures
- Implement the quality system
- Implement good manufacturing practice

Co-requisites:
- Analyse and convey workplace information
- Monitor the implementation of occupational health and safety
- Monitor the implementation of the quality system
- Monitor the implement the good manufacturing practice

Related units:
- Facilitate teams

Where related units form an integral part of system operation in the workplace, these units should be co-assessed.

Relationship to learning resources

Main learning resource:
- Advanced Production Processes 4A (Technical)
- Advanced Production Processes 4B (Co-ordination)

Related learning resources:
- Industrial Communication C
- Quality Assurance C
- Occupational Health and Safety C
- Good Manufacturing Practice C
- Work Team Communication