

FDF30210 Certificate III in Pharmaceutical Manufacturing

Revision Number: 1



FDF30210 Certificate III in Pharmaceutical Manufacturing

Modification History

Not applicable.

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Description

This qualification covers the Pharmaceutical Manufacturing specialisation.

Job Roles The Certificate III in Pharmaceutical Manufacturing targets those requiring team leader and higher production skills for pharmaceutical manufacturing environments. It builds upon industry specific skills and knowledge and allows greater emphasis on leadership, problem solving as well as increased technical ability.

Pathways into **the qualification** Pathways for candidates considering this qualification include:

- FDF20210 Certificate II in Pharmaceutical Manufacturing
- direct entry
- relevant vocational training and/or work experience.

Pathways from **the qualification** After achieving this qualification, candidates may undertake the FDF40210 Certificate IV in Pharmaceutical Manufacturing or any other suitable qualification.

Additional qualification advice

Units selected from other Training Packages must be relevant to the work outcome, local industry requirements and the qualification level.

Many units in this qualification assume a basic level of mathematics equivalent to a school sector Year 10 standard. If a student does not possess this level of mathematics then the unit FDFOP2061A Use numerical applications in the workplace should be selected as part of this qualification.

Note: AgriFood Skills Australia expects that the design of any training delivery and assessment program to support the achievement of this qualification is based on:

- the context required by the industry and/or enterprise
- a holistic and integrated training delivery and assessment plan that identifies learning activities and evidence required
- flexible delivery options including on-the-job and work-based training that support the development of competency.

Pathways Information

Not applicable.

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Licensing/Regulatory Information

Licensing, Legislative, Regulatory or Certification Considerations There is no direct link between this qualification and licensing, legislative and/or regulatory requirements. However, an individual unit of competency may specify relevant licensing, legislative and/or regulatory requirements. In addition, all work must comply with Good Manufacturing Practice, occupational health and safety (OHS) and environmental regulations and legislation that apply to the workplace.

Entry Requirements

Not applicable.

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Employability Skills Summary

EMPLOYABILITY SKILLS QUALIFICATION SUMMARY

Certificate III in Pharmaceutical Manufacturing

The following table contains a summary of the employability skills as identified by the Pharmaceutical Manufacturing industries for this qualification. This table should be interpreted in conjunction with the detailed requirements of each unit of competency packaged in this qualification. The outcomes described here are broad industry requirements that reflect skill requirements for this level.

Employability Skill	Industry/enterprise requirements for this qualification include:
Communication	 Confirm relevant industry and workplace requirements Understand personal and team requirements of relevant industry and workplace standards, regulations and policies Complete standard documentation Use communication technologies efficiently Provide relevant work-related information to others Ensure records are accurate and legible Establish effective working relationships with colleagues Undertake interactive workplace communication Support team communication practices
Teamwork	 Explain and implement work team reporting requirements Provide support to team members Monitor work team tasks in accordance with regulatory and workplace requirements Demonstrate and encourage others in working cooperatively with people of different ages, gender, race or religion Undertake appropriate and effective communication with team members
Problem-solving	 Identify risks and implement risk control measures for machinery and equipment Identify and address problems and faults Provide problem solving support to team members Evaluate skill requirements of work tasks Use problem solving techniques to determine work requirements Assess processes and outcomes against quality criteria
Initiative and enterprise	 Contribute to and promote continuous improvement processes Seek and provide feedback on procedures and processes Collect and assess data and information on work processes Identify non-conformances to standards and take appropriate action

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EMPLOYABILITY SKILLS QUALIFICATION SUMMARY		
	Rectify problems promptly and appropriately	
	• Monitor and adjust activity in response to operational variations	
	Identify, assess and act on existing and potential risks	
Planning and organising	Determine work requirements in order to meet output targets	
	Identify priorities and variables that impact on work planning	
	Plan work tasks for self and others as required	
	Allocate tasks to operators and monitor outcomes	
	Implement contingency plan promptly when incidents occur	
	Ensure work tools are ready and available for operations	
Self-management	Manage own work to meet performance criteria	
Sen management	Monitor information in work area	
	Conduct regular housekeeping activities during shift to keep work area clean and tidy at all times	
	Maintain currency of relevant work-related information	
	Monitor own work against quality standards and identify areas for improvement	
	 Understand own work activities and responsibilities 	
	Identify and apply safety procedures, including the use of protective equipment	
	Manage work load priorities and timelines	
Learning	Recognise limits of own expertise and seek skill development if required	
	Assess competencies in meeting job requirements	
	Ask questions to expand own knowledge	
	Maintain skill and knowledge currency	
	Participate in meetings to inform work practices	
Technology	• Use work machines and equipment in correct operational mode	
1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Monitor machine operation	
	Perform minor maintenance on machinery	
	Work with technology safely and according to workplace standards	

Packaging Rules

Packaging Rules

This qualification requires the achievement of **sixteen** (16) units of competency in accordance with the following rules.

Total units must include a minimum of nine (9) units coded FDF.

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Four (4) Core units Twelve (12) Elective units

Elective selection must include:

- One (1) Group A elective unit
- Five (5) Group B elective units. The Group B selection may include the unit not previously selected from Group A.

Six (6) remaining elective units may be selected from:

- Group A elective units below, not previously selected
- Group B elective units, not previously selected
- Group C elective units (maximum of 3 units)
- Units packaged at Group A in FDF20210 Certificate II in Pharmaceutical Manufacturing (maximum of 5)
- Units packaged at FDF40210 Certificate in IV in Pharmaceutical Manufacturing (maximum of 3)
- Units from any nationally endorsed Training Package and accredited course that are packaged at Certificate I level (maximum 1 unit), Certificate II level (maximum 2 units) and Certificate III level (maximum 3)

NOTE: Units marked with an asterisk (*) require completion of prerequisite unit/s identified under the unit.

CORE UNITS

Complete the following four (4) units.

FDFOHS3001A Contribute to OHS processes

FDFOP2064A Provide and apply workplace information

FDFPH3001A Monitor and maintain Good Manufacturing Practice

procedures

MSAENV272A Participate in environmentally sustainable work

practices

ELECTIVE UNITS

GROUP A

Complete one (1) Group A unit

FDFOP3003A Operate inter-related processes in a production system

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FDFOP3003A Operate inter-related processes in a production system

FDFOP3004A Operate inter-related processes in a packaging system

GROUP B

Select a minimum of five (5) Group B elective units

FDFPL3001A Participate in improvement processes

FDFPPL3002A Report on workplace performance

FDFPPL3003A Support and mentor individuals and groups

FDFPPL3004A Lead work teams and groups

FDFPPL3005A Participate in an audit process*

FDFOHS2001A Participate in OHS processes

FDF0P2063A Apply quality systems and procedures

MSAENV272A Participate in environmentally

sustainable work practices

FDFPPL3006A Establish compliance requirements for work area

FDFTEC3002A Implement the pest prevention program

FDFTEC3003A Apply raw materials, ingredient and process knowledge

to production problems

FDFOP3002A Set up a production or packaging line for operation

FDFOP2061A Use numerical applications in the workplace

BSBSMB405A Monitor and manage small business operations

BSBSMB407A Manage a small team

LMTGN3007B Monitor and operate trade waste process

MEM13003B Work safely with industrial chemicals and materials

MSACMC411A Lead a competitive manufacturing team

MSACMC413A Lead team culture improvement

MSAENV472A Implement and monitor environmentally sustainable

work practices

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FDFPL3001A Participate in improvement processes

MSAPMSUP303A Identify equipment faults

MSAPMSUP330A Develop and adjust a production schedule

MSL973001A Perform basic tests

TLIA1507C Complete receival/despatch documentation

TLIA1607C Use inventory systems to organise stock control

TLIA1807C Organise despatch operations

TLIA1907C Organise receival operations

TLIA2607C Monitor storage facilities

TLIA3807B Control and order stock

TLIA3907B Receive and store stock

SIRXINV002A Maintain and order stock

SIRXRSK002A Maintain store security

GROUP C

FDFOHS2001A Participate in OHS processes

FDFOP2063A Apply quality systems and procedures

BSBCUS301A Deliver and monitor a service to customers

BSBSMB301A Investigate micro business opportunities

BSBSMB401A Establish legal and risk management requirements of

small business

BSBSMB402A Plan small business finances

BSBSMB403A Market the small business

BSBSMB404A Undertake small business planning

BSBSMB406A Manage small business finances

BSBWRT301A Write simple documents

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FDFOHS2001A Participate in OHS processes

HLTFA301B Apply first aid

MSACMC210A Manage the impact of change on own work

MSACMC410A Lead change in a manufacturing environment

MSACMS200A Apply competitive manufacturing practices

MSACMS201A Sustain process improvements

MSACMS401A Ensure process improvements are sustained

MSACMT221A Apply Just in Time (JIT) procedures

MSACMT230A Apply cost factors to work practices

MSACMT231A Interpret product costs in terms of customer requirements

MSACMT240A Apply 5S procedures in a manufacturing environment

MSACMT250A Monitor process capability

MSACMT251A Apply quality standards

MSACMT260A Use planning software systems in manufacturing

MSACMT261A Use SCADA systems in manufacturing

MSACMT280A Undertake root cause analysis

MSACMT281A Contribute to the application of a proactive maintenance

strategy

MSACMT421A Facilitate a Just in Time (JIT) system

MSACMT423A Monitor a manufacturing levelled pull system*

MSACMT280A Undertake root cause analysis

MSACMT440A Lead 5S in a manufacturing environment

MSACMT441A Facilitate continuous improvement in manufacturing

MSACMT450A Undertake process capability improvements*

MSACMT452A Apply statistics to processes in

manufacturing

MSACMT451A Mistake proof a production process

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FDFOHS2001A Participate in OHS processes

MSACMT452A Apply statistics to processes in manufacturing

MSACMT460A Facilitate the use of planning software systems in

manufacturing*

MSACMT260A Use planning software systems in

manufacturing

MSACMT482A Assist in implementing a proactive maintenance strategy

MSACMT483A Support proactive maintenance

MSAPMOPS405A Identify problems in fluid power system

MSAPMOPS406A Identify problems in electronic control systems

MSAPMPER300A Issue work permits

MSAPMSUP310A Contribute to development of plant documentation

MSAPMSUP390A Use structured problem solving tools

MSL922001A Record and present data

TAEASS401A Plan assessment activities and processes

TAEASS402A Assess competence

TAEASS403A Participate in assessment validation

TAEDEL301A Provide work skill instruction

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