# FDF30210 Certificate III in Pharmaceutical Manufacturing

**Release 3**

**INDUSTRY SKILLS COUNCILS**
Creating Australia's Future

## FDF30210 Certificate III in Pharmaceutical Manufacturing

## Modification History

September 2012: Replacement of superseded imported Units.
November 2011: Update to imported Units, minor edits.

## 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.

**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

**Pathways into the Qualification**

Pathways for candidates considering this Qualification include:

- FDF20211 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.

# Licensing/Regulatory Information

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.

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

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

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# 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**.

**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 |
| MSAENV272B | Participate in environmentally sustainable work practices |

## ELECTIVE UNITS

## GROUP A

Complete one (1) Group A Unit

| FDFOP3003A | Operate interrelated processes in a production system |
|---|---|
| FDFOP3004A | Operate interrelated processes in a packaging system |

## GROUP B

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

| FDFPPL3001A | 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*<br>*FDFOHS2001A Participate in OHS processes*<br>*FDFOP2063A Apply quality systems and procedures*<br>*MSAENV272B 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 |
| BSBSMB405B | Monitor and manage small business operations |
| BSBSMB407A | Manage a small team |
| LMTGN3007B | Monitor and operate trade waste |
| MEM13003B | Work safely with industrial chemicals and materials |
| MSS403011A | Facilitate implementation of competitive systems and practices |
| MSS403013A | Lead team culture improvement |
| MSAENV472B | Implement and monitor environmentally sustainable work practices |
| MSAPMSUP303A | Identify equipment faults |
| MSAPMSUP330A | Develop and adjust a production schedule |
| MSL973001A | Perform basic tests |
| TLIA3015A | Complete receival/despatch documentation |
| TLIA3016A | Use inventory systems to organise stock control |
| TLIA3018A | Organise despatch operations |
| TLIA3019A | Organise receival operations |

| TLIA3026A | Monitor storage facilities |
|-----------|----------------------------|
| TLIA3038A | Control and order stock |
| TLIA3039A | 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 |
| BSBCUS301B | 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 |
| HLTFA301C | Apply first aid |
| MSS402010A | Manage the impact of change on own work |
| MSS403010A | Facilitate change in an organisation implementing competitive systems and practices |
| MSS402001A | Apply competitive systems and practices |
| MSS402002A | Sustain process improvements |
| MSS403002A | Ensure process improvements are sustained |
| MSS402021A | Apply Just in Time procedures |
| MSS402030A | Apply cost factors to work practices |
| MSS402031A | Interpret product costs in terms of customer requirements |
| MSS402040A | Apply 5S procedures |
| MSS402050A | Monitor process capability |
| MSS402051A | Apply quality standards |
| MSS402060A | Use planning software systems in operations |

| MSS402061A | Use SCADA systems in operations |
|---|---|
| MSS402080A | Undertake root cause analysis |
| MSS402081A | Contribute to the application of a proactive maintenance strategy |
| MSS403021A | Facilitate a Just in Time system |
| MSS403023A | Monitor a levelled pull system of operations |
| MSS403040A | Facilitate and improve implementation of 5S |
| MSS403041A | Facilitate breakthrough improvements |
| MSS404050A | Undertake process capability improvements*<br>*MSS404052A Apply statistics to operational processes* |
| MSS403051A | Mistake proof an operational process |
| MSS404052A | Apply statistics to operational processes |
| MSS404060A | Facilitate the use of planning software systems in a work area or team |
| MSS404082A | Assist in implementing a proactive maintenance strategy |
| MSS404083A | Support proactive maintenance |
| MSAPMOPS405A | Identify problems in fluid power system |
| MSAPMOPS406A | Identify problems in electronic control systems |
| MSAPMPER300C | Issue work permits*<br>*RIIRIS201B Conduct local risk control* |
| MSAPMSUP310A | Contribute to development of plant documentation |
| MSAPMSUP390A | Use structured problem solving tools |
| MSL922001A | Record and present data |
| TAEASS401B | Plan assessment activities and processes |
| TAEASS402B | Assess competence |
| TAEASS403B | Participate in assessment validation |
| TAEDEL301A | Provide work skill instruction |

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