



**Australian Government**

**Department of Education, Employment and Workplace Relations**

# **FDF20211 Certificate II in Pharmaceutical Manufacturing**

**Release 3**

## **FDF20211 Certificate II in Pharmaceutical Manufacturing**

### **Modification History**

This Qualification supersedes and is equivalent to FDF20210 Certificate II in Pharmaceutical Manufacturing.

September 2012: Replacement of superseded imported Units.

April 2012: Update of imported SUG Units to new FDFSUG Units. Minor typographical corrections.

November 2011: Update to imported Units, including one non-equivalent Unit. Minor edits.

### **Description**

This Qualification covers the Pharmaceutical Manufacturing specialisation.

#### **Job Roles**

The Certificate II in Pharmaceutical Manufacturing targets those working within production or production support roles, such as packing within pharmaceutical manufacturing environments. This Qualification is designed for application in supervised environments where the work is predictable with some basic problem solving requirements.

#### **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:

- FDF10110 Certificate I in Food Processing or FDF10210 Certificate I in Pharmaceutical Manufacturing
- direct entry
- limited vocational training and/or work experience.

### **Pathways from the Qualification**

After achieving this Qualification, candidates may undertake FDF30210 Certificate III 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

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.

<b>Employability Skill</b>	<b>Industry/enterprise requirements for this Qualification include:</b>
Communication	<ul style="list-style-type: none"> <li>• Complete work forms and required written documentation.</li> <li>• Use communication and information technologies to support work operations.</li> <li>• Demonstrate effective and appropriate interpersonal skills.</li> <li>• Interpret and apply workplace procedures and instructions.</li> <li>• Share workplace information.</li> <li>• Communicate information about problems with work.</li> <li>• Communicate information relating to OHS.</li> </ul>
Teamwork	<ul style="list-style-type: none"> <li>• Work as part of a team.</li> <li>• Provide assistance to others in the work area.</li> <li>• Identify own role and responsibilities within a team.</li> <li>• Identify team goals.</li> <li>• Share work-related information.</li> <li>• Maintain health and safety of work area for self and others.</li> </ul>
Problem-solving	<ul style="list-style-type: none"> <li>• Identify and report any workplace hazards.</li> <li>• Identify workplace problems and make contributions to their solution.</li> <li>• Identify health and safety issues relating to work in the food industry.</li> <li>• Apply knowledge of materials, product purpose and processes to work operations.</li> <li>• Check performance of machines and equipment and identify signs of faulty operations.</li> <li>• Monitor workplace activities and identify and report non-compliances.</li> </ul>
Initiative and enterprise	<ul style="list-style-type: none"> <li>• Provide feedback on procedures and processes.</li> <li>• Gather and interpret information to support safe and efficient work.</li> <li>• Ask questions regarding requirements and expectations.</li> <li>• Make suggestions for continuous improvement.</li> <li>• Inspect quality of work on an ongoing basis.</li> <li>• Record basic information on the quality and other indicators of work outcomes.</li> </ul>

Planning and organising	<ul style="list-style-type: none"> <li>• Identify work requirements and work load priorities.</li> <li>• Plan work activities to meet daily work requirements.</li> <li>• Direct items to the correct area for further processing.</li> <li>• Identify and use relevant personal protective equipment.</li> <li>• Organise work area to maintain housekeeping standards.</li> <li>• Select and organise relevant equipment and tools.</li> <li>• Identify and report issues affecting ability to meet work outcomes.</li> </ul>
Self-management	<ul style="list-style-type: none"> <li>• Understand own work activities.</li> <li>• Identify personal responsibilities.</li> <li>• Accept responsibility for quality of own work.</li> <li>• Follow OHS and food safety practices.</li> <li>• Plan to meet required work outcomes of self and team.</li> <li>• Monitor own work.</li> <li>• Maintain own work efficiency.</li> <li>• Keep the work area clean and tidy at all times.</li> </ul>
Learning	<ul style="list-style-type: none"> <li>• Assess own competencies in meeting job requirements.</li> <li>• Listen to feedback and advice of supervisors.</li> <li>• Identify own skill requirements and seek skill development if require.</li> <li>• Attend training or skill development activities.</li> <li>• Ask questions to expand own knowledge.</li> </ul>
Technology	<ul style="list-style-type: none"> <li>• Use work tools, machines and equipment safely and effectively.</li> <li>• Perform minor maintenance on machinery in accordance with workplace practice.</li> <li>• Use manual handling technologies in the workplace.</li> </ul>

## Packaging Rules

This Qualification requires the achievement of **twelve (12)** Units of Competency in accordance with the following rules.

**Total Units must include a minimum of seven (7) Units coded FDF.**

**Four (4) Core Units**

**Eight (8) Elective Units**

**Elective selection must include:**

- Five (5) Group A elective Units

**Three (3) remaining elective Units may be selected from:**

- Group A elective Units below, not previously selected
- Group B elective Units
- Units from this Training Package, any other nationally endorsed Training Package and accredited course that are packaged at Certificate I level (maximum 1 Unit), Certificate II (maximum 2 Units), and Certificate III level (maximum 1 Unit)

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

### CORE UNITS

Complete the following four (4) Units:

FDFOHS2001A	Participate in OHS processes
FDFOP2064A	Provide and apply workplace information
FDFPH2001A	Apply Good Manufacturing Practice procedures
MSAENV272B	Participate in environmentally sustainable work practices

### ELECTIVE UNITS

#### GROUP A

Select a minimum of five (5) Units from the Sector Specialist and Cross Sector Units below. A minimum of one (1) pharmaceutical manufacturing specialist Unit coded FDFPH must be included in the selection.

Sector Specialist Units	
FDFPH2002A	Operate a concentration process
FDFPH2003A	Operate an extraction process
FDFPH2004A	Operate a separation process using chromatography* <i>FDFOP2032A Work in a clean room environment</i>

<b>Sector Specialist Units</b>	
FDFPH2005A	Operate an aseptic fill and seal process* <i>FDFOP2032A Work in a clean room environment</i>
FDFPH2006A	Operate an aseptic form, fill and seal process* <i>FDFOP2032A Work in a clean room environment</i>
FDFPH2007A	Coordinate a label store
FDFPH2008A	Operate a compressing process
FDFPH2009A	Dispense pharmaceutical raw materials
FDFPH2010A	Operate an encapsulation process
FDFPH2011A	Operate a granulation process
FDFPH2012A	Operate a liquid manufacturing process
FDFPH2013A	Operate a tablet coating process
FDFPH2014A	Operate a terminal sterilisation process
<b>Cross Sector Units</b>	
FDFOP1003A	Carry out manual handling tasks
FDFOP2001A	Work effectively in the food processing industry
FDFOP2002A	Inspect and sort materials and product
FDFOP2003A	Clean equipment in place
FDFOP2004A	Clean and sanitise equipment
FDFOP2006A	Operate a bulk dry goods transfer process
FDFOP2007A	Work in a freezer storage area
FDFOP2008A	Operate a bulk liquid transfer process
FDFOP2009A	Load and unload tankers
FDFOP2010A	Work with temperature controlled stock
FDFOP2011A	Conduct routine maintenance
FDFOP2012A	Maintain food safety when loading, unloading and transporting food
FDFOP2013A	Apply sampling procedures
FDFOP2014A	Participate in sensory analyses
FDFOP2015A	Apply principles of statistical process control* <i>FDFOP2061A Use numerical applications in the workplace</i>
FDFOP2016A	Work in a food handling area for non-food handlers
FDFOP2017A	Operate a blending, sieving and bagging process

<b>Sector Specialist Units</b>	
FDFOP2018A	Operate a case packing process
FDFOP2019A	Fill and close product in cans
FDFOP2020A	Operate a form, fill and seal process
FDFOP2021A	Operate a fill and seal process
FDFOP2022A	Operate a high speed wrapping process
FDFOP2023A	Operate a packaging process
FDFOP2024A	Operate a cooling, slicing and wrapping process
FDFOP2025A	Manufacture extruded and toasted products
FDFOP2026A	Operate a forming or shaping process
FDFOP2027A	Dispense non-bulk ingredients
FDFOP2028A	Operate a mixing or blending process
FDFOP2029A	Operate a baking process
FDFOP2030A	Operate a process control interface
FDFOP2031A	Operate a coating application process
FDFOP2032A	Work in a clean room environment* <i>FDFFS2001A Implement food safety program and procedures OR FDFPH2001A Apply Good Manufacturing Practice procedures</i>
FDFOP2033A	Operate a depositing process
FDFOP2034A	Operate an evaporation process
FDFOP2035A	Operate an enrobing process
FDFOP2036A	Operate an extrusion process
FDFOP2037A	Operate a filtration process
FDFOP2038A	Operate a grinding process
FDFOP2039A	Operate a frying process
FDFOP2040A	Operate a heat treatment process
FDFOP2041A	Operate a mixing or blending and cooking process
FDFOP2042A	Operate a drying process
FDFOP2043A	Operate an homogenising process
FDFOP2044A	Operate a retort process
FDFOP2045A	Operate pumping equipment
FDFOP2046A	Operate a production process
FDFOP2047A	Operate a portion saw



<b>Sector Specialist Units</b>	
FDFOP2048A	Pre-process raw materials
FDFOP2049A	Operate a reduction process
FDFOP2050A	Operate a separation process
FDFOP2051A	Operate a spreads production process
FDFOP2052A	Operate a chocolate tempering process
FDFOP2053A	Operate a washing and drying process
FDFOP2054A	Operate a water purification process
FDFOP2055A	Freeze dough
FDFOP2056A	Operate a freezing process
FDFOP2057A	Operate a membrane process
FDFOP2058A	Operate a holding and storage process
FDFOP2059A	Operate a continuous freezing process
FDFOP2060A	Operate an automated cutting process
FDFOP2061A	Use numerical applications in the workplace
FDFPPL2001A	Participate in work teams and groups
FDFSUG222A	Operate a waste water treatment system
MSL973001A	Perform basic tests
MTMPSR203A	Sharpen knives
MTMPSR201C	Vacuum pack product
PMBPROD211B	Operate blow moulding equipment
PMBPROD270B	Operate injection blow moulding equipment
TLIA2009A	Complete and check import/export documentation
TLIA2014A	Use product knowledge to complete work operations
TLIA2021A	Despatch stock
TLIA4025A	Regulate temperature controlled stock
TLID2003A	Handle dangerous goods/hazardous substances
TLID2004A	Load and unload goods/cargo
TLID2010A	Operate a forklift
TLIK2010A	Use infotechnology devices in the workplace

**GROUP B**

FDFOP2005A	Work in a socially diverse environment
FDFSUG218A	Operate a boiler - basic
BSBITU201A	Produce simple word processed documents
BSBITU202A	Create and use spreadsheets
BSBWOR204A	Use business technology
HLTFA201B	Provide basic emergency life support
MSS402010A	Manage the impact of change on own work
MSS402001A	Apply competitive systems and practices
MSS402002A	Sustain process improvements
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
SIRXFIN201	Balance and secure point-of-sale terminal
SIRXFIN002A	Perform retail finance duties
SIRXMER201	Merchandise products
SIRXRSK001A	Minimise theft
SIRXSLS002A	Advise on products and services