Australian Government

Department of Education, Employment and Workplace Relations

FDF50210 Diploma of Pharmaceutical Manufacturing

Release 3

INDUSTRY SKILLS COUNCILS
Creating Australia's Future

FDF50210 Diploma of Pharmaceutical Manufacturing

Modification History

September 2012: Replacement of superseded imported Units.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

Description

This Qualification covers the pharmaceutical manufacturing specialisation.

Job Roles The Diploma of Pharmaceutical Manufacturing targets those in senior management, technician or similar roles within pharmaceutical manufacturing industries. It provides extensive skills and knowledge of industry management functions and environment, and the ability to take responsibility for workplace systems.

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

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:

- FDF40210 Certificate IV in Pharmaceutical Manufacturing
- direct entry
- relevant vocational training and/or work experience.

Pathways from the Qualification
After achieving this Qualification, candidates may undertake a relevant Advanced Diploma Qualification.

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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

Diploma of Pharmaceutical Manufacturing
The following table contains a summary of the Employability Skills as identified by the pharmaceutical manufacturing related 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	• Complete a range of workplace documentation and records. • Select communication technologies to support work operations • Develop work instructions, specifications and procedures. • Demonstrate effective and appropriate communication and interpersonal skills when dealing with people. • Communicate with all people at all levels of the organisation in a professional manner. • Select and apply documentation, communication and interpersonal strategies when dealing with internal and external clients. • Select communication methods according to priority, cost and audience needs. • Analyse and apply technical information. • Analyse data and information to determine implications for work operations.
Teamwork	• Lead cooperative work relations with people of different ages, gender, race or religion. • Provide leadership. • Determine performance required to meet internal and external customer needs. • Manage organisational processes and provide problem solving support to others. • Facilitate team achievements.
Problem-solving	• Investigate problem causes and implement corrective strategies. • Identify and address potential and actual problems associated with work operations or in achieving work outcomes. • Identify environmental features, regulations, insurance requirements, legal requirements and other factors which may affect the product or service to be provided. • Use material and process knowledge to solve problems. • Identify hazards and suggest control measures. • Analyse food safety practices.
Initiative and enterprise	• Determine information gathering requirements to monitor work processes and procedures.

	• Determine quality and other indicators of work. • Identify efficient production processes. • Determine and act on situations requiring further information or problem solving. • Implement continuous improvement processes. • Provide leadership in the workplace. • Implement business development processes.
Planning and organising	• Identify hazards and implement appropriate hazard control measures. • Demonstrate time management skills. • Determine resource requirements. • Determine work timelines and output targets. • Optimise work processes. • Conduct business planning processes.
Self-management	• Analyse implications of relevant acts and regulations on work practices. • Monitor work operations and identify and act on any quality and performance issues. • Manage own time to meet deadlines. • Determine workplace procedures and instructions. • Conduct work reviews to determine improvement requirements.
Learning	• Develop learning opportunities. • Be supportive, assertive and use interpersonal skills to encourage workplace learning. • Identify own training needs and seek skill development if required. • Gather feedback to own work to assess effectiveness in meeting objectives and integrate information into own practice. • Assess work data and information to identify areas for improved performance. • Maintain currency of industry skill and knowledge.
Technology	• Select computer software applications to perform work operations. • Work with technology safely and according to workplace standards. • Help others use technology efficiently and safely. • Ensure readiness and operational efficiency of workplace technology.

Packaging Rules

This Qualification requires the achievement of **twenty nine** (**29**) Units of Competency in accordance with the following rules.

Total Units must include a minimum of eleven (**11**) **Units coded FDF**.
Nine (**9**) **Core Units**
Twenty (**20**) **Elective Units**

Elective selection must include:

- One (1) Group A elective Unit
- One (1) Group B elective Unit
- Six (6) Group C elective Units
- Five (5) Specialist and Cross Sector Units packaged at Certificate IV Group C

Seven (**7**) **remaining elective Units may be selected from**:

- Group A elective Units below, not previously selected
- Group B elective Units below, not previously selected
- Group C elective Units below, not previously selected
- Group D elective Units
- Units packaged at FDF30210 Certificate III in Pharmaceutical Manufacturing or FDF40210 Certificate IV in Pharmaceutical Manufacturing (maximum of 5)
- Units packaged at FDF20210 Certificate II in Pharmaceutical Manufacturing (maximum of 5)
- A maximum of 4 Units from any nationally endorsed Training Package and accredited course that are packaged at Certificate II level (maximum 2 Units), Certificate III level (maximum 2 Units), Certificate IV level (maximum 3 Units), Diploma or Advanced Diploma level (maximum 3 Units)

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

CORE UNITS

Complete the following nine (9) Units:

FDFPH4001A	Prepare and review workplace documentation to support GMP
FDFPH4002A	Facilitate and monitor Good Manufacturing Practice
FDFPH4003A	Facilitate contamination control
FDFPH4005A	Participate in validation processes
FDFPH4006A	Respond to non-conformance

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FDFPH4001A	Prepare and review workplace documentation to support GMP
FDFPPL3002A	Report on workplace performance
FDFPPL4001A	Manage people in the work area
FDFTEC4007A	Describe and analyse data using mathematical principles
MSAENV472B	Implement and monitor environmentally sustainable work practices

ELECTIVE UNITS

GROUP A

Select a minimum of one (1) Group A elective Units.

FDFOHS4001A	Identify, assess and control OHS risk in own work
FDFOHS5001A	Manage OHS processes

GROUP B

Select a minimum of one (1) Group B elective Units.

FDFOP3003A	Operate inter-related processes in a production system
FDFOP3004A	Operate inter-related processes in a packaging system

GROUP C

Select a minimum of six (6) Group C elective Units.

FDFPPL4003A	Schedule and manage production
FDFPPL4007A	Manage supplier agreements and contracts
FDFPPL5001A	Design and maintain programs to support legal compliance
FDFTEC5001A	Manage and evaluate new product trials
FDFTEC5002A	Manage utilities and energy for a production process
BSBATSIM507B	Establish and maintain a strategic planning cycle

FDFPPL4003A	Schedule and manage production
BSBCOM502B	Evaluate and review compliance
BSBCOM503B	Develop processes for the management of breaches in compliance requirements
BSBMGT502B	Manage people performance
BSBMGT515A	Manage operational plan
BSBMGT516C	Facilitate continuous improvement
BSBPMG510A	Manage projects
MEM15001B	Perform basic statistical quality control
MSS405011A	Manage people relationships
MSS405001A	Develop competitive systems and practices for an organisation
MSS405020A	Develop quick changeover procedures
MSS405050A	Determine and improve process capability* MSS404052A *Apply statistics to operational processes*
MSS405070A	Develop and manage sustainable energy practices
MSACMT671A	Develop and manage sustainable environmental practices

GROUP D

BSBCUS501C	Manage quality customer service
BSBFIM501A	Manage budgets and financial plans
BSBMKG501B	Identify and evaluate marketing opportunities
BSBOHS503B	Assist in the design and development of OHS participative arrangements
BSBWOR502A	Ensure team effectiveness
MSS403010A	Facilitate change in an organisation implementing competitive systems and practices

BSBCUS501C	Manage quality customer service
MSS405010A	Manage relationships with non-customer external organisations
MSS405012A	Manage workplace learning
MSS405013A	Facilitate holistic culture improvement in an organisation
MSS405014A	Develop a communications strategy to support operations
MSS405002A	Analyse and map a value stream
MSS405006A	Develop a Balanced Scorecard
MSS405007A	Introduce competitive systems and practices to a small or medium enterprise
MSS402030A	Apply cost factors to work practices
MSS402080A	Undertake root cause analysis
MSS404052A	Apply statistics to operational processes
MSS405022A	Design a process layout
MSS405023A	Develop a levelled pull system for operations and processes
MSS405030A	Optimise cost of a product or service
MSS405031A	Undertake value analysis of product or process costs in terms of customer requirements
MSS405032A	Analyse cost implications of maintenance strategy
MSS405040A	Manage 5S system in an organisation
MSS405061A	Determine and establish information collection requirements and processes
MSS405062A	Develop a documentation control strategy for an organisation
MSS405075A	Facilitate the development of a new product* *MSS404052A Apply statistics to operational processes*

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BSBCUS501C	Manage quality customer service
MSS405081A	Develop a proactive maintenance strategy
MSS405082A	Adapt a proactive maintenance strategy to the process operations sector* *MSS405081A Develop a proactive maintenance strategy*
MSS405083A	Adapt a proactive maintenance strategy for a seasonal or cyclical business* *MSS405081A Develop a proactive maintenance strategy*
MSS405060A	Develop the application of enterprise control systems in an organisation

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