Australian Government

Department of Education, Employment and Workplace Relations

FDF50210 Diploma of Pharmaceutical Manufacturing

Revision Number: 1

FDF50210 Diploma of Pharmaceutical Manufacturing

Modification History

Not applicable.

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.

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.

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.
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Pathways Information

Not applicable.

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.

Employability Skills Summary

EMPLOYABILITY SKILLS QUALIFICATION 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

EMPLOYABILITY SKILLS QUALIFICATION SUMMARY	
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

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

FDFPH4001A	Prepare and review workplace documentation to support GMP
FDFPH4005A	Participate in validation processes
FDFPH4006A	Respond to non-conformance
FDFPPL3002A	Report on workplace performance
FDFPPL4001A	Manage people in the work area
FDFTEC4007A	Describe and analyse data using mathematical principles
MSAENV472A	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

FDFPPL4003A	Schedule and manage production
FDFTEC5001A	Manage and evaluate new product trials
FDFTEC5002A	Manage utilities and energy for a production process
BSBATSIM507B	Establish and maintain a strategic planning cycle
BSBCOM502B	Evaluate and review compliance
BSBCOM503B	Develop processes for the management of breaches in compliance requirements
BSBMGT502B	Manage people performance
BSBMGT515A	Manage operational plan
BSBMGT516A	Facilitate continuous improvement
BSBPMG510A	Manage projects
MEM15001B	Perform basic statistical quality control
MSACMC611A	Manage people relationships
MSACMS600A	Develop a competitive manufacturing system
MSACMT620A	Develop quick changeover procedures
MSACMT650A	Determine and improve process capability* *MSACMT452A Apply statistics to processes in manufacturing*
MSACMT670A	Develop and manage sustainable energy practices
MSACMT671A	Develop and manage sustainable environmental practices

GROUP D

BSBCUS501A	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

BSBCUS501A	Manage quality customer service
BSBWOR502A	Ensure team effectiveness
MSACMC410A	Lead change in a manufacturing environment
MSACMC610A	Manage relationships with non-customer external organisations
MSACMC612A	Manage workplace learning
MSACMC613A	Facilitate holistic culture improvement in a manufacturing enterprise
MSACMC614A	Develop a communications strategy to support production
MSACMS601A	Analyse and map a value chain
MSACMS605A	Develop a balanced score card for use in competitive manufacturing* *MSACMS601A Analyse and map a value chain* *MSACMT280A Undertake root cause analysis* *MSACMT631A Undertake value analysis of product costs in terms of customer requirements*
MSACMS606A	Introduce competitive manufacturing to a small or medium enterprise
MSACMT230A	Apply cost factors to work practices
MSACMT280A	Undertake root cause analysis
MSACMT452A	Apply statistics to processes in manufacturing
MSACMT622A	Design a process layout
MSACMT623A	Develop a levelled pull system of manufacturing
MSACMT630A	Optimise cost of product* *MSACMT631A Undertake value analysis of product costs in terms of customer requirements*
MSACMT631A	Undertake value analysis of product costs in terms of customer requirements
MSACMT632A	Analyse cost implications of maintenance strategy

BSBCUS501A	Manage quality customer service
MSACMT640A	Manage 5S system in a manufacturing environment
MSACMT661A	Determine and establish information collection requirements and processes
MSACMT662A	Develop a documentation control strategy for a manufacturing enterprise
MSACMT675A	Facilitate the development of a new product* *MSACMT452 Apply statistics to processes in manufacturing*
MSACMT681A	Develop a proactive maintenance strategy
MSACMT682A	Adapt a proactive maintenance strategy to the process manufacturing sector* *MSACMT681A Develop a proactive maintenance strategy*
MSACMT683A	Adapt a proactive maintenance strategy for a seasonal or cyclical manufacturing operation* *MSACMT681A Develop a proactive maintenance strategy*
MSACMT660A	Develop the application of enterprise systems in manufacturing