Australian Government

Department of Education, Employment and Workplace Relations

FDF40210 Certificate IV in Pharmaceutical Manufacturing

Revision Number: 2

ISC INDUSTRY SKILLS COUNCILS
Creating Australia's Future

FDF40210 Certificate IV in Pharmaceutical Manufacturing

Modification History

November 2011: updates to imported units, minor edits.

Description

This qualification covers the Pharmaceutical Manufacturing specialisation.

Job Roles The Certificate IV in Pharmaceutical Manufacturing targets those working in supervisory, middle management or those requiring technical roles within pharmaceutical manufacturing environments. Emphasis is on monitoring of pharmaceutical manufacturing systems and procedures with input into management functions of the organisation.

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:

- FDF30210 Certificate III in Pharmaceutical Manufacturing
- direct entry
- relevant vocational training and/or work experience.

Pathways from **the qualification** After achieving this qualification, candidates may undertake the FDF50210 Diploma of Pharmaceutical Manufacturing or any other suitable qualification.

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
Certificate IV in 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 workplace documentation and records • Use a range of 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 team members in a professional manner • Demonstrate effective and appropriate documentation, communication and interpersonal skills when dealing with internal and external clients • Use most appropriate communication method given priority, cost and audience needs • Access, interpret and apply technical information • Analyse data and information to determine implications for work operations
Teamwork	• Work cooperatively with people of different ages, gender, race or religion • Liaise with and provide support to other team members • Demonstrate leadership skills • Identify and manage performance required to meet internal and external customer needs in own work and team work • Manage organisational processes and provide problem solving support to others
Problem-solving	• Investigate problem causes • Identify, rectify or report potential and actual problems associated with work operations • Identify 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 • Monitor food safety practices

EMPLOYABILITY SKILLS QUALIFICATION SUMMARY

Initiative and enterprise	• Gather and analyse feedback on products, processes and procedures • Assess quality and other indicators of products • Support achievement of efficient production processes • Determine and act on situations requiring further information or problem solving • Assist in the implementation of continuous improvement processes • Provide leadership in the workplace
Planning and organising	• Identify hazards and implement appropriate hazard control measures • Demonstrate time management skills • Source and prepare materials and resources and ensure availability to support work operations • Schedule and sequence work to maximise safety and productivity • Optimise work processes
Self-management	• Interpret and apply relevant acts and regulations • Keep the work area clean and tidy at all times • Monitor own work and work of team and identify and act on any quality issues • Manage own time to meet deadlines • Implement and monitor workplace procedures and instructions
Learning	• Implement learning activities as appropriate to ensure achievement of specified work requirements • 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
Technology	• Use computer software applications effectively • 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 one** (**21**) units of competency in accordance with the following rules.

Total units must include a minimum of eleven (**11**) **units coded FDF**.

Seven (**7**) **Core units**
Fourteen (**14**) **Elective units**

Elective selection must include:

- A minimum of one (1) Group A elective unit
- A minimum of one (1) Group B elective unit
- A minimum of five (5) Specialist Technical Group C elective units
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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 FDF20210 Certificate II in Pharmaceutical Manufacturing (maximum of 3)
- Units packaged at FDF30210 Certificate III in Pharmaceutical Manufacturing (maximum of 5)
- Units packaged at FDF50210 Diploma of Pharmaceutical Manufacturing (maximum of 2)
- 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 4 units), and Diploma level (maximum 2 units)

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

CORE UNITS

Complete the following seven (7) units.

FDFPH4001A	Prepare and review workplace documentation to support Good Manufacturing Practice
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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FDFPPL3002A	Report on workplace performance
MSAENV472B	Implement and monitor environmentally sustainable work practices

ELECTIVE UNITS

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

GROUP A

FDFOHS4001A	Identify, assess and control OHS risk in own work
FDFOHS4002A	Maintain OHS processes

Select a minimum of one (1) Group B elective unit

GROUP B

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

Select a minimum of five (5) Group C Specialist Technical and Cross Sector elective units.

GROUP C

Specialist Technical units	
FDFPH4004A	Participate in change control procedures
FDFPH4005A	Participate in validation processes
FDFPPL4002A	Plan and coordinate maintenance
FDFPPL4004A	Optimise a work process* *FDFPPL3001A Participate in improvement processes*
FDFPPL4005A	Establish process capability* *FDFOP2015A Apply principles of statistical process control* *FDFOP2061A Use numerical applications in the workplace* *FDFTEC4007A Describe and analyse data using mathematical principles*
FDFTEC4001A	Determine handling processes for perishable food items
FDFTEC4002A	Manage controlled atmosphere storage
FDFTEC4003A	Control food contamination and spoilage* *FDFFS3001A Monitor the implementation of quality and food safety*

	programs
FDFTEC4004A	Apply basic process engineering principles to food processing* *FDFOP2030A Operate a process control interface* *FDFTEC4007A Describe and analyse data using mathematical principles*
FDFTEC4005A	Apply an understanding of food additives
FDFTEC4006A	Apply an understanding of legal requirements of food production
FDFTEC4007A	Describe and analyse data using mathematical principles* *FDFOP2015A Apply principle of statistical process control* *FDFOP2061A Use numerical applications in the workplace*
FDFTEC4008A	Apply principles of food packaging
FDFTEC4009A	Identify the physical and chemical properties of materials, food and related products
FDFTEC4010A	Manage water treatment processes* *MSAENV272B Participate in environmentally sustainable work practices*
FDFTEC4011A	Participate in product recalls* *FDFFS3001A Monitor the implementation of quality and food safety programs*
MSACMT481A	Undertake proactive maintenance analyses
MSACMT482A	Assist in implementing a proactive maintenance strategy
MSACMT483A	Support proactive maintenance
MSAPMOPS404A	Co-ordinate maintenance
MSAPMOPS405A	Identify problems in fluid power system
MSAPMOPS406A	Identify problems in electronic control systems
MSAPMOPS401A	Trial new process or product
MSAPMOPS400A	Optimise process/plant area* *MSAPMSUP390A Use structured problem solving tools*
PMASUP420B	Minimise environmental impact of process
PMBTECH406A	Diagnose production equipment problems
Cross Sector units	
FDFPPL4001A	Manage people in the work area* *FDFPPL3003A Support and mentor individuals and groups*
FDFPPL4003A	Schedule and manage production
FDFPPL4006A	Manage a work area within budget

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FDFPPL4007A	Manage supplier agreements and contracts
FDFPPL4008A	Manage internal audits* *FDFOHS2001A Participate in OHS processes* *FDFOP2063A Apply quality systems and procedures* *FDFPPL3005A Participate in an audit process* MSAENV272B Participate in environmentally sustainable work practices
BSBINN301A	Promote innovation in a team environment
BSBLED401A	Develop teams and individuals
BSBMGT402A	Implement operational plan
BSBMGT403A	Implement continuous improvement
BSBSMB407A	Manage a small team
MSACMC411A	Lead a competitive manufacturing team
MSACMS400A	Implement a competitive manufacturing system
MSACMS401A	Ensure process improvements are sustained
MSACMT430A	Improve cost factors in work practices
MSACMT432A	Analyse manual handling processes
MSACMT450A	Undertake process capability improvements* *MSACMT452A Apply statistics to processes in manufacturing*
MSACMT451A	Mistake proof a production process
MSACMT452A	Apply statistics to processes in manufacturing
TAEASS401A	Plan assessment activities and processes
TAEASS402A	Assess competence
TAEASS403A	Participate in assessment validation
TAEDES401A	Design and develop learning programs

GROUP D

FDFOHS2001A	Participate in OHS processes
FDFOP2030A	Operate a process control interface
FDFOP2061A	Use numerical applications in the workplace
FDFOP2063A	Apply quality systems and procedures
FDFPPL3005A	Participate in audit processes
AHCBUS405A	Participate in an e-business supply chain

BSBCUS501B	Manage quality customer service
BSBHRM402A	Recruit, select and induct staff
BSBMGT401A	Show leadership in the workplace
BSBRES401A	Analyse and present research information
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
BSBSMB405A	Monitor and manage small business operations
BSBSMB406A	Manage small business finances
BSBWOR401A	Establish effective workplace relationships
BSBWOR402A	Promote team effectiveness
BSBWOR403A	Manage stress in the workplace
BSBWOR404B	Develop work priorities
BSBWRT401A	Write complex documents
MEM15001B	Perform basic statistical quality control
MSACMC410A	Lead change in a manufacturing environment
MSACMC413A	Lead team culture improvement
MSACMS405A	Lead a manufacturing team using a balanced score card approach
MSACMT260A	Use planning software systems in manufacturing
MSACMT261A	Use SCADA systems in manufacturing
MSACMT280A	Undertake root cause analysis
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
MSACMT453A	Use six sigma techniques* *MSACMT452A Apply statistics to processes in manufacturing*
MSACMT460A	Facilitate the use of planning software systems in manufacturing* *MSACMT260A Use planning software systems in manufacturing*
MSACMT461A	Facilitate SCADA systems in a manufacturing team or work area*

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	MSACMT261A Use SCADA systems in manufacturing
MSAENV272B	Participate in environmentally sustainable work practices
MSAPMPER201A	Monitor and control work permits
MSAPMPER300C	Issue work permits* *RIIRIS201B Conduct local risk control*
MSAPMPER400A	Coordinate permit process* *MSAPMPER300C Issue work permits* *RIIRIS201B Conduct local risk control*
MSAPMSUP310A	Contribute to the development of plant documentation
MSAPMSUP390A	Use structured problem solving tools
RIIRIS201B	Conduct local risk control