FBP40518 Certificate IV in Pharmaceutical Manufacturing

Release 1

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Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Qualification Description

This qualification reflects the skills and knowledge for team leaders, supervisors and specialist technical roles within pharmaceutical manufacturing environments. The qualification includes technical skills, problem solving and supervisory skills to operate, monitor and improve the performance of pharmaceutical manufacturing systems, processes and team members.

Work must comply with good manufacturing practice, health and safety and environmental regulations and legislation that apply to the workplace.

No occupational licensing, legislative or certification requirements apply to this qualification at the time of publication.

Entry Requirements

There are no entry requirements for this qualification.

Packaging Rules

To achieve this qualification, competency must be demonstrated in:

- 16 units of competency:
  - 8 core units, plus
  - 8 elective units.

Elective units must ensure the integrity of the qualifications' Australian Qualification Framework (AQF) alignment and contribute to a valid, industry-supported vocational outcome. The electives are to be chosen as follows:

- 4 must be from group A
- 4 from the remaining units listed in groups A or B, or any currently endorsed Training Package or accredited course packaged at Certificate III, Certificate IV or Diploma, with no more than 2 units packaged at Certificate III or Diploma.

Core Units

BSBSMB407	Manage a small team
BSBWHS401	Implement and monitor WHS policies, procedures and programs to meet legislative requirements
FBPPHM4001	Monitor and maintain good manufacturing practice requirements
FBPPHM4002	Prepare and review workplace documentation to support good manufacturing practice requirements
FBPPHM4003	Facilitate contamination control
FBPPHM4005	Participate in validation of pharmaceutical manufacturing processes
FBPPHM4006	Respond to non-conformance
FBPPPL3006	Report on workplace performance

Elective Units

Group A

FBPOPR3005	Operate interrelated processes in a production system
FBPOPR3006	Operate interrelated processes in a packaging system
FBPPHM3002	Operate a pharmaceutical production process
FBPPHM3003	Work in a controlled environment
FBPPHM3004	Clean and sanitise facilities and equipment
FBPPHM4004	Participate in change control procedures
FBPPPL4002	Plan and coordinate production equipment maintenance
FBPTEC4007	Describe and analyse data using mathematical principles
FBPTEC4011*	Establish process capability
MSMOPS400	Optimise process/plant area
MSMSUP406	Identify faults in electronic control
MSMWHS401	Assess risk
MSS403011	Facilitate implementation of competitive systems and practices

MSS403032	Analyse manual handling processes
MSS403085	Ensure process improvements are sustained
MSS403087	Mistake proof an operational process
MSS404052	Apply statistics to operational processes
MSS404061	Facilitate the use of SCADA systems in a team or work area
MSS404082	Assist in implementing a proactive maintenance strategy
MSS404084	Undertake process capability improvements
PMBTECH406	Diagnose production equipment problems

Group B

BSBHRM405	Support the recruitment, selection and induction of staff
BSBINN301	Promote innovation in a team environment
BSBLDR402	Lead effective workplace relationships
BSBLDR403	Lead team effectiveness
BSBLED401	Develop teams and individuals
BSBMGT401	Show leadership in the workplace
BSBMGT402	Implement operational plan
BSBMGT403	Implement continuous improvement
BSBRES411	Analyse and present research information
BSBWOR403	Manage stress in the workplace
BSBWOR404	Develop work priorities
FBPOPR2069	Use numerical applications in the workplace
FBPOPR4001	Apply principles of statistical process control
FBPPPL3005	Participate in an audit process
MSL922001	Record and present data

MSMPER300*	Issue work permits
MSMSUP390	Use structured problem-solving tools
MSMWHS201	Conduct hazard analysis
MSS402080	Undertake root cause analysis
MSS402083	Use planning software systems in operations
MSS403010	Facilitate change in an organisation implementing competitive systems and practices
MSS403021	Facilitate a Just in Time system
MSS403023	Monitor a levelled pull system of operations
MSS403040	Facilitate and improve implementation in 5S
MSS403041	Facilitate breakthrough improvements
MSS404053	Use DMAIC techniques
MSS404060	Facilitate the use of planning software systems in a work area or team
TAEASS402	Assess competence
TAEASS403	Participate in assessment validation
TAEDEL301	Provide work skill instruction

Prerequisite requirements

Unit of competency	Prerequisite requirement
FBPTEC4011 Establish process capability	FBPTEC4007 Describe and analyse data using mathematical principles
MSMPER300 Issue work permits	MSMWHS201 Conduct hazard analysis

Qualification Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status

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FBP40518 Certificate IV in Pharmaceutical Manufacturing	FDF40210 Certificate IV in Pharmaceutical Manufacturing	Updated to meet Standards for Training Packages The number of units to achieve the qualification reduced from 21 to 16 Changes to packaging rules, core and elective units	No equivalent qualification

Links

Companion Volume Implementation Guides are found in VETNet: - https://vetnet.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4