Australian Government

FBP40522 Certificate IV in Pharmaceutical Manufacturing

Release 1

FBP40522 Certificate IV in Pharmaceutical Manufacturing

Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 7.0.

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 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

BSBLDR414	Lead team effectiveness

BSBWHS411	Implement and monitor WHS policies, procedures and programs
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

FBPOPR3019	Operate and monitor interrelated processes in a production or packaging system
FBPPHM3003	Work in a controlled environment
FBPPHM3004	Clean and sanitise facilities and equipment
FBPPHM3021	Operate a pharmaceutical production process
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

Skills Impact

MSS403032	Analyse manual handling processes
MSS403085	Ensure process improvements are sustained
MSS403087	Mistake proof an operational process
MSS404054	Apply statistics to operational processes
MSS404061	Facilitate the use of SCADA systems in a team or work area
MSS404084	Undertake process capability improvements
MSS404086	Assist in implementing a proactive maintenance strategy
PMBTECH406E	Diagnose production equipment problems

Group B

BSBHRM413	Support the learning and development of teams and individuals
BSBHRM415	Coordinate recruitment and onboarding
BSBINS401	Analyse and present research information
BSBLDR411	Demonstrate leadership in the workplace
BSBLDR413	Lead effective workplace relationships
BSBOPS402	Coordinate business operational plans
BSBPEF401	Manage personal health and wellbeing
BSBPEF402	Develop personal work priorities
BSBSTR401	Promote innovation in team environments
BSBSTR402	Implement continuous improvement
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 of 5S
MSS404053	Use DMAIC techniques
MSS403054	Facilitate breakthrough improvements
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	Code and title	Comments	Equivalence status

current version	previous version		
FBP40522 Certificate IV in Pharmaceutical Manufacturing	FBP40518 Certificate IV in Pharmaceutical Manufacturing	Unit codes, including core unit, updated to reflect current codes	Not equivalent

Links

Companion Volumes, including Implementation Guides, are available at VETNet: - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4