Modification History

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

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| FDF40218 | Certificate IV in Pharmaceutical Manufacturing |
| Qualification DescriptionThis Qualification covers the Pharmaceutical Manufacturing specialisation and targets those working in team leader, 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. It builds upon industry specific skills and knowledge and allows greater emphasis on leadership, problem solving as well as increased technical ability.Work must comply with good manufacturing practice, work 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 RequirementsThere are no entry requirements for this qualification. |
| Packaging RulesTo achieve this qualification, competency must be demonstrated in: * 21 units of competency:
* 7 core units plus
* 14 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:* at least 6 units coded FDF
* 1 from electives Group A below
* 1 from electives Group B below
* 5 from electives Group C below
* 7 from electives Group A, B, C or D below, or any currently endorsed Training Package or accredited course.
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| Core Units

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| FDFPHM4001 | Prepare and review workplace documentation to support good manufacturing practice requirements |
| FDFPHM4XXX | Monitor and maintain good manufacturing practice requirements |
| FDFPHM4003 | Facilitate contamination control |
| FDFPHM4005 | Participate in validation processes |
| FDFPHM4006 | Respond to non-conformance |
| FDFPPL3002 | Report on workplace performance |
| MSMENV472 | Implement and monitor environmentally sustainable work practices |

Elective UnitsGroup A

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| FDFWHS4001 | Identify, assess and control WHS risk in own work |
| FDFWHS4002 | Maintain WHS processes |

Group B

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| FDFOP3003 | Operate interrelated processes in a production system |
| FDFOP3004 | Operate interrelated processes in a packaging system |

Group C

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| BSBINN301 | Promote innovation in a team environment |
| BSBLED401 | Develop teams and individuals |
| BSBMGT402 | Implement operational plan |
| BSBMGT403 | Implement continuous improvement |
| BSBSMB407 | Manage a small team |
| FDFPHM3XXXX | Clean and sanitise facilities and equipment |
| FDFPHM3XXXX | Work in a controlled environment |
| FDFPHM3XXXX | Participate in a pharmaceutical production environment |
| FDFPHM4004 | Participate in change control procedures |
| FDFPPL4001\* | Manage people in the work area |
| FDFPPL4002 | Plan and coordinate maintenance |
| FDFPPL4003 | Schedule and manage production |
| FDFPPL4004\* | Optimise a work process |
| FDFPPL4005\* | Establish process capability  |
| FDFPPL4006 | Manage a work area within budget |
| FDFPPL4007 | Manage supplier agreements and contracts |
| FDFPPL4008\* | Manage internal audits |
| FDFTEC4002 | Manage controlled atmosphere storage |
| FDFTEC4007\* | Describe and analyse data using mathematical principles |
| FDFTEC4010\* | Manage water treatment processes |
| MSS403001 | Review competitive systems and practices |
| MSS403002 | Ensure process improvements are sustained |
| MSS403011 | Facilitate implementation of competitive systems and practices |
| MSS403030 | Improve cost factors in work practices |
| MSS403032 | Analyse manual handling processes |
| MSS403051 | Mistake proof an operational process |
| MSS404050 | Undertake process capability improvements |
| MSS404052 | Apply statistics to operational processes |
| MSS404081 | Undertake proactive maintenance analyses |
| MSS404082 | Assist in implementing a proactive maintenance strategy |
| MSS404083 | Support proactive maintenance |
| MSMOPS400 | Optimise process/plant area |
| MSMOPS401 | Trial new process or product |
| MSMSUP404 | Coordinate maintenance |
| MSMSUP405 | Identify problems in fluid power system |
| MSMSUP406 | Identify problems in electronic control systems |
| PMASUP420 | Minimise environmental impact of process |
| PMBTECH406 | Diagnose production equipment problems |
| TAEASS401 | Plan assessment activities and processes |
| TAEASS402 | Assess competence |
| TAEASS403 | Participate in assessment validation |
| TAEDEL301 | Provide work skill instruction |
| TAEDES401 | Design and develop learning programs |

Group D

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| AHCBUS405 | Participate in an e-business supply chain |
| BSBHRM405 | Support the recruitment, selection and induction of staff |
| BSBLDR402 | Lead effective workplace relationships |
| BSBLDR403 | Lead team effectiveness |
| BSBMGT401 | Show leadership in the workplace |
| BSBRES401 | Analyse and present research information |
| BSBWOR403 | Manage stress in the workplace |
| BSBWOR404 | Develop work priorities |
| BSBWRT401 | Write complex documents |
| FDFPPL3005 | Participate in audit processes |
| MSMPER201 | Monitor and control work permits |
| MSMPER300\* | Issue work permits |
| MSMPER400\* | Coordinate permit process |
| MSMSUP310 | Contribute to the development of plant documentation |
| MSMSUP390 | Use structured problem solving tools |
| MSS402060 | Use planning software systems in operations |
| MSS402061 | Use SCADA systems in operations |
| MSS402080 | Undertake root cause analysis |
| MSS403005 | Facilitate use of a Balanced Scorecard for performance improvement |
| MSS403010 | Facilitate change in an organisation implementing competitive systems and practices |
| MSS403013 | Lead team culture improvement |
| 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 |
| MSS404061 | Facilitate the use of SCADA systems in a team or work area |
| RIIRIS201D | Conduct local risk control |

Prerequisite requirements

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| Unit of competency | Prerequisite requirement |
| FDFPPL4001 Manage people in the work area | FDFPPL3003 Support and mentor individuals and groups |
| FDFPPL4004 Optimise a work process | FDFPPL3001 Participate in improvement processes |
| FDFPPL4005 Establish process capability | FDFOP2015 Apply principles of statistical process control\*FDFOP2061 Use numerical applications in the workplaceFDFTEC4007 Describe and analyse data using mathematical principles |
| FDFPPL4008 Manage internal audits | FDFWHS2001 Participate in WHS processesFDFOP2063 Apply quality systems and proceduresFDFPPL3005 Participate in an audit processMSAENV272B Participate in environmentally sustainable work practices |
| FDFTEC4007 Describe and analyse data using mathematical principles | FDFOP2015 Apply principles of statistical process control\*FDFOP2061 Use numerical applications in the workplace |
| FDFTEC4010 Manage water treatment processes | MSAENV272B Participate in environmentally sustainable work practices |
| MSMPER300 Issue work permits | MSMWHS201 Conduct hazard analysis |
| MSMPER400 Coordinate permit process | MSMPER300 Issue work permits\* |

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| Qualification Mapping Information

| Code and title current version | Code and title previous version | Comments | Equivalence status |
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| FDF40218 Certificate IV in Pharmaceutical Manufacturing  | FDF40210 Certificate IV in Pharmaceutical Manufacturing | Minor changes to meet Standards for Training PackagesUnits added to and deleted from core and electives list | Equivalent qualification |

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