Pharmaceutical Manufacturing Standards Project

Summary of Feedback, Responses and Actions

11 January 2018

This project included the redesign of three draft qualifications and 21 units of competency, and the development of three new units of competency for pharmaceutical manufacturing. The project also identified the deletion of two qualifications and one unit of competency. The revised qualifications, new and redesigned units that will be included in the *FBP Food Beverage and Pharmaceutical Training Package* are listed below.

Qualifications

1. FBP2XX18 Certificate II in Pharmaceutical Manufacturing (which supersedes *FDF20211 Certificate II in Pharmaceutical Manufacturing*)
2. FBP3XX18 Certificate III in Pharmaceutical Manufacturing (which supersedes *FDF30210 Certificate III in Pharmaceutical Manufacturing*)
3. FBP4XX18 Certificate IV in Pharmaceutical Manufacturing (which supersedes *FDF40210 Certificate IV in Pharmaceutical Manufacturing*)

Units

1. FBPPHM2001 Follow work procedures to maintain good manufacturing practice requirements (which supersedes *FDFPH1001A Follow work procedures to maintain Good Manufacturing Practice*)
2. FBPPHM3001 Apply good manufacturing practice requirements (which supersedes *FDFPH2001A Apply Good Manufacturing Practice procedures*)
3. FBPPHM3002 Operate a pharmaceutical production process (new unit)
4. FBPPHM3003 Work in a controlled environment (new unit)
5. FBPPHM3004 Clean and sanitise facilities and equipment (new unit)
6. FBPPHM3005 Operate a concentration process (which supersedes *FDFPH2002A* Operate a concentration process)
7. FBPPHM3006 Operate an extraction process (which supersedes *FDFPH2003A* Operate an extraction process)
8. FBPPHM3007 Operate a separation process using chromatography (which supersedes *FDFPH2004A* Operate a separation process using chromatography)
9. FBPPHM3008 Operate an aseptic fill and seal process (which supersedes *FDFPH2005A* Operate an aseptic fill and seal process)
10. FBPPHM3009 Operate an aseptic form, fill and seal process (which supersedes *FDFPH006A* Operate an aseptic form, fill and seal process)
11. FBPPHM3010 Operate a compressing process (which supersedes *FDFPH2008A* Operate a compressing process)
12. FBPPHM3011 Dispense pharmaceutical raw materials (which supersedes *FDFPH2009A* Dispense pharmaceutical raw materials)
13. FBPPHM3012 Operate an encapsulation process (which supersedes *FDFPH2010A* Operate an encapsulation process)

14. FBPPHM3013 Operate a granulation process (which supersedes *FDFPH2011A* Operate a granulation process)
15. FBPPHM3014 Operate a liquid manufacturing process (which supersedes *FDFPH2012A* Operate a liquid manufacturing process)
16. FBPPHM3015 Operate a tablet coating process (which supersedes *FDFPH2013A* Operate a tablet coating process)
17. FBPPHM3016 Operate a sterilisation process using an autoclave (which supersedes *FDFPH2014A Operate a terminal sterilisation process*)
18. FBPPHM3017 Coordinate a label store (which supersedes *FDFPH2007A Coordinate a label store*)
19. FBPPHM4001 Monitor and maintain good manufacturing practice requirements (which supersedes *FDFPH3001A Monitor and maintain Good Manufacturing Practice procedures*)
20. FBPPHM4002 Prepare and review workplace documentation to support good manufacturing practice requirements (which supersedes *FDFPH4001A* Prepare and review workplace documentation to support Good Manufacturing Practice)
21. FBPPHM4003 Facilitate contamination control (which supersedes *FDFPH4003A* Facilitate contamination control)
22. FBPPHM4004 Participate in change control procedures (which supersedes *FDFPH4004A* Participate in change control procedures)
23. FBPPHM4005 Participate in validation processes (which supersedes *FDFPH4005A* Participate in validation processes)
24. FBPPHM4006 Respond to non-conformance (which supersedes *FDFPH4006A* Respond to non-conformance)

Components proposed for deletion

1. *FDF10210 Certificate I in Pharmaceutical Manufacturing*
2. *FDF50210 Diploma of Pharmaceutical Manufacturing*
3. *FDFPH4002A Facilitate and monitor Good Manufacturing Practice*

The draft qualifications, including the new and redesigned units, and the proposed qualifications and unit for deletion, were available for broader stakeholder consultation and feedback between 31 October and 7 December 2017. Twelve responses were received, representing one State Training Authority (VIC) one training provider (VIC), one Industry Training Advisory Body (ITAB) (QLD), and nine industry (national).

Below is a summary of the issues raised and how these issues have been dealt with. This involves a consideration of the information provided, views of industry stakeholders where known and views provided by the people who are part of the Subject Matter Expert Working Group process. Resolutions are constructed to take into account the needs and views of stakeholders to the extent possible, and to comply with the *Standards for Training Package 2012*. The resolutions may represent a compromise on one or more stakeholder views with the aim of a workable outcome for industry, STAs and Training Providers.

Stakeholders Comments and Identified Issues		Consideration and Proposed Resolution
Certificate II in Pharmaceutical Manufacturing		
1. Industry, National	The targeted workers for the Certificate II are support personnel, i.e. equipment cleaners, facility cleaners, packing line personnel	Added these support roles to the qualification descriptor.
2. Industry, National	Core units should cover; GMP, housekeeping, documentation and record keeping (possibly). Recommend FBPPHM3004 Clean and sanitise facilities and equipment be moved from Group A electives to the core units.	GMP and documentation/record keeping covered in the core of the qualification (FDFOP2064 and FBPPHM2001). Housekeeping/cleaning covered in Group A electives (FDFPHM3004). The SME Working Group agreed to FBPPHM3004 Clean and sanitise facilities and equipment moving from Group A electives to the core units. Packaging rules were adjusted accordingly.
3. Industry, National	Elective units should cover; team work, continuous improvement (CI), quality systems and safety issues.	Safety is covered in the core of the qualification (FBPWHS2001). Teamwork, quality systems and CI covered in Group B electives (BSBWOR203 and FBPOPR2063). No further action.
4. CMM, Vic	The redevelopment of the Certificate II appears very necessary.	Industry agrees and has provided advice to better align the qualification to industry roles.
5. CMM, Vic	The rationalisation of packaging rules to ensure that qualifications are much more accurately focussed to provide the skills and knowledge required by the industry is a sound approach. Care must be taken to ensure that the full diversity of the industry sector is still provided for. Flexibility around 'imported units' must be provided but should not be excessive so as to lead to a 'watering down' of the relevance of qualifications to the industry.	The SME Working Group discussed the packaging rules and agreed to the redevelopment of the Certificate II to align with pharmaceutical manufacturing support roles. A redesigned Certificate II in Pharmaceutical Manufacturing (requiring 5 core and 7 electives to achieve) has been created with input from the SME Working Group. While the qualification ensures pharmaceutical manufacture support roles are achieved, it also includes teamwork and logistics units within the electives and allows up to 3 units to be imported as electives.

Certificate III in Pharmaceutical Manufacturing		
6. Industry, National	I like the idea of grouping or specialisations. I am not sure of the significance of the difference. However, I can see that specialising in solid dose, biological, aseptic, quality assurance, warehousing, continuous improvement etc would be helpful for both learners and companies.	The SME Working Group discussed the packaging rules and grouping or specialisations. It was agreed not to proceed with groupings or specialisations as this was not consistent with the variations between workplaces. It was agreed to remove support roles from the qualification descriptor as these roles are targeted by the redesigned Certificate II qualification. The redevelopment of the Certificate III to align with pharmaceutical manufacturing production and packaging roles.
7. CMM, Vic	The rationalisation of packaging rules to ensure that qualifications are much more accurately focussed to provide the skills and knowledge required by the industry is a sound approach. Care must be taken to ensure that the full diversity of the industry sector is still provided for. Flexibility around 'imported units' must be provided but should not be excessive so as to lead to a 'watering down' of the relevance of qualifications to the industry.	The SME Working Group discussed the packaging rules and agreed to the redevelopment of the Certificate III to align with pharmaceutical manufacturing production and packaging roles. A redesigned Certificate III in Pharmaceutical Manufacturing (requiring 5 core and 11 electives to achieve) has been created with input from the SME Working Group. While the qualification ensures pharmaceutical manufacture production and packaging roles are achieved, it also allows up to 2 units to be imported as electives. More than 70 units, many of which are native Food Processing units aligned to Australian Qualifications Framework (AQF) level II have been removed from the listed electives in the qualification. This combined with a tightening of the packaging rules will ensure the qualification outcomes meet industry needs.

Certificate IV in Pharmaceutical Manufacturing		
8. Industry, National	21 units of competency, large number of units for a Certificate IV, consider reducing. Consider reducing the number of electives that can be brought in from another training package.	The SME Working Group discussed the packaging rules and agreed to change the rules so that the total units to achieve the qualification is 16, and to reduce the number of units that can be imported from outside the qualification from 7 to 4.
9. CMM, Vic	The rationalisation of packaging rules to ensure that qualifications are much more accurately focussed to provide the skills and knowledge required by the industry is a sound approach. Care must be taken to ensure that the full diversity of the industry sector is still provided for. Flexibility around 'imported units' must be provided but should not be excessive so as to lead to a 'watering down' of the relevance of qualifications to the industry.	The SME Working Group discussed the packaging rules and agreed to the redevelopment of the Certificate IV to align with pharmaceutical manufacturing team leaders, supervisors and specialist technical roles. A redesigned Certificate IV in Pharmaceutical Manufacturing (requiring 8 core and 8 electives to achieve) has been created with input from the SME Working Group. While the qualification ensures pharmaceutical manufacture team leaders, supervisors and specialist technical roles are achieved, it also allows up to 4 units to be imported as electives. More than 20 units have been removed from the listed electives in the qualification. This combined with a tightening of the packaging rules will ensure the qualification outcomes meet industry needs.

Stakeholders Comments and Identified Issues		Consideration and Proposed Resolution
Twenty one (21) redesigned units		
10. STA, Vic	While transitioning these units we would ask that you remove bold and italic formatting which links the Range Statements to Performance Criteria. This type of formatting is not supported by the 2012 standards.	The term Range Statement was part of the TRAINING PACKAGE DEVELOPMENT HANDBOOK GUIDELINES but it is not used in the Standards for Training Packages 2012 (STP 2012) Range of Conditions is part of the Unit of Competency template available in the STP 2012. This template does not include any reference on how to format any text. There are precedents of RoC statements in units of competency endorsed recently by the AISC that have as bold and italic formatting on terms in Performance Criteria that are subsequently expanded upon in the RoC. Skills Impact understands Training Package users appreciate the bold and italic formatting when navigating units of competency, so will continue this practice.
11. ITAB, Qld	FDFPHM1001 Follow work procedures to maintain good manufacturing practice, should be recoded to AQF2.	The unit has been reviewed, modified slightly and recoded to align with AQF level 2; FBPPHM2001 Follow work procedures to maintain good manufacturing practice requirements.
12. ITAB, Qld	FDFPHM3XXX Implement good manufacturing practice, implement seems too high for an AQF3 unit, perhaps “apply” or “follow”.	The unit has been reviewed and the title updated. The unit code and title is now; FBPPHM3001 Apply good manufacturing practice requirements.
13. Industry, National	FBPPHM3001 Apply good manufacturing practice requirements, recommend changes to: • Performance Criteria 2.1, 5.3 and 6.3 • Range of Conditions • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria, Range of Conditions, Performance Evidence and Knowledge Evidence.
14. Industry, National	FBPPHM3008 Operate an aseptic fill and seal process, recommend changes to: • Application • Performance Criteria 1.1, 1.2, 1.3, 1.7, 2.8 and 3.2 • Range of Conditions • Performance Evidence	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Application, Performance Criteria, Range of Conditions, Performance Evidence, Knowledge Evidence and Assessment Conditions.

Stakeholders Comments and Identified Issues		Consideration and Proposed Resolution
	• Knowledge Evidence • Assessment Conditions.	
15. Industry, National	FBPPHM3009 Operate an aseptic form, fill and seal process, recommend changes to: • Foundation Skills • Range of Conditions • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Foundation Skills, Range of Conditions, Performance Evidence and Knowledge Evidence.
16. Industry, National	FBPPHM3011 Dispense pharmaceutical raw materials, recommend changes to: • Performance Criteria 1.1 • Range of Conditions • Performance Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria, Range of Conditions and Performance Evidence.
17. Industry, National	FBPPHM3014 Operate a liquid manufacturing process, recommend changes to: • Performance Criteria 2.4 • Foundation Skills • Range of Conditions • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria, Foundation Skills, Range of Conditions, Performance Evidence and Knowledge Evidence.
18. Industry, National	FBPPHM3016 Operate a sterilisation process using an autoclave, recommend changes to: • Unit title change from “Operate a terminal sterilisation process” to “Operate a sterilisation process using an autoclave” • Performance Criteria 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.1, 2.3, 3.2 and 3.3 • Foundation Skills • Range of Conditions • Performance Evidence • Knowledge Evidence • Assessment Conditions.	Skills Impact has reviewed the redesigned unit, title changed to “Operate a sterilisation process using an autoclave”, minor revisions have been made to the Performance Criteria, Foundation Skills, Range of Conditions, Performance Evidence, Knowledge Evidence and Assessment Conditions.

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19. Industry, National	FBPPHM4001 Monitor and maintain good manufacturing practice requirements, recommend changes to: • Performance Criteria 1.1, 3.2, 3.3 and 3.4 • Element 4 and 5 – remove (covered in FBPPHM4005) • Element 6 – change to “Take corrective and preventative action in response to GMP non-compliance” and renumber Performance Criteria • Foundation Skills • Range of Conditions • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria, Foundation Skills, Range of Conditions and Knowledge Evidence. Element 4 and 5 have been removed. Element 6 has been renumbered to 4 and changed to “Maintain and facilitate continuous improvement of GMP” and the Performance Criteria have been renumbered.
20. Industry, National	FBPPHM4002 Prepare and review workplace documentation to support good manufacturing practice requirements, recommend changes to: • Application • Performance Criteria 1.1, 1.2, 1.3 and 1.4 • Element 2 split into two elements “Develop workplace documentation” and “Communicate changes to workplace documentation” and rework/renumber all Performance Criteria in new elements • Foundation Skills.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Application Performance Criteria and Foundation Skills. Element 2 has been split into two elements “Finalise workplace documentation to meet GMP requirements” and “Communicate changes to workplace documentation” the Performance Criteria for the new elements have been renumbered and rewritten.
21. Industry, National	FBPPHM4003 Facilitate contamination control, recommend changes to: • Application • Performance Criteria 1.3 • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Application, Performance Criteria, Performance Evidence and Knowledge Evidence.
22. Industry, National	FBPPHM4004 Participate in change control procedures, recommend changes to: • Performance Criteria 1.1 • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria and Knowledge Evidence.

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23. Industry, National	FBPPHM4005 Participate in validation processes, recommend changes to: • Performance Criteria 1.3 and 2.3 • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Performance Criteria and Knowledge Evidence.
24. Industry, National	FBPPHM4006 Respond to non-conformance, recommend changes to: • Application • Performance Criteria 1.3, 2.2 and 3.3 • Foundation Skills • Knowledge Evidence.	Skills Impact has reviewed the redesigned unit, minor revisions have been made to the Application, Performance Criteria, Foundation Skills and Knowledge Evidence.
Three (3) new units		
25. Industry, National	FBPPHM3002 Operate a pharmaceutical production process, recommend changes to: • Title • Performance Criteria 1.3 • Range of Conditions • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the draft unit and sought advice from the SME Working Group. Minor revisions have been made to the Title, Performance Criteria, Range of Conditions, Performance Evidence and Knowledge Evidence.
26. Industry, National	FBPPHM3003 Work in a controlled environment, recommend changes to: • Performance Criteria 1.2 and 3.3 • Range of Conditions • Performance Evidence • Knowledge Evidence.	Skills Impact has reviewed the draft unit and sought advice from the SME Working Group. Minor revisions have been made to the Performance Criteria, Range of Conditions, Performance Evidence and Knowledge Evidence.
27. Industry, National	FBPPHM3004 Clean and sanitise facilities and equipment, recommend changes to: • Performance Criteria 1.1, 1.2, 1.6, 1.9, 3.1, 3.6, 4.5, 5.4 and 5.5 • Range of Conditions	Skills Impact has reviewed the draft unit and sought advice from the SME Working Group. Minor revisions have been made to the Performance Criteria, Range of Conditions, Performance Evidence and Knowledge Evidence.

Stakeholders Comments and Identified Issues		Consideration and Proposed Resolution
	• Performance Evidence • Knowledge Evidence.	

Stakeholders Comments and Identified Issues		Consideration and Proposed Resolution
Components proposed for deletion		
28. CMM, Vic	The deletion of the Certificate I appears appropriate – qualification creep, increasing skill levels required by the industry seem to have rendered this qualification obsolete.	The deletion of the Certificate I will be progressed as part of this project.
29. STA, Vic	Deletion of Certificate I and the redevelopment of Certificate II are a suitable way to move forward with this Training Package.	The deletion of the Certificate I and the redevelopment of the Certificate II will be progressed as part of this project.
30. CMM, Vic	I do not generally support the deletion of qualifications. The current directive to 'delete where possible' is not necessarily a wise approach. Once a qualification is deleted it is very expensive to re-establish. Low or zero enrolments do not necessarily indicate that there is no current or medium term future need for the training product. Zero enrolments can result from many causes; the training product is out of date, the industry is unaware of the existence of the product, government subsidy is not available or has been withdrawn, RTOs have closed down, RTO business models do not currently support delivery. My personal preference would be for there to be an investigation of the supervisory work roles in the sector to determine whether or not the Diploma is relevant. Also low enrolments may well be appropriate for qualifications. Some work roles are essential for an industry sector but only involve a small number of employees. In this case the appropriate qualifications should be available. Maintenance of qualifications is not costly. Redevelopment is hugely expensive!	There were no enrolments in the existing FDF50210 Diploma of Pharmaceutical Manufacturing during 2014 - 2016 Currently, there are no Pharmaceutical Manufacturing sector units of competency which lead to a qualification that would align to AQF Diploma level in the FDF10 Food Processing Training Package The Pharmaceutical Manufacturing sector units in the current FDF50210 Diploma of Pharmaceutical Manufacturing are the same six units (aligned to AQF level IV) listed in the core of the existing Certificate IV in Pharmaceutical Manufacturing. Skills Impact research has confirmed that these six units are suitable for the Certificate IV. The 'Job Roles' section of the existing FDF50210 Diploma of Pharmaceutical Manufacturing states the qualification targets those in senior management, technician and similar roles within Pharmaceutical Manufacturing industries. Consultation with industry during the current project has found that individuals employed in these roles typically require higher education qualifications (such as a Bachelor Degree in Chemistry, Chemical Engineering or Pharmacy) and are then trained in

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31. STA, Vic	With respect to the Diploma, we are not convinced that deletion is the most appropriate decision. We would request that further research and analysis be undertaken to ascertain the future direction of this qualification. Research conducted into supervisory job roles where this qualification may be utilised would be supported.	house by their employer and may undertake other generic business management qualifications. Consultation with industry stakeholders did not reveal a need for a diploma qualification as there are no direct job outcomes. The SME Working Group agrees with the deletion of the Diploma qualification.