Bioprocessing in Pharmaceutical Manufacturing

Summary of Validation Feedback, Responses and Actions
July 2020

Units of competency for the Pharmaceutical Bioprocessing Project were made available on the Skills Impact website for stakeholder 'Validation' from 6 – 19 July 2020 to check that they were accurate. This was following an the earlier 'Drafts Available' round of consultation on the drafts from 15 May – 14 June 2020. Please visit the website to view a full list of the documents that were submitted for consultation during these phases.

During Validation, feedback was received from a variety of stakeholders around the country via email, the Skills Impact Feedback Hub, at face-to-face meetings and webinars, via phone and email, as follows:

	ACT	NSW	NT	Qld	SA	Tas	Vic	WA	National
Industry (employer / employee)	*		*			*			*
Industry Associations	*		*			*			*
Unions			*			*			
Registered Training Organisation (RTO)	*		*		*	*		*	*
Government department	*		*			*			*
Industry Training Advisory Bodies (ITABs) / Industry Skills Boards (ISBs) / Skills Advisory Councils (SAC)	*		*			*			*

** Note: Feedback received from a national industry association and an Industry Training Advisory Body confirming few to no relevant stakeholders in the boxes marked with an asterix*

Feedback received during the 'Drafts Available' period for the units of competency that were developed for bioprocessing in pharmaceutical manufacturing was positive, with minor changes or updates suggested by stakeholders for the majority of the units of competency.

Below is a summary of the issues raised for the draft units of competency reviewed for the Pharmaceutical Bioprocessing Project at the 'Validation' stage, and how these issues have been dealt with. This involves a consideration of the information provided, views of industry stakeholders and from people who are part of the Subject Matter Expert Working Group process. Resolutions are constructed to consider 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, State and Territory Training Authorities (STAs) and training providers.

Acronyms - PC – performance criteria, PE – performance evidence, KE – knowledge evidence, AC – assessment conditions, SMEs – Subject Matter Experts

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Summary of feedback on draft qualification

Comments related to whether there should be a qualification

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• VIC, Industry (employee) • NSW RTO • VIC industry Employer • QLD RTO • Qld Industry	There should not be a qualification for this sector. The SMEWG reviewed the question and a webinar was held to find a resolution. SMEWG decided that the creation of a qualification is not feasible at this time, as there would not be the update in enrolments to sustain it.	Feedback adopted, no qualification has been created at this time.

Summary of feedback on draft Skill Set

Feedback regarding whether there should be a skill set for the unit cluster

Stakeholder Comments and Identified Issues		**Consideration and Proposed Resolution**
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	SMEWG advises that no Skill Set be created at this time.	Feedback adopted, no skill set has been created.

Summary of feedback on draft Units of Competency

General feedback received

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
All units		
• VIC Industry (employee)	Can the Assessment Criteria point from FBHPHM3007 under Specifications- 'Product and intermediate product specifications, control points and processing parameters' be used in all these level 3 units? It's an important point that I only see here	Feedback adopted. All units Assessment Criteria now contain this dot point.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	The Range of Conditions should be removed from all these units. They can limit delivery and as they are written they contribute nothing to the units. Better to take them out.	Feedback adopted. Range of Conditions removed from all units.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Remove mention of GDP (Good Documentation Practice) from the Assessment Conditions in all units.	Feedback adopted.
• VIC industry (employer)	Many of these units are not bioprocessing specific enough and seem more pharmaceutical manufacturing based (although they do work for bioprocessing). Should they be placed in that pharmaceutical sector and new bioprocessing units created?	Units are already in the PHM (Pharmaceutical) unit code sector. SMEWG asked to review this piece of feedback and decided that if new units were created, there would be far too much cross over in content with the existing units. Existing units work for bioprocessing as they are, and as such new units should not be created.

Revised units of competency

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
FBPPHM3005 Operate a concentration process		
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	PC 2.1, Change 'specifications to 'process parameters'	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Remove the list of gowning materials in the PE and just mention the Standard Operating Procedures. Current format is confusing and unnecessary	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	• PE dot point 6, change 'number of passes' to 'process parameters PE dot point 7, reference the Standard Operating Procedures PE, add in new dot point 8 'taken corrective action in response to a non-conformance according to Standard Operating Procedure'	Feedback adopted Feedback adopted. Feedback adopted
FBPPHM3006 Operate an extraction process		
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Remove the list of gowning materials in the PE and just mention the Standard Operating Procedures. Current format is confusing and unnecessary	Feedback adopted.
FBPPHM3XXX Operate a chromatography manufacturing process (formerly FBPPHM3007 Operate a separation process using chromatography)		

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please change the title to better reflect unit content and how it should be used within the industry. New title should be 'Operate a chromatography manufacturing process'	Feedback adopted. Title has been updated.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	PE dot point 4, please delete 'for loading and product info into columns' and replace with 'columns and for loading material into columns'	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	KE dot point 5.1, please remove 'fractions' and replace with 'in process samples, and please add in 'specified in documentation' KE dot point 5.2, please replace 'identifying' with 'interpreting' Please delete KE dot point 5.3	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	AC dot point 2.4, replace existing statement with 'materials dispensed for the process'	Feedback adopted.
FBPPHM3008 Operate an aseptic fill and seal process		
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please delete KE dot point 6	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please replace AC dot point 3.1 with 'product and intermediate product specifications, control points and processing parameters'	Feedback adopted.

FBPPHM3009 Operate an aseptic form, fill and seal process		
		This unit was supported generally, but no significant comments or feedback was received.
FBPPHM3011 Dispense pharmaceutical raw materials		
		This unit was supported generally, but no significant comments or feedback was received.
FBPPHM3014 Operate a liquid manufacturing process		
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	PE dot point 5.3, please re-write to read 'operate the process to meet production requirements' PE dot point 7, please replace the word 'inspected' with 'tested' PE dot point 9.6, please replace the word 'dirty' with 'to be cleaned'	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please delete KE dot point 5.8. Please add in new dot point 8 for KE 'filter system establishment as appropriate to batch requirements' Please delete E dot point 12	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please alter wording of AC dot point 2.1 to read 'personal protective equipment and contamination prevention clothing for a liquid manufacturing process'	Feedback adopted.

FBPPHM30XX Operate a sterilisation process using an autoclave (formerly FBPPHM3016, unit to be re-coded due to changes made during Public Consultation)		
• NSW RTO	Can we remove reference to Good Manufacturing Process (GMP) in this unit so that it is broad enough to be used across scientific sectors. It is a great unit and needs no other tweaking to be appropriate for other sectors, and with instructions from governing bodies to not create new units where existing training already exists, we could not justify creating an identical unit with the only difference not using GMP. I recommend we use the phrase 'Accreditation Requirements', as it encompasses all the official guideline practices.	SMEWG asked to review this piece of feedback. They wished to retain the use of GMP in this unit. This piece of feedback will now be escalated as it needs to be discussed across Industry Reference Committee's (IRC's) for a resolution. A meeting between IRC's will be established and a resolution found then.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please mention Standard Operating Procedures in the PC 1.2	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Insert word 'sterilising' into PE dot points 6.4 and 7. Change the word 'configured' to 'set up' in dot point 7	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Delete dot points 2.1 and 2.2. KE dot point 5, change word 'services' to 'utilities' and replace 'town water' with 'processed water'	

Stakeholder Comments and Identified Issues	Consideration and Proposed Resolution
FBPPHM4003 Facilitate contamination control	

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please change the word ‘workplace’ to ‘process’ in the PE, second sentence before the dot points.	Feedback adopted.
• VIC, Industry (employee) • NSW RTO • VIC industry (employer) • QLD RTO • Qld Industry	Please add word ‘requirements’ to the end of KE dot point 5.7.	Feedback adopted.