Pharmaceutical Bioprocessing Project

Summary of Feedback, Responses and Actions

July 2020

Units of competency for the Bioprocessing in Pharmaceutical Manufacturing project were made available on the Skills Impact website for stakeholder review from 15/5/2020 to 14/6/2020. Please visit the website to view a full list of the documents that were available for consultation during these phases.

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, 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 have been developed for Bioprocessing in Pharmaceutical Manufacturing has been positive, with minor changes or updates to the majority of the units of competency suggested by stakeholders.

Below is a summary of the issues raised for the draft units of competency developed and reviewed for the Pharmaceutical Bioprocessing Project, 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 regarding a qualification

Comments related to whether there should be a qualification

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• VIC, Industry (employee)	There should be a qualification for the unit cluster. It doesn't matter that it's non-deliverable currently in Australia, the knowledge should be captured in case it's needed in the future and a qualification is a good way to do so. If we have a qualification, it might encourage more industry and allow employers to have greater faith in the VET sector, as opposed to hiring staff from universities.	SMEWG to review this piece of feedback. We have received conflicting feedback and further discussion and consultation must be undertaken before a decision is reached.
• VIC, Industry (employee)	Please include the document 'Illustrative guide to manufacturing actives within the scope of Annex 2' from the Application of GMP to Bioprocessing report.	Feedback adopted. This document will appear in the Implementation Guide.
• VIC, Industry (employer)	There should not be a qualification or skill set for this sector. There is not the industry need to sustain it.	SMEWG to review this piece of feedback. We have received conflicting feedback and further discussion and consultation must be undertaken before a decision is reached.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.

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
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
• VIC Industry (Employer)	There should not be a qualification or skill set for this sector. There is not the industry need to sustain it.	Feedback noted.

Summary of feedback on draft Units of Competency

General feedback received

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
All units		
• National Union	From the XX Union's perspective – these are basically OK – we do note that some of the employability skill requirements have been removed from some units.	Thank you for your feedback. Please note: Prior to 19 July 2019, Skills Impact used two frameworks to complete the requirements for Foundation Skills • Australian Core Skills Framework (ACSF) • Core Skills for Work Framework (CSfW) . From 19 July 2019, the CSfW is no longer used in Skills Impact Foundation Skills tables in units of competency.

Revised units of competency

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
FBPPHM3005 Operate a concentration process		
• QLD RTO	It is intended to be a general UoC and for a range of products, not just biologicals	Feedback adopted. The language in this unit works as a general unit of competency for the sector and is not specific to biologicals.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders; however, we have received no feedback to date.	Feedback noted.
• QLD RTO	Covered in GMP	Feedback noted. SMEWG to decide if passage should be altered due to duplication of knowledge, or maintained to retain emphasis on the points mentioned in the KE dot point 1

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• QLD RTO	Don't agree. Not all products require aseptic sampling, e.g. herbal products	Feedback adopted. KE Dot point 9 deleted.
• QLD RTO	Don't agree. A concentration process does not require cleanroom garments for all products.	SMEWG to provide guidance on this piece of feedback. PE dot point 2 stipulates that only one of the following sub-dot points needs to have been performed, not all the gowning requirements.
• QLD RTO	Range is intended to provide flexibility for the RTO. It is inappropriate to include specified conditions as this will negate the flexibility.	Feedback adopted. Statement changed from 'pre-start checks must include' to 'pre-start checks may include'. This is further reinforced by the overarching statement explaining the scope of the Range of Conditions.
• VIC Industry (employee)	Should you break contamination risks microbiological and cross contamination (chemical)?	Feedback adopted. These two contamination risks have been entered into the KE dot point.
• VIC Industry (Employee)	restriction of movement belongs in environmental controls.	Feedback adopted. Restriction of movement added into KE dot point 15
• VIC Industry (Employee)	There should be a knowledge element that is about restriction of movement. And one about bioburden control (more specific than just contamination control).	Feedback adopted. Restriction of movement included in KE dot point 15
• VIC Industry (Employee)	Why is this the only condition listed? (pre-start checks in the Range of Conditions).	No other conditions in the Range of Conditions have been suggested. Please contact Skills Impact to suggest additional conditions to the Range of Conditions if you believe they should be included.
• VIC Industry (Employee)	Typically buffers and/or other reagents are required for a concentration step. Should they be part of the range of conditions? Such buffers should be sterile.	This piece of feedback has been referred to the SMEWG. A buffer might fall under 'all equipment'.

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
	Also - concentration should be conducted in a cleanroom. Is this a a pre- or co-requisite?	Feedback adopted. A pre-start cleanroom check has been added to the Range of Conditions.
• VIC Industry (Employee)	As a general comment, the unit seems fairly generic. Is that the intent? I mean you could meet the requirements of this unit and not be manufacturing a biological product. I would have thought in the Range Statements, you might have listed some typical bioprocessing concentration technologies. Likewise for some typical concentration measurements.	Feedback noted. The unit is generic by design to allow usage cross-sector without affecting it's quality for use within pharmaceutical manufacturing. Feedback noted. SMEWG asked to consider this piece of feedback Range statements have been kept broad to allow for cross-sector use, not just within bioprocessing.
• VIC Industry (Employee)	These are each potentially big topics. What specifically is required to be known? Is it the skill of correctly making the connection or knowing when to use what grade of each type of service?	For a piece of Knowledge Evidence, all that needs to be understood by a person studying the unit is the knowledge that these are the services used in a concentration process. There is no requirement for knowledge of the skill of connection or knowing when to use what grade.
• VIC Industry (Employee)	Product defect might not be observable at the concentration stage - usually relies on process checks (as previously listed). May be better to include take samples for product testing in an aseptic manner.	Feedback adopted. KE Dot point 9 deleted and replaced with what has been recommended.
• VIC Industry (Employee)	need to include face mask and goggles, although goggles might not be required in some workplaces.	Feedback adopted. PE dot point 2 stipulates that only 1 of the following sub-dot points needs to be performed by a student. Face masks have been added and can be used by an RTO on request of an employer who requires the use of face masks.
• VIC Industry (Employee)	I would like to see the term "cleanroom garments" used here e.g. (noting that not all coveralls are disposable. - sterile cleanroom coverall	SMEWG asked to review this piece of feedback as it clashes with an above piece of feedback. PE dot point 2 stipulates that only one of the following sub-dot points needs to have been performed, not all the gowning requirements.

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
FBPPHM3006 Operate an extraction process		
• VIC Industry (Employee)	Why is it only limited to one section of the scope? In days gone past, this use to include specific workplace situations such as different types of processes, equipment etc. I found that quite useful.	SMEWG asked to review this piece of feedback. Range of Conditions can be expanded beyond existing pre-start checks, but under the guidance of industry experts. Specific examples of what to include for Range of Conditions will need to be provided by industry. h
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
• VIC Industry (Employee)	1.7 is too specific. But I like the use of specific terms. Can the examples be included in the Range Statements.	Feedback adopted. Addition of solvents removed from PC 1.7 and added to Range of Conditions.
• VIC Industry (Employee)	This is being too specific. In bioprocessing, "extraction" is called "isolation". And the products of interest are not restricted to phytochemical from organic materials. More often proteins from living cells.	Feedback adopted. Phytochemicals removed from the sentence, ‘extract’ replaced with ‘isolate’.
FBPPHM3007 Operate a separation process using chromatography		
• VIC Industry (Employee)	This is a test for the column performance (efficiency) not the product coming through the system. It is important but not sure if it is what is meant by "sample test methods".	Feedback adopted. Example of sample test method removed.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
FBPPHM3008 Operate an aseptic fill and seal process		

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
• VIC Industry (Employee)	There is both a knowledge and skill item that is missing, which relates to Environmental Monitoring. Operators will need to follow procedures for taking samples of air and surfaces using a variety of sampling devices (air sampling and settle plates and contact plates.)	Feedback adopted. Environmental monitoring and use of these procedures has been added to the Performance Evidence, as it is a task to perform, not simply knowledge to be understood. Please check new draft of unit to make sure this has been captured correctly.
• QLD Industry (employee)	Remove the word 'workplace' from PC 1.4	Feedback adopted.
• QLD Industry (employee)	Range of conditions- include 'undergarments in first block of dot point. Alter dot point 2 to read- Sterile coveralls, overshoes and head covering	Feedback adopted.
• QLD Industry (employee)	KE- Replace 'principles of heat sterilisation' with 'depyrogenation and presterilised components'	Feedback adopted.
• QLD Industry (employee)	PE- Add dot point saying 'become validated for sterile gowning via operator gowning validation' Add environmental monitoring equipment to dot point 7.3 Add the line 'and aseptic components installed' to dot point 7.4	Feedback adopted, developer confirmed with stakeholder that this validation does not constitute prior knowledge or a prerequisite.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.

FBPPHM3009 Operate an aseptic form, fill and seal process		
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products.	Feedback noted.

	The materials have been circulated to stakeholders, however we have received no feedback to date.	
FBPPHM3011 Dispense pharmaceutical raw materials		
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
FBPPHM3014 Operate a liquid manufacturing process		
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
FBPPHM3016 Operate a sterilisation process using an autoclave		
• QLD Industry (employee)	Check the items are dry and that the chemical indicator shows the product has been sterilised.	Feedback adopted.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.
• QLD Industry (employee)	I'm not sure what "post cycle sampling" is? Maybe remove the word "sampling"	Feedback adopted.
• QLD Industry (employee)	Section 2 (2.1) occurs as part of Section 3. Most GMP autoclaves printout a cycle record at the end of the sterilisation cycle so it's important the operator knows how to do this	Feedback adopted.

• NSW RTO	This unit with a little tweaking will work for MSL, PMB and possibly a few other training packages. (This would remove the need to duplicate the unit in the MSL training package) Reword the application to cover a range of industries such as medical, laboratory, polymer processing, food etc Remove GMP, could replace with GxP or accreditation requirements or to standards or similar	Feedback adopted. Application re-tooled for purposes outlined in feedback. Feedback adopted. Application broadened to include these and other fields for cross sector unit use.
• NSW RTO	Replace clothing with covering - in the NSW state veterinary diagnostic laboratory (EMAI) they use foil, paper and other materials	Feedback adopted. Clothing has been removed.
• NSW RTO	Use accreditation requirements again to open the unit up for use in laboratory, food, polymers etc	SMEWG asked to review this piece of feedback. Inclusion of accreditation requirements may restrict those seeking to study the unit, inadvertently placing a barrier on those from these sectors who wish to study it.
• NSW RTO	Remove the words pharmaceutical manufacturing workplace - you only need a workplace or simulated environment - the most important thing is access to the resource and materials listed below.	Feedback adopted.
• NSW RTO	I believe NATA have a technical note on autoclave that might be worth reviewing - maybe change to accreditation requirements as this would cover GMP, GLP, GXP, ISO17025 etc	SMEWG asked to review this piece of feedback. Inclusion of accreditation requirements may restrict those seeking to study the unit, inadvertently placing a barrier on those from these sectors who wish to study it.
• NSW RTO	Not sure all autoclaves still have load probes that you can move?? Maybe say 'Position any movable load probes.... Also, clarify if required area or line clearances applies for all autoclaves	Feedback adopted. Required area or line clearances would not apply for all autoclaves. SMEWG asked how best to include this in the unit

• NSW RTO	Please include me in the consultation I am on the MSL IRC and I would love to use this unit and not need to duplicate it. Thanks :-)	Feedback adopted. Stakeholder emailed and will be included in all future discussions
• QLD Industry (Employee)	Edit Application paragraph 2 to read 'The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the terminal sterilisation of product and sterilisation of goods for aseptic processing using an autoclave. Individuals work under broad direction and take responsibility for their own work.	Feedback adopted.
• QLD Industry (Employee)	Rename Elements 1 and 2 to better represent how the procedure is completed in the workplace. Update the PC's accordingly	Feedback adopted.
• QLD Industry (Employee)	Re-word the PC's in Element 3 to better represent the work undertaken in the workplace. Remove the word 'workplace', include the words 'standard operating' in its place.	Feedback adopted.
• QLD Industry (Employee)	PE- remove word 'workplace' and replace with 'standard operating procedure' Dot point 2- replace list of items with word 'product' or 'material' Dot point 3- replace word 'materials' with 'chemical indicators' Delete dot points 9 and 13 Include a review of the cycle print out	Feedback adopted.
• QLD Industry (Employee)	KE- Dot point 1, reword to include 'autoclave and specify that it's for microbial reduction/ sterility Dot point 2.4, include Fo values. Dot point 3, mention the different cycle types explicitly Dot point 5.2, include new dot point mentioning the service requirements for a GMP Autoclave including air, electricity, steam, town water and supply and cooling water	Feedback adopted. Fo valued to be included in Implementation Guide
• QLD Industry (Employee)	AC- Include loading in bags for dot point 2.2	Feedback adopted.

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
FBPPHM4003 Facilitate contamination control		
• QLD Industry (employee)	The unit doesn't talk much about active air samplers or particle counter used in environmental monitoring of cleanrooms?	Feedback adopted. Air samplers added to KE
• QLD Industry (employee)	...measures "as part of a facility Contamination Control Strategy in a pharmaceutical facility. If you want to also address cross-contamination then they should reference the PIC/S Aide Memoire for Cross-contamination	Feedback adopted, recommended sentence used to replace the former. Use of PIC/S referenced. Please note, it may be further recommended that PIC/S be moved to the Implementation Guide
• QLD Industry (employee)	add Contamination Control Strategy and maybe the PIC/S Aide de Memoire on contamination	Feedback adopted. PIC/S referenced in the PE
• QLD Industry (employee)	I would avoid the term "cross-contamination' as this refers to contamination by other products and is fairly specific. Just use "contamination"	Feedback adopted.
• QLD Industry (Employee)	Application- remove mention of cleaning, sanitation, change control and validation, and replace it all with 'contamination control'	Feedback adopted.
• QLD Industry (Employee)	PE- Dot point 4.1, replace the word regarding with 'including the', and include the Contamination Control Strategy	Feedback adopted.
• QLD Industry (Employee)	KE- Dot point 1.5, add new dot point saying 'product cross-contamination' Include non-viable particle limits, monitoring methods and reporting and recording format and requirements.	Feedback adopted.
• QLD Industry (Employee)	Need to mention PIC/S Annex 1 in the Implementation Guide in regards to this unit	Feedback adopted.
• WA Govt	Thank you for the opportunity to provide feedback on the Pharmaceutical Bioprocessing products. The materials have been circulated to stakeholders, however we have received no feedback to date.	Feedback noted.