Pharmaceutical GMP Project

Summary of Feedback, Responses and Actions

5 November 2021

Draft units of competency for the Pharmaceutical Good Manufacturing Process project were made available on the Skills Impact website for stakeholder review from 23 September to 2 November 2021. Please visit the website to view a full list of the documents that were submitted for consultation during this phase.

Feedback was received from a variety of stakeholders around the country via email, the Skills Impact Feedback Hub and during webinars, as follows:

	ACT	NSW	NT	Qld	SA	Tas	Vic	WA	National
Industry (employer / employee)	*		*			*		*	
Industry association	*	*	*	*	*	*	*	*	
Union	*	*	*	*	*	*	*	*	
Registered Training Organisation (RTO)	*					*		*	*
Government department	*					*			

** Note: Asterix denotes that there is no industry type, RTO, associations or government bodies for the sector within this state or territory. Government departments in NSW, NT, QLD, SA and nationally were contacted with the opportunity to provide feedback, as were RTOs in NT and SA.*

Feedback received during the 'drafts available' period for the units developed as part of the Pharmaceutical GMP Project has been positive, with a mix of minor and major updates suggested by stakeholders.

Below is a summary of the feedback raised for the draft units reviewed for the project, and how these 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 (SMEWG) process. Resolutions are constructed to consider the needs and views of stakeholders to the extent possible, and to comply with the *Standards for Training Packages 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, , SMEWG – Subject Matter Expert Working Group, GMP– Good Manufacturing Process

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Summary of feedback on draft Units of Competency

Revised units of competency

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
General Comments		
VIC RTO VIC Industry Employer VIC Industry Employee VIC Government NSW RTO National Association QLD RTO SA Industry Employee	We approve all changes made to the units during the Public Consultation Phase of the project	Thank you for this feedback
VIC Industry Employee	I think the title could be misleading. Normally the manufacturing industry sector is divided into 'pharmaceutical' and 'healthcare'. While the principles of good manufacturing practice (as a subset of quality assurance) are uniform, the extent to which some GMP practices are applied and enforced are different. My estimate for AU is 90:10 as healthcare:pharma. In past times it was much more heavily in favour of pharma. (Effective systems covering recruitment, induction, training and self-inspection are requirements for all licensed manufacturers. This is a top-down system, applied in AU by the TGA. If I understand the proposed modules, you are looking at a bottom-up system, with additional training provided directly at operational people. There is a need for a module that *explains and tests understanding* of good manufacturing practice as a sub-unit of quality assurance.	Thank you for this feedback. This piece of feedback was reviewed by the SMEWG. They informed Skills Impact that the industry sector name is appropriate, as it is prefaced with 'Pharmaceutical', making it Pharmaceutical Good Manufacturing Practice. The units also fall under the 'Pharmaceutical' cluster. Thank you for this feedback. This project is only reviewing four units of competency specific to Good Manufacturing Practice within the pharmaceutical sector. It is specific to the training within those documents and does not include a complete review of laboratory training requirements. It addresses specific skills required to understand and utilise Good Manufacturing Practices within a workplace. Thank you for this feedback. Understanding of Good Manufacturing Practice is a Knowledge requirement for all four of the units being reviewed, and as such a person undertaking the training must prove competent in their understanding of GMP.
VIC Govt	Is the RTO sector comfortable re-scoping those units that will receive major changes?	All RTOs that currently have these units of competency on their scope were contacted and all have informed Skills Impact that any re-scoping of a unit or units is not an issue as they believe the suggested changes will improve the quality of the training and will improve the outcome of the training.

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
VIC RTO	New wording in Performance Evidence that says 'One or more' in regards to how many times a task must be demonstrated is clear and appropriate.	Thank you for this feedback.
FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements		
VIC Industry Employee	The target audience could be expanded to include junior-level management people as well as production operators, quality control, engineering, maintenance, warehouse and support people (e.g. cleaners and contractors).	Feedback adopted. This level of detail will be included in the Companion Volume Implementation Guide.
WA Govt	Will this unit require be a major or minor change?	Feedback received so far means this unit will receive a minor update as a result of the work undertaken.
FBPPHM3XXX Apply Good Manufacturing Practice requirements		
VIC Govt VIC RTO	Can reference to the Therapeutic Goods Act, Manufacturing Principles and GMP code of practice be re-introduced to the Knowledge Evidence? They are specific to Australia and are critical knowledge for students.	Thank you for this feedback, which has been adopted.
FBPPHM3XXX Operate a pharmaceutical production process		
VIC Govt	Element 1's title should be altered to be read in the 'active' voice. Why was Element 3 deleted?	Thank you for this feedback, which has been adopted. Element 1 now titled *Move goods and components.* The SMEWG identified Element 3 as a duplication of an existing unit of competency and not relevant to applying GMP requirements. Content specific to the unit has been included in PC 2.1.
FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements		
WA Govt	Will this unit require be a major or minor change?	Feedback received so far means this unit will receive a minor update as a result of the work undertaken