

Pharmaceutical GMP Project

Summary of Validation Feedback, Responses and Actions



December 2021

Draft units of competency for the Pharmaceutical Good Manufacturing Process project were made available on the [Skills Impact website](#) for stakeholder review and validation from 3 November to 10 December 2021. Please visit the website to view a full list of the documents that were submitted for validation during this phase.

Validation was received from a variety of stakeholders around Australia 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	*					*			

**Please note - the industry is very small in Australia, and the asterix denotes that there were no identifiable persons to consult with in this jurisdiction/sector.*

Feedback received during the 'Validation period for the units developed as part of the Pharmaceutical GMP project has been positive, with only minor changes suggested since the first drafts.

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

Summary of feedback on draft Units of Competency

Revised units of competency

Stakeholder Comments and Identified Issues		Consideration and Proposed Resolution
FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements		
VIC Industry Employer QLD RTO QLD Industry Employer NSW RTO VIC Govt National Govt National Association	We support the training materials to become nationally endorsed training.	Feedback noted.
FBPPHM3XXX Apply Good Manufacturing Practice requirements		
VIC Industry Employer QLD RTO QLD Industry Employer NSW RTO VIC Govt National Govt National Association	We support the training materials to become nationally endorsed training.	Feedback noted.
VIC Industry Employer QLD RTO QLD Industry Employer NSW RTO VIC Govt National Govt National Association	Can GMP Code of Practice in the KE be changed to Guide to GMP?	Feedback adopted.
FBPPHM3XXX Operate a pharmaceutical production process		
VIC Industry Employer QLD RTO QLD Industry Employer NSW RTO VIC Govt National Govt National Association	We support the training materials to become nationally endorsed training.	Feedback noted.
FBPPHM4001 Monitor and maintain Good Manufacturing Practice requirements		
VIC Industry Employer QLD RTO QLD Industry Employer NSW RTO VIC Govt National Govt National Association	We support the training materials to become nationally endorsed training.	Feedback noted.