Australian Industry and Skills Committee

PHARMACEUTICAL GOOD MANUFACTURING PRACTICE

Case for Endorsement

Name of allocated IRC(s): Pharmaceutical Manufacturing Industry Reference Committee
Name of the SSO: Skills Impact
Training Package: FBP Food, Beverage and Pharmaceutical
Version 7

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1. Administrative details of the Case for Endorsement

*Refer to **Attachment A** for the title and code for each of the training package components that are submitted for approval, and an indication of whether these are updated (including equivalence or non-equivalence status), new or deleted products.*

The *FBP Food, Beverage and Pharmaceutical Training Package Version 7.0* Case for Endorsement includes one project, the updates to the Pharmaceutical Good Manufacturing Practice units of competency.

1.1 Case for Change details

The Case for Change (Reference number: Skills Impact/TPD/2020-21-008) was approved on 28 June 2021. The requirements set by the Australian Industry and Skills Committee (AISC) in relation to the training package development work for the FBP Food, Beverage and Pharmaceutical Training Package are:

- Review 4 units of competency
- Review 3 qualifications
- Develop 1 skill set

1.2 Timeframes and delays

The project has been delivered within the agreed timeframe. Acceptance by the Commonwealth of the Case for Endorsement is scheduled for February 2022.

2. Changes to training products and how these will meet the needs of industry

*Refer to **Attachment B** for information on how the proposed updates to qualifications will better support job roles in industry.*

Research of endorsed Pharmaceutical Good Manufacturing Practice (GMP) related training components on the national system revealed that the current units of competency could be altered to better align with work practices while also optimising the units for training delivery.

While these changes were minimal, they were important and endorsed by all facets of the sector, as they better reflect the work undertaken in the sector, and make the training more deliverable.
This has been achieved through the removal of elements which do not correlate with the work undertaken as part of the job task the unit describes, and through removal of Knowledge Evidence not pertinent to the job task described by the unit.

Industry have indicated that if these changes are endorsed, the training will become a more attractive option for Australia's small but internationally important pharmaceutical and bioprocessing industries, which is of great benefit as the sector is currently over reliant on university graduates for positions better suited to VET training.

The project included the scope to create one skill set for GMP in Pharmaceutical, however industry informed Skills Impact they preferred the existing packaging of the training and that a Skill Set would not be utilised.

Key messages from stakeholders engaged in the project and the subsequent changes to training products include:

- Removal of all non-Australian GMP knowledge evidence. The previous versions required those undertaking the training to know the GMP requirements for US and European nations. Feedback unanimously agreed that this was superfluous to the work being undertaken in Australia and thus it has been removed from the Knowledge Evidence where appropriate
- Removal of duplicate content across multiple units, specifically with regards to waste materials. Waste materials are not relevant to the work tasks described in the units for review, and in addition are already

addressed in a specific, well supported unit of competency. In order to remove duplication within the system, references to waste materials have been removed from the proposed units where appropriate to the job task.

The following components resulted from the work undertaken in this Food and Beverage Processing project:

Case for Change Requirements		Components for endorsement in FBP V7 CfE

Pharmaceutical GMP	• Review 3 qualifications
	• Review of 4 units of competency
	• Development of 1 skill set
		• 3 updated qualifications:
		  • 2 with code change to reflect unit code updates in core
		  • 1 with minor updates
		• 4 units of competency:
		  • 2 incurring a major change
		  • 2 needing a minor change
		• No new skill sets being developed.

3. Stakeholder consultation strategy

*Refer to **Attachment C** for:*
- *List of stakeholders that actively participated in consultation on the project.*
- *Summary feedback provided by stakeholder type and the IRCs response to this feedback.*
- *Summary of issues raised during stakeholder consultation and the IRCs response to these issues.*

3.1 Identification of stakeholders

Stakeholders were identified and targeted for participation in this project, and included:
- IRC and Subject Matter Expert Working Group (SMEWG) members' recommended key stakeholders.
- RTOs with the Pharmaceutical GMP units on their scope of registration.
- Unions with relevant food processing/manufacturing coverage.
- Members of relevant associations.
- Stakeholders identified by IRC members.
- Participants from previous pharmaceutical projects.
- Stakeholders recommended by other stakeholders in their industry/organisational networks.
- Stakeholders identified as having an interest in pharmaceutical GMP who have registered for Skills Impact's database.

All stakeholders identified as potentially having an interest in the project were contacted via phone and/ or email at the start of the project in July 2021 and continuously throughout project development.

3.2 Strategies for engaging stakeholders

- A project page was set up on the Skills Impact website (https://www.skillsimpact.com.au/pharmaceutical-manufacturing/training-package-projects/pharmaceutical-gmp-project/) containing information about the project together with progress updates.
- News articles and stories in Skills Impact newsletters distributed to the Skills Impact database of subscribers and on the Skills Impact website as news articles and were shared on the Skills Impact Twitter and LinkedIn accounts.
- IRC members were updated throughout the project and in turn, they informed their industry networks.
- Stakeholders identified as potentially having an interest in the project were contacted via phone or email at the start of the project in July 2021. These stakeholders were kept informed throughout project development.
- Monthly emails and newsletters were sent to State and Territory Training Authorities (S/TTAs), VET regulators, industry training advisory bodies (ITABs) and other stakeholders to keep them informed of the project's progress.
- SMEWG and functional analysis workshops.

- Consultation draft 1 held for 4 weeks comprising of 4 webinars.
- Validation phase held for 4 weeks - survey, webinars, targeted phone calls and emails.
- Messaging about project in external publications:
  - Food, Fibre & Timber Industries Training Council WA
  - Skills@Work newsletter
  - VETinfoNews
  - The Australian Industry Group Newsletter.

Additional consultation activities for other related updates:
- All *FBP Food, Beverage and Pharmaceutical Training Package*-related Alerts and e-Newsletters distributed between July 2021 and November 2021.
- All work was discussed during each public consultation phase to give stakeholders a further opportunity to raise any queries or issues with the proposed changes.
- No concerns or objections were raised by stakeholders about the proposed changes.

3.3 Participation by different types of stakeholders

Every effort was made to ensure that as many stakeholders as possible were informed about the project and understood the implications of any changes made. Stakeholders included:
- Employers
- Professional associations
- Industry groups
- Expert individuals and groups (Australian and international)
- Pharmaceutical GMP workers/operators
- RTO managers and staff (including those delivering existing qualifications)
- State and Territory Training Authorities.

Initially, stakeholders were contacted by phone or email to invite them to contribute to the project either by providing expert advice at workshops and/or webinars. Stakeholders were contacted again throughout the project and invited to provide further feedback on draft components. This approach ensured that stakeholders from rural, regional and remote areas, from all states and territories had numerous ways of engaging and providing feedback whilst also ensuring the project maximised stakeholder participation.

Stakeholders engaged during the project are described in the matrix below, with a full list of all engaged stakeholders available in ***Attachment C***.

**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.*

	ACT	NSW	NT	Qld	SA	Tas	Vic	WA	National
Employers (Non-IRC)	*		*			*		*	
Government department									
Industry Reference Committee (IRC) Representatives	*		*			*		*	
Peak Industry Bodies	*	*	*		*	*		*	
Registered Training Organisations (RTO)	*		*			*		*	
State and Territory Training Authorities (STAs)	*		*						*
Training Boards/Other	*	*	*	*	*	*	*	*	*
Unions									

4. Evidence of industry support

4.1 Industry support

The project development team were active in contacting employers, industry associations and training providers early in the project planning process to ensure stakeholders were aware of the project and the potential impact of changes, encouraging them to be involved in whatever way was suitable.

Industry representatives were involved at all stages of this project. The Subject Matter Expert Working Group (SMEWG) covered all units of competency being reviewed, and there was constant interaction between industry stakeholders and the project development team.

The consultation process included extra time for stakeholders to provide feedback at the validation stage, with a 4-week public consultation phase and a 4-week validation phase carried out to ensure as many stakeholders as possible could review and provide feedback on the important changes made.

Each stage included engagement with many stakeholders, with several stakeholders contributing detailed and practical feedback, which was considered by the SMEWG and adopted where possible. Others reviewed and acknowledged the work completed and confirmed their agreement.

During the validation phase of this project stakeholders were invited to complete an online survey to show their support for each of the training components. There was also an option to communicate concerns and/or changes via email or telephone for those who preferred this method of communication. Extensive feedback was received through emails and telephone conversations with all components in the project validated with pharmaceutical industry stakeholder support.

The sector is extremely small in Australia; however, an excellent cross section of experts gave their time and expertise to improve the 4 units being reviewed.

The extent of consultation and support for the proposed changes are as follows:

- 51 stakeholders were contacted and invited to be involved
- 27 people provided feedback throughout the project comprising:
  - 18 people representing employers
  - 4 representing state and national based peak bodies
  - 5 representing RTOs
  - 2 representing 2 STAs
  - 4 representing a research institute
  - 1 representing unions
  - 1 representing a commonwealth government organisation
  - 4 representing state government organisations (including Apprenticeship and Traineeship services), and
  - 3 IRC members.
- Out of the 27 people who participated in this project, six also provided support for the components produced at validation with 100% of all participants supporting the finalised components. Out of this, 2 people represented pharmaceutical employers, 3 were from peak industry bodies, 2 from RTOs, and 1 STA.

See Attachment C for a full list of stakeholders who participated.

4.2 Engagement of States and Territories

- Monthly emails and newsletters were sent to State and Territory Training Authorities, VET regulators, industry training advisory bodies (ITABs) and other stakeholders to keep them informed of the project's progress.
- All public consultation and validation phases included online webinars to allow stakeholders from all states and territories to participate and contribute to the project.

4.3 Mitigation strategies

The units of competency have been revised to be a better fit with current industry training needs and job roles. Two of the four revised units have been recoded due to major changes within them regarding the Knowledge Evidence and the Elements. the recoding of the components will ensure training providers are aware of the need to update their Training and Assessment Strategy (TAS), training materials and support documentation. The draft components were throughout the project presented with temporary codes and the impending changes were specifically referred to in webinars. There are no units being proposed for deletion as a part of this project.

4.4 Letters of industry support

Attach any industry letters of support for the proposed training products.

Letters of support have been received from two employers, one peak body and one RTO. These can be viewed in **Attachment G**. Support has been provided by the following organisations:

Name	Organisation	Stakeholder Group
Dan Grant	MPT Connect	Industry Employer
Louise White	Seer Pharma	IRC, Peak Industry Association, Industry Employer
Michael Kimber	Healthstar Training	RTO
Paul MacLeman	Pharmaceutical Industry Reference Committee	IRC

5. Dissenting views

5.1 Dissenting views/issues raised

No outstanding issues remain – all issues raised during this project were considered, addressed, and resolved.

5.2 Rationale for approval

Not applicable

6. Reports by exception

No reports by exception.

7. Mandatory Workplace Requirements

*Refer to **Attachment D** for a list of the units of competency, the MWR, the rationale for this, and evidence of employer support for this requirement.*

There are no Mandatory Workplace Requirements in any of the proposed units in this project. All units can be assessed in a workplace or an environment that reflects a real workplace, providing it is set up with the appropriate equipment, systems and guiding procedures that reflect an actual workplace.

8. Implementation of the new training packages

8.1 Implementation issues

In general, no implementation issues have been raised by states or territories or other stakeholders. However, there is a change resulting from this project which may have a minor impact on implementation:

- Two of the units of competency are no longer equivalent. All RTOs delivering the training are in favour of these changes and have communicated to Skills Impact that it is not burdensome to re-scope the units for delivery. This change has been communicated thoroughly throughout the project to help stakeholders plan accordingly.
- In addition, two qualifications impacted by the changes to these GMP units have also been recoded and deemed not equivalent due to code updates in the core. Again, disruption to implementation is anticipated to be minimal due to impacted RTOs being involved in this project, and few RTOs having the original qualifications on scope.

8.2 Potential for traineeship or apprenticeships

No qualifications were revised as a part of this project. Those qualifications included in the Case for Change were only included to allow for the update of codes of the reviewed units, and their recommended delivery remains unchanged. The three qualifications may be suitable for delivery as apprenticeships/traineeships; however, training package users are advised to contact the relevant STA/TTA for further advice.

8.3 Occupational and licensing requirements

No components have specific occupational and/or licensing requirements.

8.4 Extension to transition period

Not applicable.

9. Quality Assurance

The Case for Endorsement meets the following requirements:	
Standards for Training Packages 2012	☒
Training Package Products Policy	☒
Training Package Development and Endorsement Process Policy	☒
Companion Volume Implementation Guide is available and quality assured.	☒
*Copies of quality assurance reports are included in **Attachment F**.*	

10. Implementation of the Minister's priorities in training packages

*Refer to **Attachment E** for information on no enrolment and low enrolment qualifications reviewed as part of this project, and the outcomes of this review (i.e. product proposed for deletion or retention). **Attachment D** also includes the rationale for retaining no and/or low enrolment products when this is the proposal.*

Please include an explanation of how approval of the proposed training products will support the reform priorities for training packages agreed by skills ministers in November 2015 and October 2020:

Streamlining/rationalisation of training products	This project reviewed 4 units of competency • duplication of content and unrelated requirements of job tasks reduced by removing references to waste material from units.
Ensure that more information about industry's expectations of training delivery is available to training providers to improve their delivery and to consumers to enable more informed course choices	The Companion Volume Implementation Guide details information that covers key industry expectations about: • qualifications suitable for vocational education and training delivered to secondary students • qualifications suitable for delivery as apprenticeships or traineeships • amount of training/volume of learning requirements to ensure that the individual can gain the necessary skills and knowledge • key legislative requirements • essential knowledge requirements.
Ensure the training system better supports individuals to move more easily between related occupations	• The removal of international Knowledge Evidence requirements allows for a more seamless transition between pharmaceutical and bioprocessing positions by removing barriers that were previously specific to GMP practices. With the revised units of competency, a student's GMP knowledge is better grounded for all laboratory GMP requirements, not just that of bioprocessing and pharmaceuticals.
Improve the efficiency of the training system by creating units that can be owned and used by multiple industry sectors **Foster greater recognition of skill sets and work with industry to support their implementation**	• No new units or skill sets were created within this project.

11. A link to the full content of the proposed training package component(s)

The AISC should be provided with a link to the full, developed training package component(s) to be approved under the Case for Endorsement.
A link to the training package components proposed for endorsement is included here.

A link will be inserted here prior to submission of this CfE to the AISC

This Case for Endorsement was agreed to by the Pharmaceutical Manufacturing IRC

Name of IRC	Food, Beverage and Pharmaceutical Industry Reference Committee
Name of Chair	Fiona Fleming
Signature of Chair	

Date	21 December 2021

Name of IRC	Pharmaceutical Manufacturing Industry Reference Committee
Name of Chair	Paul MacLeman
Signature of Chair	
Date	21 December 2021

Attachment A: Training products submitted for approval

Please set out in the table below, the training products submitted for approval, including showing whether this is an updated, new or deleted product.

Training Product Code	Training Product Name	Type	For existing products, equivalence/non-equivalence status	For updated products, rationale for equivalence/non-equivalence status
Qualifications				
FBP20418	Certificate II in Pharmaceutical Manufacturing	**Updated**	Equivalent	Unit codes updated where out of date
FBP30822	Certificate III in Pharmaceutical Manufacturing	**Updated**	Not equivalent	Unit codes, including core unit, updated to reflect current codes
FBP40522	Certificate IV in Pharmaceutical Manufacturing	**Updated**	Not equivalent	Unit codes, including core unit, updated to reflect current codes
Units of competency				
FBPPHM2001 (Release 2)	Follow work procedures to maintain Good Manufacturing Practice requirements	**Updated**	Equivalent	Removed Foundation Skills Navigate the world of work and Interact with others Minor updates to Knowledge Evidence
FBPPHM3020	Apply Good Manufacturing Practice requirements	**Updated**	Not equivalent	Element removed. Changes to Element, Performance Criteria, Foundation Skills, Performance Evidence, Knowledge Evidence and Assessment Conditions
FBPPHM3021	Operate a pharmaceutical production process	**Updated**	Not equivalent	Deletion of Element that relates to dispensing of pharmaceutical material Changes to Element, Performance Criteria and Performance Evidence
FBPPHM4001 (Release 2)	Monitor and maintain Good Manufacturing Practice requirements	**Updated**	Equivalent	Minor word change in Performance Evidence 3.2 Removal of Foundation Skills Interact with others and Get the work done Minor changes in Performance Evidence

Attachment B: How qualification updates support job roles

Please use the table below to demonstrate how the proposed updates to qualifications will better support job roles.

Job role	Qualification	Proposed updates and how these better support the job role
Not applicable	Not applicable	Not applicable

Attachment C: Stakeholder consultation

List of stakeholders that actively participated in stakeholder consultation for the project:

Name	Organisation	Title	Industry	Representation Type	State
Rebecca McCrae	Commonwealth Serum Laboratories (CSL Behring)	Production Manager	Laboratory work/ Bioprocessing	Employee	VIC/ National
Ian McLeod	MTO Group	CEO	Laboratory work/ Bioprocessing	Employer	QLD
Louise White	SeerPharma	Partner and senior consultant	Laboratory work/ Bioprocessing	Peak Industry Body, Employer	VIC
Michael Kimber	Health Star Training	Principal	Laboratory work/ Bioprocessing	RTO	QLD
Michelle McIntosh	Monash University	Professor	Laboratory work/ Bioprocessing	RTO/ Employee	VIC
Natalie Scott	Pivotal Training and Development	CEO	Laboratory work/ Bioprocessing	Employer	NSW
Paul Baxter	Australian Manufacturing Workers Union	Organiser	Laboratory work/ Bioprocessing	Union	National
Paul MacLeman	AdAlta	Chairperson	Laboratory work/ Bioprocessing	Peak Industry Body/ IRC/ Employer	VIC/ National
Glenn Blair	Monash University	Head of Education Strategy and Development	Laboratory work/ Bioprocessing	RTO/ Peak Industry Body	VIC
David Wilson	Pacific Life Sciences	Retired	Laboratory work/ Bioprocessing	Employee	VIC
Luke Jones	Luina Bio	People and Culture Manager	Laboratory work/ Bioprocessing	Employer/ Peak Industry Body	QLD
Vincent Chung	Seqirus BioCSL	Director of Influenza Manufacturing	Laboratory work/ Bioprocessing	Employer	VIC/ National
Geoff Dumsday	CSIRO	Senior Research Scientist	Laboratory work/ Bioprocessing	Employee	VIC

Name	Organisation	Title	Industry	Representation Type	State
Anthony Morgan	Pfizer	Business Development Manager	Laboratory work/ Bioprocessing	Employer/ RTO/ Peak Industry Body	SA
Majella Clifton	Thermo Fisher	Project Manager	Laboratory work/ Bioprocessing	Employer/ Peak Industry Body	QLD/ National
Andrew Groth	University of Technology Sydney	Faculty Business Development Manager	Laboratory work/ Bioprocessing	RTO/ Peak Industry Body/ Employer	NSW
Jarrod Belcher	MTPConnect	Senior Director of Stakeholder Engagement	Laboratory work/ Bioprocessing	Employer	VIC
Dan Grant	MTPConnect	CEO	Laboratory work/ Bioprocessing	Employer	VIC
Chris Roberts	Monash University	Partnership and Development Manager	Laboratory work/ Bioprocessing	RTO	VIC
Rachel Jensen	Centre for Biopharmaceutical Excellence	Consultant	Laboratory work/ Bioprocessing	Employer	VIC
Katrina Myers	Box Hill Institute	Manager for contract delivery	Laboratory work/ Bioprocessing	RTO	VIC
Kien Chai	Box Hill Institute	Teacher	Laboratory work/ Bioprocessing	RTO	VIC
Paul Saunders	Chisholm Institute	Victorian Curriculum Maintenance Manager	Laboratory work/ Bioprocessing	RTO/ Government/ Peak Industry Body/ STA	VIC
Anne Nicholls	Box Hill TAFE	Teacher	Laboratory work/ Bioprocessing	RTO	VIC
Susie Hounsham	WA Department of Training and Workforce Development	Senior Program Officer	Laboratory work/ Bioprocessing	Government/ STA	WA
David Azzopardi	Commonwealth Serum Laboratories (CSL Behring)	Human Resources	Laboratory work/ Bioprocessing	Employee	VIC
Martha Keyse	Thermo Fisher	Business Development Manager	Laboratory work/ Bioprocessing	Employee	QLD

Summary of Feedback by Stakeholder type:

Stakeholder Type	Key Feedback Points	Actions Taken to Address Feedback
Industry Reference Committee (IRC) Representatives	Units must be reviewed to remove information that does not pertain to the work undertaken in Australia	Non-Australian Knowledge Evidence dot points removed, Element removed from a unit to better reflect how the work is undertaken in Australia
Peak Industry Bodies	No key feedback points, supported IRC's feedback.	Non-Australian Knowledge Evidence dot points removed, Element removed from a unit to better reflect how the work is undertaken in Australia
Employers (Non-IRC)	No key feedback points, supported IRC's feedback.	Non-Australian Knowledge Evidence dot points removed, Element removed from a unit to better reflect how the work is undertaken in Australia
Registered Training Organisations (RTOs)	Units should be updated to allow for graduates to immediately pick up work within Australia. Tailoring units to overseas students, or to students with a mind to move overseas for work, is contrary to the values of the VET system.	Knowledge Evidence updated by removing knowledge not specific to Australian GMP.
State and Territory Training Authorities (STAs)	Work undertaken needs to have the support of the RTO's and the industry employers. Whatever work is produced needs to be unified and work for both parties.	Industry employment sector and RTO sector offered no contradictory feedback through the duration of the project.
Unions	No key feedback points, supported IRC's feedback	Non-Australian Knowledge Evidence dot points removed, Element removed from a unit to better reflect how the work is undertaken in Australia

Attachment D: Mandatory Workplace Requirements in Training Products

No training products within this project have any mandatory workplace requirements.

Attachment E: No enrolment and low enrolment training products

No training products in this project have had low or no enrolments.

Attachment F: Quality assurance reports

Quality Assurance Report

Quality Report Template

Section 1 – Cover page

Information required	Detail
Training Package title and code	**FBP Food, Beverage and Pharmaceutical**
Number of new qualifications and their titles[1]	**0**
Number of revised qualifications and their titles	2 FBP30822 Certificate III in Pharmaceutical Manufacturing FBP40522 Certificate IV in Pharmaceutical Manufacturing
Number of new units of competency and their titles	0
Number of revised units of competency and their titles	2 FBPPHM3020 Apply Good Manufacturing Practice requirements FBPPHM3021 Operate a pharmaceutical production process
Confirmation that the panel member is independent of: • the Training Package or Training Package components review ('Yes' or 'No') • development and/or validation activities associated with the Case for Endorsement ('Yes' or 'No') • undertaking the Equity and/or Editorial Reports for the training package products that are the subject of this quality report ('Yes' or 'No')	I confirm that I, Maree Thorne, am independent of: • the Training Package or Training Package components' review (Yes) • development and/or validation activities associated with the Case for Endorsement (Yes) • undertaking the Equity and/or Editorial Reports for the training package products that are the subject of this quality report (Yes)
Confirmation of the Training Packages or components thereof being compliant with the *Standards for Training Packages 2012*	**Yes, I confirm that the Training Package components for endorsement are compliant with the *Standards for Training Packages 2012***
Confirmation of the Training Packages or components thereof being compliant with the *Training Package Products Policy*	**Yes, I confirm that the Training Package components for endorsement are compliant with the *Training Package Products Policy***
Confirmation of the Training Packages or components thereof being compliant with the *Training Package Development and Endorsement Process Policy*	**Yes, I confirm that the Training Package components for endorsement are compliant with the *Training Package Development and Endorsement Process Policy***

[1] When the number of training products is high the t*itles can be presented as an attached list.*

Information required	Detail
Panel member's view about whether: • the evidence of consultation and validation process being fit for purpose and commensurate with the scope • estimated impact of the proposed changes is sufficient and convincing	It is the panel member's view that the evidence of consultation and validation is fit for purpose and commensurate with the scope of the project, being, review of four units of competency in Good Manufacturing Practices (GMP) and resultant qualification changes specifically due to updating units within qualifications. The CfE notes engagement of 27 stakeholders including state/national peak industry bodies, STAs, state and commonwealth departments, RTOs and employers with all jurisdictions represented in some way. The estimated impact of the proposed changes is minimal (only one RTO currently has effected Certificate III and Certificate IV qualifications on scope, whilst one RTOs has Certificate III on scope) and the CfE confirms that RTOs who will be predominately impacted by the non-equivalence of revised units, are aware of the impacts and supportive of the proposed changes.
Name of panel member completing Quality Report	**Maree Thorne**
Date of completion of the Quality Report	**17/12/2021** **Revised 19/1/2022 following changes**

Section 2 – Compliance with the Standards for Training Packages 2012

Standards for Training Packages	Standard met 'yes' or 'no'	Evidence supporting the statement of compliance or noncompliance (including evidence from equity and editorial reports)
Standard 1 Training Packages consist of the following: 1. AISC endorsed components: • qualifications • units of competency • assessment requirements (associated with each unit of competency) • credit arrangements 2. One or more quality assured companion volumes	***Yes***	The proposed components for endorsement of the FBP Food, Beverage and Pharmaceutical Training Package Version 7.0 meet the requirements of Standard 1. The Training Package components in the Case for Endorsement (CfE) include: • two revised qualifications One additional qualification is referred to in the CfE as a minor change to update unit codes and was not included in the QA process. • Two revised units of competency, each with associated assessment requirement Two additional units are referred to in the CfE as minor changes, version releases. Both units were included in the QA process with feedback provided. The FBP Food, Beverage and Pharmaceutical Training Package v7.0 Companion Volume Implementation Guides (CVIG) in two parts provides implementation advice, has been updated to include the revised qualifications and units of competency, as well as the minor changes, and both parts have been quality assured in this process.

Standards for Training Packages	Standard met 'yes' or 'no'	Evidence supporting the statement of compliance or noncompliance (including evidence from equity and editorial reports)
Standard 2 Training Package developers comply with the *Training Package Products Policy*	***Yes***	Skills Impact has complied with the requirements of the *Standards for Training Packages 2012* for the four revised units of competency and their associated assessment requirements. Supporting evidence includes: • Compliance with coding and titling of qualifications and units of competency. Two qualifications updated with changes to unit codes of core units have been recoded to reflect. Where a minor change to one qualification was made to update elective unit codes only, qualification is not recoded and is a minor release. Release versions have not been quality assured. Where units of competency have undergone review with changes to performance criteria, knowledge or performance evidence or assessment conditions, codes have been changed. • Neither of the two revised units of competency for endorsement have prerequisite requirements • The CVIG has had minor updates to include the updated components • Foundation Skills have been reviewed in the two units of competency for endorsement and the two minor change units • Information about qualification and unit mapping to inform users of changes to both equivalent and not equivalent components is provided in the CVIGs

Standards for Training Packages	Standard met 'yes' or 'no'	Evidence supporting the statement of compliance or noncompliance (including evidence from equity and editorial reports)
Standard 3 Training Package developers comply with the AISC *Training Package Development and Endorsement Process Policy*	***Yes***	The initial Case for Change in the FBP_IRC Skills Forecast 2021 was specifically to review, update and rewrite four GMP units of competency, and to subsequently update the pharmaceutical manufacturing qualifications with the revised units and update imported unit codes and titles. It is noted that whilst reference is made in the CfE to the AISC Case for Change to reviewing three qualifications, the project was specifically 'to update four national units of competency'. Review of qualifications was limited to updating the units, which has resulting in two non-equivalent qualifications requiring endorsement. The CfE outlines details of consultation undertaken, including an extended period of four weeks for validation, and a range of communication and engagement strategies with evidence of contributing personnel listed in Appendices. A summary of feedback, responses and actions for the project were available on the Skills Impact website and were examined in the quality assurance process to validate stakeholder agreement.
Standard 4 Units of competency specify the standards of performance required in the workplace	***Yes***	Both units for endorsement and minor change units of competency were reviewed. The standards of performance required in the workplace are presumed to be confirmed through stakeholder consultation and validation during development.
Standard 5 The structure of units of competency complies with the unit of competency template	***Yes***	All units of competency comply with the unit of competency template requirements including code, title, application, unit sector, elements, performance criteria, foundation skills, unit mapping information and links to the CVIG. Range of Conditions are included in two units specifying the conditions that must be included.
Standard 6 Assessment requirements specify the evidence and required conditions for assessment	***Yes***	Assessment requirements associated with the units of competency specify the performance evidence and knowledge evidence to be demonstrated for assessment, along with required conditions for assessment.

Standards for Training Packages	Standard met 'yes' or 'no'	Evidence supporting the statement of compliance or noncompliance (including evidence from equity and editorial reports)
Standard 7 Every unit of competency has associated assessment requirements. The structure of assessment requirements complies with the assessment requirements template	***Yes***	All units of competency have associated assessment requirements, including Performance Evidence, Knowledge Evidence, Assessment Conditions and a link to the FBP CVIG, as required by the Assessment Requirements template.
Standard 8 Qualifications comply with the Australian Qualifications Framework specification for that qualification type	***Yes***	As indicated above, no structural changes have been made to the qualifications proposed for endorsement. Existing qualification packaging rules specify requirements to ensure AQF outcomes for qualifications are met by the specified packaging rules and elective selection supported with the wording: *Elective units must ensure the integrity of the qualification's Australian Qualification Framework (AQF) alignment and contribute to a valid, industry-supported vocational outcome.*
Standard 9 The structure of the information for the Australian Qualifications Framework qualification complies with the qualification template	***Yes***	QA confirms the Editorial Report comment that '*The structure of the information for FBP30822 complies with the qualification template*'. The structure of information for FBP40522 also complies with the qualification template.
Standard 10 Credit arrangements existing between Training Package qualifications and Higher Education qualifications are listed in a format that complies with the credit arrangements template	***Yes***	The CVIG Part 1 indicates that no national credit arrangements exist at this time for the proposed qualifications.
Standard 11 A quality assured companion volume implementation guide produced by the Training Package developer is available at the time of endorsement and complies with the companion volume implementation guide template.	***Yes***	The training package components in this submission are accompanied by the FBP Food, Beverage and Pharmaceutical Training Package Companion Volume Implementation Guide (CVIG) Version 7.0 in two parts: Part 1: *Overview and Implementation* Part 2: *Component Details* The FBP CVIG complies with the companion volume implementation guide template included in the 2012 Standards and was reviewed in this QA process, including for alignment to the CfE and with the proposed components for endorsement.

Standards for Training Packages	Standard met 'yes' or 'no'	Evidence supporting the statement of compliance or noncompliance (including evidence from equity and editorial reports)
Standard 12 Training Package developers produce other quality assured companion volumes to meet the needs of their stakeholders as required.	***Not Applicable***	

Section 3 – Compliance with the training package quality principles

Note: *not all training package quality principles might be applicable to every training package or its components. Please provide a supporting statement/evidence of compliance or non-compliance against each principle.*

Quality principle 1. Reflect identified workforce outcomes

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance/non compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Driven by industry's needs	Yes	Project work undertaken demonstrates a clear link to the initial Case for Change in the FBP_IRC Skills Forecast 2021 to review, update and rewrite four GMP units of competency to remove complex and redundant knowledge of international GMP requirements, and to subsequently update the pharmaceutical manufacturing qualifications with the revised units and updated imported units.
Compliant and responds to government policy initiatives Training package component responds to the COAG Industry and Skills Council's (CISC) training package-related initiatives or directions, in particular the 2015 training package reforms. Please specify which of the following CISC reforms are relevant to the training product and identify supporting evidence: • ensure obsolete and superfluous qualifications are removed from the system • ensure that more information about industry's expectations of training delivery is available to training providers to improve their delivery and to consumers to enable more informed course choices • ensure that the training system better supports individuals to move easily from one related occupation to another	Yes	The endorsed components respond to the COAG Industry and Skills Council's (CISC) training package reforms, specifically: • **ensure that the training system better supports individuals to move easily from one related occupation to another** • **improve the efficiency of the training system by creating units that can be owned and used by multiple industry sectors** • **ensure that more information about industry's expectations of training delivery is available to training providers to improve their delivery and to consumers to enable more informed course choices** As noted in the CfE, evidence of compliance with and response to government policy initiatives includes the removal of international knowledge requirements which allows for a more seamless transition between pharmaceutical and bioprocessing positions by removing barriers that were previously specific to GMP practices. The changes made enable student's GMP knowledge to be better grounded for all laboratory GMP requirements, not just that of bioprocessing and pharmaceuticals. Project feedback notes that RTOs that currently have these revised units of competency on their scope were contacted and all have informed Skills Impact that they believe the suggested changes will improve the quality of the training and will improve the outcome of the training.

• improve the efficiency of the training system by creating units that can be owned and used by multiple industry sectors • foster greater recognition of skill sets		
Reflect contemporary work organisation and job profiles incorporating a future orientation	Yes	Information in the CfE about drivers for the projects, discussions and decisions made by industry during development confirm the revised components reflect contemporary job profiles and industry work.

Quality principle 2: Support portability of skills and competencies including reflecting licensing and regulatory requirements

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Support movement of skills within and across organisations and sectors	Yes	Packaging rules in the existing qualifications enable flexibility in the selection of elective units to suit specific organisation or broader industry applications. Options to import units from other training packages enable movement within organisations, within each industry sector, and through inclusion of import units, to other sectors.
Promote national and international portability	Yes	The CfE indicates national consensus in the development of the components for endorsement, which implies support for national portability of the components within these industries.
Reflect regulatory requirements and licensing	Yes	No licencing requirements apply to the revised component. The key driver for the revisions was the inclusion of Australian GMP compliance principles and procedures in the components.

Quality principle 3: Reflect national agreement about the core transferable skills and core job-specific skills required for job roles as identified by industry

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Reflect national consensus	Yes	The case for endorsement details the consultation that was conducted and confirms no dissenting views. The CfE evidences a national consultation process providing stakeholders with opportunities to participate via several communication channels (SMEWG, email and online, direct engagement via email/phone, newsletter alerts inviting feedback) to capture input on the endorsed components throughout the duration of the review. Appendix 2 details the range of national respondent stakeholders including industry participants, government representatives and training advisory associations, industry /content expert and training practitioners.
Recognise convergence and connectivity of skills	Yes	Units listed in the qualification include imported units from other nationally endorsed training packages.

Quality principle 4: Be flexible to meet the diversity of individual and employer needs including the capacity to adapt to changing job roles and workplaces

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Meet the diversity of individual and employer needs	Yes	The qualification packaging includes elective choices, and options to choose units from any other training package or accredited course, suitable to vocational requirements and context – which ensures that the qualification can be packaged to suit different settings and a range of employer and individual needs. The assessment conditions of the four units allows for assessment to 'demonstrated [in a workplace] or an environment that accurately represents workplace conditions' thereby enabling flexibility of the components to meet a broad range of individual and employer needs.
Support equitable access and progression of learners	Yes	The qualification does not specify any entry requirements, and there are no prerequisites for the revised units.

Quality principle 5: Facilitate recognition of an individual's skills and knowledge and support movement between the school, vocational education and higher education sectors

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Support learner transition between education sectors	Yes	Pathways and transition between education sectors is detailed in CVIG. The qualification proposed for endorsement is already recommended by the IRC as suitable for an apprenticeship/traineeship pathway. The CVIG specifies that there are no national credit arrangements between the qualification and Higher Education qualifications at the time of endorsement.

Quality principle 6: Support interpretation by training providers and others through the use of simple, concise language and clear articulation of assessment requirements

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Support implementation across a range of settings	Yes	Industry advice about delivery implementation is provided via the FBP Food, Beverage and Pharmaceutical Training Package Version 7.0 Companion Volume Implementation Guide (CVIG) Parts 1 and 2, both of which have been quality assured in this process and are ready for publication at the same time as the Training Package components. As noted in the Equity Report, the CVIG provides guidance about occupational outcomes of pharmaceutical manufacturing pathways, and access and equity (including advice regarding reasonable adjustment for learners with disabilities). Information about how Foundation Skills are addressed in units of competency is included in the CVIG.
Support sound assessment practice	Yes	The draft Units of Competency and associated Assessment Requirements include references to frequency ('on one or more occasions', 'one or more pharmaceutical production processes' or 'one or more work teams') of Performance Evidence and include Assessment Conditions specifying how evidence must be gathered. Knowledge and Performance Evidence requirements in the Assessment Requirements aligns to the unit of competency elements and performance criteria.

Key features	Quality principle is met: Yes / No or N/A	Evidence demonstrating compliance with the quality principle Please see examples of evidence in the *Training Package Development and Endorsement Process Policy*
Support implementation	Yes	The training package components provided for quality assurance were presented in full and in a format required to comply with the National Register requirements for publication. The Editorial Report confirms that editorial suggestions made were incorporated or explained, and feedback made in this quality assurance process has been similarly incorporated or advised to be an industry requirement. Components contain links as required by the templates to the FBP CVIG 7.0 which has been updated to include the components proposed for endorsement, has been quality assured in this process and is ready for publication at the same time as the Training Package components.

Equity Report

Section 1 – Cover page

Information required	Detail
Training Package title and code	FBP Food, Beverage and Pharmaceutical Training Package Version 7.0
Number of new qualifications and their titles 1	Nil
Number of revised qualifications and their titles	One revised qualification: FBP30822 Certificate III in Pharmaceutical Manufacturing
Number of new units of competency and their titles	Nil
Number of revised units of competency and their titles	2 revised unit comprising of: FBPPHM3020 Apply Good Manufacturing Practice requirements FBPPHM3021 Operate a pharmaceutical production process.
Confirmation that the draft training package components meet the requirements in Section 2 Equity checklist of draft training package components	The draft training package components meet the requirements in Section 2 Equity checklist of draft training package components.
Is the Equity Report prepared by a member of the Quality Assurance Panel? If 'yes' please provide the name.	Lina Robinson
Date of completion of the report	15 December 2021

1 *When the number of training products is high* t*he titles can be presented as an attached list.*

Section 2 – Equity checklist of draft training package components

Equity requirements	Equity reviewer comments Provide brief commentary on whether the draft endorsed components meet each of the equity requirements
The training package component(s) comply with Standard 2 of the Standards for Training Packages 2012. The standard requires compliance with the Training Package Products Policy, specifically with the access and equity requirements: Training Package developers must meet their obligations under Commonwealth anti-discrimination legislation and associated standards and regulations. Training Package developers must ensure that Training Packages are flexible and that they provide guidance and recommendations to enable reasonable adjustments in implementation.	The draft training package components reviewed, follow the Standards for Training Packages and Training Package Products Policy in relation to access and equity. The FBP Food, Beverage and Pharmaceutical Companion Volume Implementation Guide (FBP CVIG) updated as Version 7.0 has a section on access and equity considerations that details practical ways on how to incorporate reasonable adjustment in delivery and assessment and training products, particularly for learners with disabilities.

Section 3 - Training Package Quality Principles

Quality Principle 4

Be flexible to meet the diversity of individual and employer needs, including the capacity to adapt to changing job roles and workplaces.

Key features

Do the units of competency meet the diversity of individual and employer needs and support equitable access and progression of learners?

What evidence demonstrates that the units of competency and their associated assessment requirements are clearly written and have consistent breadth and depth so that they support implementation across a range of settings?

Are there other examples that demonstrate how the key features of flexibility are being achieved?

Equity requirements	Equity reviewer comments
1. What evidence demonstrates that the draft components provide flexible qualifications/units of competency that enable application in different contexts?'	FBP30822 contains a wide selection of electives that enable application in a wide range of pharmaceutical manufacturing contents and allows for 2 units not listed in the elective banks to be imported from other training packages or accredited courses. The two FBP units can be applied across pharmaceutical and bioprocessing settings.
2. Is there evidence of multiple entry and exit points?	The FBP units are contained in FBP skill sets and FBP and PMA qualifications that allows entry and progression to higher qualifications. FBP30822 provides a clear pathway to higher level qualifications. The FBP CVIG includes a section that outlines the multiple pathways to gain qualifications showing the possible pathways into, and from qualifications.
3. Have prerequisite units of competency been minimised where possible?	The FBP units do not contain any prerequisite units.
4. Are there other examples of evidence that demonstrate how the	FBP30822 does not contain any prerequisite requirements, presenting no barrier to entry.

Equity requirements	Equity reviewer comments
key features of the flexibility principle are being achieved?	

Quality Principle 5

Facilitate recognition of an individual's skills and knowledge and support movement between the school, vocational education and higher education sectors.

Key features

Support learner transition between education sectors.

Equity requirements	Equity reviewer comments
1. What evidence demonstrates pathways from entry and preparatory level as appropriate to facilitate movement between schools and VET, from entry level into work, and between VET and higher education qualifications?	The FBP CVIG outlines the multiple pathways to gain qualifications including training and assessment pathway, recognition of prior learning pathway or combinations of each pathway to complete a qualification.

Quality Principle 6

Support interpretation by training providers and others through the use of simple, concise language and clear articulation of assessment requirements.

Key features

Support implementation across a range of settings and support sound assessment practices.

Equity requirements	Equity reviewer comments
1. Does the Companion Volume Implementation Guide include advice about: Pathways Access and equity Foundation skills? (see Training Package Standard 11)	Yes, the FBP CVIG provides advice on pathways, access and equity and foundation skills.
2. Are the foundation skills explicit and recognisable within the training package and do they reflect and not exceed the foundation skills required in the workplace?	Yes, foundation skills are recognised in the units of competency reviewed, and do not exceed the foundation skills required in the workplace.

Editorial Report

1. Cover page	
Information required	Detail
Training Package title and code	FBP Food, Beverage and Pharmaceutical Training Package Version 7.0
Number of new qualifications and their titles	Nil
Number of revised qualifications and their titles	One revised qualification: FBP30822 Certificate III in Pharmaceutical Manufacturing
Number of new units of competency and their titles	Nil
Number of revised units of competency and their titles	Two revised units: FBPPHM3020 Apply Good Manufacturing Practice requirements FBPPHM3021 Operate a pharmaceutical production process
Confirmation that the draft training package components are publication-ready	The draft training package components are publication-ready. The case for endorsement also includes 2 qualifications and 2 units of competency that are described as 'updated' but are presented as 'minor change' components.
Is the Editorial Report prepared by a member of the Quality Assurance Panel? If 'yes' please provide a name.	Lina Robinson
Date of completion of the report	15 December 2021

2. Content and structure

Units of competency

Editorial requirements	Comments
Standard 5: The structure of units of competency complies with the unit of competency template.	The structure of the reviewed units complies with the unit of competency template.
Standard 7: The structure of assessment requirements complies with the assessment requirements template.	The structure of the assessment requirements complies with the assessment requirements template.

Qualifications

Editorial requirements	Comments by the editor
Standard 9: The structure of the information for qualifications complies with the qualification template.	The structure of the information for FBP30822 complies with the qualification template.
Standard 10: Credit arrangements existing between Training Package qualifications and Higher Education qualifications are listed in a format that complies with the credit arrangements template.	N/A

Companion Volumes

Editorial requirements	Comments by the editor
Standard 11: A quality assured companion volume implementation guide is available and complies with the companion volume implementation guide template.	The FBP companion volume implementation guide has been updated as Version 7.0 and complies with the required template.

3. Proofreading

Editorial requirements	Comments by the editor
Unit codes and titles and qualification codes and titles are accurately cross-referenced throughout the training package product(s) including mapping information and packaging rules, and in the companion volume implementation guide.	The unit and qualification codes and titles have been checked and cross referenced throughout the training package products.
Units of competency and their content are presented in full.	All units of competency are presented in full.
The author of the Editorial Report is satisfied with the quality of the training products, specifically with regard to: absence of spelling, grammatical and typing mistakes consistency of language and formatting logical structure and presentation of the document. compliance with the required templates.	All draft training products have been checked for: absence of spelling, grammatical and typing mistakes consistency of language and formatting logical structure and presentation of the document compliance with the required templates.

Editorial Report Template

1. Cover page	
Information required	Detail
Training Package title and code	FBP Food, Beverage and Pharmaceutical Training Package Version 7.0
Number of new qualifications and their titles	Nil
Number of revised qualifications and their titles	One revised qualification: FBP30822 Certificate III in Pharmaceutical Manufacturing
Number of new units of competency and their titles	Nil
Number of revised units of competency and their titles	Two revised units: FBPPHM3020 Apply Good Manufacturing Practice requirements FBPPHM3021 Operate a pharmaceutical production process
Confirmation that the draft training package components are publication-ready	The draft training package components are publication-ready. The case for endorsement also includes 2 qualifications and 2 units of competency that are described as 'updated' but are presented as 'minor change' components.
Is the Editorial Report prepared by a member of the Quality Assurance Panel? If 'yes' please provide a name.	Lina Robinson
Date of completion of the report	15 December 2021

2. Content and structure

Units of competency

Editorial requirements	Comments
Standard 5: The structure of units of competency complies with the unit of competency template.	The structure of the reviewed units complies with the unit of competency template.
Standard 7: The structure of assessment requirements complies with the assessment requirements template.	The structure of the assessment requirements complies with the assessment requirements template.

Qualifications

Editorial requirements	Comments by the editor
Standard 9: The structure of the information for qualifications complies with the qualification template.	The structure of the information for FBP30822 complies with the qualification template.
Standard 10: Credit arrangements existing between Training Package qualifications and Higher Education qualifications are listed in a format that complies with the credit arrangements template.	N/A

Companion Volumes

Editorial requirements	Comments by the editor
Standard 11: A quality assured companion volume implementation guide is available and complies with the companion volume implementation guide template.	The FBP companion volume implementation guide has been updated as Version 7.0 and complies with the required template.

3. Proofreading

Editorial requirements	Comments by the editor
Unit codes and titles and qualification codes and titles are accurately cross-referenced throughout the training package product(s) including mapping information and packaging rules, and in the companion volume implementation guide.	The unit and qualification codes and titles have been checked and cross referenced throughout the training package products.
Units of competency and their content are presented in full.	All units of competency are presented in full.
The author of the Editorial Report is satisfied with the quality of the training products, specifically with regard to: absence of spelling, grammatical and typing mistakes consistency of language and formatting logical structure and presentation of the document. compliance with the required templates.	All draft training products have been checked for: absence of spelling, grammatical and typing mistakes consistency of language and formatting logical structure and presentation of the document compliance with the required templates.

Attachment G: Copies of Letters of Support

MTPConnect
MedTech and Pharma Growth Centre

20 December 2021

To William Henderson and Julie Stratford, Skills Impact.

This letter is to support the changes proposed to the Good Manufacturing Practice (GMP) units within Certificates II, III and IV in Pharmaceutical Manufacturing.

As CEO of MTP Connect, a member of the Pharmaceutical Manufacturing Industry Reference Committee and a government-funded growth centre for this industry, I was consulted about modifications proposed to the GMP units within these qualifications.

I agree with the proposed changes that were decided after discussions with a range of industry representatives at several workshops during September- December 2021. These changes will bring these units into line with current practices in manufacturing plants and reflect the skills needed in the pharmaceutical manufacturing industry.

Sincerely,

Dan Grant, Ph.D., M.B.A.
Managing Director and Chief Executive Officer
MTPConnect (MedTech and Pharma Growth Centre -MTP-IIGC Ltd)

Head Office & Postal address Ground floor, Suite 2, 155 Cremorne Street, Cremorne VIC 3121 Australia Phone +61 3 9070 8298 Email info@mtpconnect.org.au

SeerPharma®
CONFIDENCE IN COMPLIANCE

18 December 2021

To Whom It May Concern,

I am writing as a provider of professional education and services in the Australian biopharmaceutical industry in support of the Pharmaceutical GMP Units of Competency.

SeerPharma has been providing training and consulting to the Australian biopharmaceutical industry since the introduction of the national manufacturing licencing scheme in 1990. We have also partnered with Swinburne University of Technology and, more recently, the University of Technology Sydney (UTS) to develop and deliver post graduate qualifications in Good Manufacturing Practices https://www.seerpharma.com/services/qa-and-gmp-training/postgraduate-gmp-training.

In October 2020, the Federal Government announced the A$1.3 billion Modern Manufacturing Initiative (MMI) and the National Manufacturing Priorities. This initiative is intended to strengthen the "ecosystem of research and development partnerships that are vital to domestic commercialization, advanced manufacturing and stronger supply chains." [1] If rolled out efficiently and effectively, this initiative will see an increase in the number and size of pharmaceutical manufacturing companies operating in Australia.

Underpinning the skills utilised in pharmaceutical industry is the need for personnel to be trained in the requirements GMP (Good Manufacturing Practices). GMP is a regulatory concept unique to the biopharmaceutical industry. It needs to be taught within the context of the manufacturing environment.

If Australia is to take full advantage of the growth and expansion of the pharmaceutical industry, it must meet the demand for a pool of skilled workers capable of working in a GMP environment. And, as there will be competition in the market for these workers trained in GMP, employers are likely to face ongoing difficulties in filling and holding onto qualified and experienced personnel.

While many of the jobs in a processing manufacturing facility are filled by tertiary qualified people, there is still a need for operational personnel with good technical skills and process knowledge. A standardised and comprehensive vocational education and training (VET) program, with a recognised GMP credential, such as provided by the Pharmaceutical GMP Units of Competency, is needed to fill these roles and to provide an alternate pathway to employment for our secondary students.

I fully support the Pharmaceutical GMP Units of Competency.

Yours sincerely

Louise White

[1] https://www.industry.gov.au/news/modern-manufacturing-initiative-and-national-manufacturing-priorities-announced

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Level 3, 439 Canterbury Rd
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Julie Stratford

From: Paul MacLeman <paul@macleman.com>
Sent: Wednesday, 15 December 2021 5:44 PM
To: William Henderson
Cc: Julie Stratford
Subject: Letter of support

Dear Skills Impact,

This letter is to support the changes proposed to the Good Manufacturing Practice (GMP) units within Certificates II, III and IV in Pharmaceutical Manufacturing, comprising:

- FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements
- FBPPHM3001- Apply Good Manufacturing Practice Requirements
- FBPPHM3002 Operate a pharmaceutical production process
- FBPPHM4001 Monitor and maintain good manufacturing practice requirements

As a subject matter expert in the field of pharmaceutical manufacturing and also the Chair of the Pharmaceutical Manufacturing Industry Reference Committee, I participated in several teleconference consultation workshops held between September and December, 2021.

I agree with the comments and feedback from the various industry representatives at those consultations about wording and terms to remove, add or change in these four units. These changes will bring the three qualifications closer to reflecting the practices and skill needs of this industry.

Best regards,

Dr Paul MacLeman
MBA, DVM, Grad Dip Eng, Grad Cert Eng, FAICD
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ABN 73 179 904 960
Website: healthstar.edu.au
Email; mbk@healthstar.edu.au

Skills Impact

Level 1, 165 Bouverie Street, Carlton, 3053

Dear Skills Impact,

This letter is to support the changes proposed to the Good Manufacturing Practice (GMP) units within Certificates II, III and IV in Pharmaceutical Manufacturing.

As a subject matter expert in the field of pharmaceutical manufacturing (former Manufacturing Director of Astra Pharmaceuticals) and also an experienced educator (retired Associate Professor, JCU School of Pharmacy and RTO owner), I participated in several teleconference consultation workshops held by Zoom between September and December 2021.

I participated by providing comment and feedback on the appropriate wording to be used in replacement of current descriptions within four units of competency. I discussed the issues with other industry representatives at each meeting and was in agreement about what to remove, add or change in these four units, which has now been implemented.

I agree with the proposed changes to the following units as proposed in the final draft provided by Skills Impact. I believe these changes better reflect the needs and practices of the pharmaceutical manufacturing industry.

- FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements
- FBPPHM3001- Apply Good Manufacturing Practice Requirements
- FBPPHM3002 Operate a pharmaceutical production process
- FBPPHM4001 Monitor and maintain good manufacturing practice requirements

Your truly,

Michael Kimber

Dr Michael Kimber