Case for endorsement

FBP Food Beverage and Pharmaceutical Training Package Version 5.0

Submitted by Skills Impact

on behalf of

Pharmaceutical Manufacturing IRC

October 2020

Contents

A. Administrative details **4**

B. Description of work and request for approval **5**

C. Evidence of Industry support **8**

D. Industry expectations about training delivery **9**

E. Implementation of the training package components **10**

F. Quality assurance reports **11**

G. Evidence of completion **12**

H. IRC support **13**

Appendix 1: Components for endorsement **14**

Appendix 2: Industry support **16**

Appendix 3: Minor updates **24**

Appendix 4: Quality assurance report **26**

A. Administrative details

This section provides an overview of the relevant organisations, the case for change and training package components for endorsement.

Organisational details

This submission is made by the following Industry Reference Committee (IRC):

- Pharmaceutical Manufacturing IRC

Skills Impact Ltd is the Skills Service Organisation (SSO) supporting this submission.

Component details

The Case for Endorsement comprises one qualification and two units of competency and their associated assessment requirements as part of the *FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.* Seven units of competency with minor upgrades are also listed.

The Pharmaceutical Manufacturing Bioprocessing Technologies project produced the following updated components.

For endorsement	Not for endorsement (minor changes)
• FBP30820 Certificate III in Pharmaceutical Manufacturing • FBPPHM3018 Operate a sterilisation process using an autoclave • FBPPHM3019 Operate a chromatography manufacturing process	• FBPPHM3005 Operate a concentration process • FBPPHM3006 Operate an extraction process • FBPPHM3008 Operate an aseptic fill and seal process • FBPPHM3009 Operate an aseptic form, fill and seal process • FBPPHM3011 Dispense pharmaceutical raw materials • FBPPHM3014 Operate a liquid manufacturing process • FBPPHM4003 Facilitate contamination control

A full list of components proposed for endorsement appears in **Appendix 1:** Components for Endorsement. Units of competency reviewed as minor updates appear in **Appendix 3**: Minor Updates

Case for Change details

The Case for Change (Skills Impact/TPD/2017–18/003) was approved in June 2018. The requirements set by the Australian Industry and Skills Committee (AISC) in relation to the training package development work are:

- develop one qualification, one skill set and 15 units of competency, and
- update a further 9 units of competency.

B. Description of work and request for approval

This section describes the work undertaken and the decision being sought from the AISC. The components submitted for endorsement have been reviewed as part of the following project.

Pharmaceutical Manufacturing Bioprocessing Technologies project work undertaken and why

Skill Description:

Bioprocessing in Pharmaceutical Manufacturing was identified as a key skill priority in the *2018 Pharmaceutical Manufacturing IRC Skills Forecast (page 4)*.

The biotechnological sector in the Australian pharmaceutical manufacturing industry is expanding and attracting significant investment, with further growth expected.

Biotechnology is currently used in applied immunology, pharmaceutical therapies and diagnostic tests.

Relevant occupations include:

- Manufacturing operators
- Plant operators
- Bioprocess technicians
- Quality assurance and quality control staff
- Research and development staff
- Fill finish/packaging operators
- Project managers
- Stock management and distribution staff.

Driver for this project:

Bioprocessing involves the manufacture of products from or via living organisms. Examples of such organisms include bacteria, yeast and mammalian cells. The skills required by this growing workforce are not currently addressed within the vocational education and training sector. Primarily, industrial biotechnology deals with the manufacture of protein-based products. Working with these “large molecules” involves a more complex production process. This requires a specific set of skills and knowledge. It involves complex analytical techniques and managing higher risks of product degradation, process variability and contamination.

The skills and knowledge required to work in this growing field include:

- contamination control
- cleanroom operations
- recombinant DNA technology
- cell culture manufacturing
- aseptic and sterile manufacturing
- purification processing
- manufacturing execution systems
- stainless steel and single use technology manufacturing
- data analytics, including process analytical technology and Industry 4.0.

This project sought to develop training package components to address the skills and knowledge needed to work with bioprocessing technologies.

Work undertaken and why:

This section of the Case for Endorsement outlines why the project outcomes are not aligned to the AISC Activity Order approved in June 2018.

It reflects the IRC recommendation to defer to current industry feedback to not proceed with development of a qualification, skill set or new units of competency as proposed, but rather to proceed with reviewing and broadening existing units to meet potentially emerging industry needs.

When the project commenced, it had been envisaged that a Subject Matter Expert Working Group (SMEWG) would be formed where the group would meet to conduct a workforce functional analysis (WFA) and discuss the gaps in existing training and assessment in the workforce.
From the outset, there were several challenges with the project, which included:

- Commercial-in-confidence is of paramount importance to the organisations who are involved in pharmaceutical bioprocessing and it was not possible to organise Subject Matter Experts (SMEs) to come together as one SMEWG. Because of this issue, each organisation was approached and communicated and/or met with individually.
- Discussion with industry experts indicated that research and development in Australia is a large area of pharmaceutical bioprocessing, whilst manufacturing in Australia is not. It was highlighted to the project team that most organisations do all their manufacturing offshore.
- Feedback received via consultation was that there has been a tendency in pharmaceutical bioprocessing activities in Australia, to hire university graduates or postgraduates who have some of the skills required for work in the sector rather than take on employees with a limited background/training in the sector.
- The organisations who were consulted had comprehensive in-house training and development departments where individuals were trained according to the company's needs. This training is very closely aligned with incremental increases in wages and it was noted that there was no desire for formalised training through the vocational education and training (VET) system due to the need of companies for bespoke and highly confidential training due to commercial-in-confidence protocols.

The current unprecedented and unpredictable health crisis may give rise to potential opportunities for increased onshore pharmaceutical manufacturing, which as a result may in the future also shift the industry demand and desire for the uptake of vocational education and training skills and credentials over higher education qualifications in the industry.

Presently, however, the industry's proprietary and well established in-house training and preference for higher education graduates limits the use of VET credentials, and managing the crisis itself is industry's current priority. The units were revised with the assistance of the IRC and made available for public consultation from 15 May – 14 June 2020, during which a meeting was held online on 2 June 2020. Changes included making the units more flexible to enable them to be used in a bioprocessing environment.

Following the public consultation, a validation period for review of the final drafts was available via the Skills Impact website from 6 – 19 July 2020. Further consultation with SMEs was undertaken during this period. Online validation meetings were held on 16 and 20 July 2020 to ensure all units were validated.

Industry input was also sought on whether the units should be broadened to include generic statements about regulations rather than making direct reference to Good Manufacturing Practice (GMP) or Good Distribution Practice (GDP). Feedback received prior to validation indicated that not all facilities use these terms, complying with other regulatory requirements and/or standards (for example, ISO standards), and that units of competency that discuss compliance should be updated to use more inclusive, generic terminology (for example, 'regulatory requirements' or 'standards').

The Pharmaceutical Manufacturing IRC advised to retain references to Good Manufacturing Practice (GMP) or Good Distribution Practice (GDP) in all of the revised units to ensure compliance standards are appropriately addressed and not overlooked. The one difference is in the Application section of unit *FBPPHM3018 Operate a sterilisation process using an autoclave* which has been amended to include the phrase 'The unit applies to individuals who apply Good Manufacturing Practice (GMP) or other accreditation or certification requirements if relevant in other industries/settings, and operating principles to the terminal sterilisation of product and sterilisation of goods for aseptic processing using an autoclave'.

This change enables the unit to be utilised across several industries who use autoclaves in their laboratories but are not required to adhere to GMP requirements. It also prevents the need to duplicate this unit in other training packages.

Note: The qualification which includes the reviewed units of competency, *Certificate III in Pharmaceutical Manufacturing*, has received administrative changes to update references to the reviewed units in this submission. In addition, some imported units of competency in this qualification have also had their codes updated to reflect latest versions. This includes units of competency from *BSB Business Services Training Package* and *HLT Health Training Package* which were endorsed by the AISC in August 2020, which Skills Services Organisations have been encouraged to use by the AISC Secretariat (Department of Education, Skills and Employment) now. One of these imported units is a BSB unit of competency which sits in the core of the *Certificate III in Pharmaceutical Manufacturing*. Whilst the updated BSB unit of competency is deemed equivalent to its predecessor and causes no changes to the vocational outcomes of the *Certificate III in Pharmaceutical Manufacturing*, this BSB unit sits in the core of the qualification, and so this update has triggered a change of code for the qualification. These updates have been approved by the Pharmaceutical Manufacturing Industry Reference Committee.

Decision being sought

This submission puts forward the Case for Endorsement for the proposed qualification and units of competency of the *FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.* The draft components submitted for endorsement by the AISC are:

- FBPPHM3018 Operate a sterilisation process using an autoclave
- FBPPHM3019 Operate a chromatography manufacturing process
- FBP30820 Certificate III in Pharmaceutical Manufacturing (updates to some unit codes)

An additional seven units of competency were updated as part of this project. These changes were minor and do not require endorsement, and will be released as part of the FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.

The proposed Training Package components are listed in **Appendix 1: Components for Endorsement**.

C. Evidence of Industry support

This section provides evidence that the FBP Food, Beverage and Pharmaceutical Training Package is supported by industry.

Support by IRC(s)

The Pharmaceutical Manufacturing IRC is responsible for the *FBP Food, Beverage and Pharmaceutical Training Package.* IRC members supported the recommendation to put forward the proposed training package products to the AISC for endorsement. Please refer to **Section I. IRC support** for written evidence of support.

Consultation with stakeholders

During development of the training package products, the following communication strategies were used for consultation with stakeholders:

- meetings - face-to face, video/teleconferences with key industry stakeholders and SMEs
- three site visits
- IRC member communications with their industry networks
- emails and newsletters to state and territory training authorities (STAs/TTAs), VET regulators and other stakeholders
- draft materials on skills impact website were available for feedback.

Please refer to **Appendix 2: Industry support** for a list of activities conducted, organisations and individuals consulted, together with letters of support.

Reports by exception

At this time, there are no reports by exception.

D. Industry expectations about training delivery

This section explains the advice provided in the Companion Volume Implementation Guide for the *FBP Food, Beverage and Pharmaceutical Training Package Version 5.0* together with recommendations for delivery of qualifications as traineeships/apprenticeships.

Companion Volume Implementation Guide

The companion volume 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.

E. Implementation of the training package components

This section explains how the training package components meet occupational and/or licensing requirements and identifies particular implementation issues and strategies to manage these issues.

How training package components meet occupation and licensing requirements

There are no licensing requirements that apply to the updated qualification, the seven revised units of competency and the two updated units of competency that are being submitted for endorsement.

Implementation issues and management strategies

The main implementation issue is the historically low uptake of these units in general. It is expected the changes that have been made to the components will assist in making them useable in broader contexts, and more appealing to industry and RTOs.

Due to the COVID-19 pandemic, the Department of Education, Skills and Employment's AISC Covid-19 response sub-committee is looking at the need for skills and training in Pharmaceutical Manufacturing, with specific emphasis on the potential for current manufacturers in any field to pivot into the manufacture of vaccines and immunity testing kits. The updated components seek to assist in this emergent skills need.

Industry may also identify the advantages of employing and training individuals who do not hold higher education qualifications but who can gain skills using vocational education and training components and on-the-job training.

F. Quality assurance reports

Skills Impact declares that the proposed components of the *FBP Food, Beverage and Pharmaceutical Training Package 5.0* meet the requirements of the *Standards for Training Packages 2012* and the *Training Package Development and Endorsement Process Policy*.

The table provides a statement of evidence that the components meet the Training Package Quality Principles.

Principle	Evidenced by:
1. Reflect identified workforce outcomes	• Training package components are compliant with the Standards for Training Packages 2012, the Training Package Products Policy and the Training Package Development and Endorsement Process Policy • Evidence that the training package components respond to Ministers' policy initiatives, in particular the CISC 2015 training package reforms • Open and inclusive consultation and validation commensurate with scope and impact has been conducted
2. Support portability of skills and competencies including reflecting licensing and regulatory requirements	• Units of competency support movement within and across sectors
3. Reflect national agreement about the core transferable skills and core job-specific skills required for job roles as identified by industry	• Active engagement across industry has sought to achieve a national consensus about the advice being provided to the AISC.
4. Support interpretation by training providers and others through the use of simple, concise language and clear articulation of assessment requirements	• Industry advice about delivery is provided via a Companion Volume Implementation Guide ready for publication at the same time as the Training Package • Units of competency and their associated assessment requirements are clearly written and have consistent breadth and depth • Compliance with the TGA/National Register requirements for publication • Implementation advice is provided in a Companion Volume Implementation Guide that is ready for publication at the same time as the FBP Food, Beverage and Pharmaceutical Training Package

The declaration and statement of evidence is confirmed by the independent Quality Report which is provided in **Appendix 4: Quality Report**.

The *FBP Food, Beverage and Pharmaceutical Training Package Companion Volume Implementation Guide* has been quality assured through Skills Impact's quality processes and is available.

G. Evidence of completion

Skills Impact confirms that the nine units of competency identified for review in the Case for Change and subsequent Activity Order as well as administrative updates to one qualification, have been completed and included in the *FBP Food, Beverage and Pharmaceutical Training Package Version 5.0*.

The developed training package components are listed in **Appendix 1: Components for Endorsement**. Full copies of the listed training package components are provided with this Case for Endorsement.

Evidence that training package component(s) are prepared for publication.

The Quality Report provides confirmation that the draft components meet the *Standards for Training Packages 2012*.

All components have been created to comply with the National Register requirements for publication. The **Mapping Summary** and **Training Package Modification History** provided in **Appendix 1 Components for endorsement** provide details of the changes to the training package components that are required to allow them to be published on the National Register.

H. IRC support

The Pharmaceutical Manufacturing IRC supports the submission of the training package components detailed in this Case for Endorsement.

Signed for and on behalf of the Pharmaceutical Manufacturing IRC by its appointed Chair.

Name of Chair:	Paul MacLeman
Signature of Chair:	
Date:	1 September 2020

Appendix 1: Components for endorsement

a. Qualification

FBP Food, Beverage and Pharmaceutical Training Package Version 5.0 **Qualification**	
Code	**Title**
FBP30820	Certificate III in Pharmaceutical Manufacturing

b. Unit title and code and associated assessment requirements

FBP Food, Beverage and Pharmaceutical Training Package Version 5.0 **Units of competency**	
Code	**Title**
FBPPHM3018	Operate a sterilisation process using an autoclave
FBPPHM3019	Operate a chromatography manufacturing process

c. Mapping information

Mapping of qualification

Mapping of qualifications between ***FBP Food, Beverage and Pharmaceutical Training Package*** **Versions 4.1 and 5.0**			
Code and title (previous version)	**Code and title (current version)**	**Comments**	**Equivalence statement**
FBP30818 Certificate III in Pharmaceutical Manufacturing	FBP30820 Certificate III in Pharmaceutical Manufacturing	Updated unit codes in core and elective bank of Packaging Rules	Equivalent

Mapping of units of competency

Mapping of units of competency between ***FBP Food, Beverage and Pharmaceutical Training Package*** **Versions 4.1 and 5.0**			
Code and title (previous version)	**Code and title (current version)**	**Comments**	**Equivalence statement**
FBPPHM3016 Operate a sterilisation process using an autoclave	FBPPHM3018 Operate a sterilisation process using an autoclave	Major changes to Performance Criteria Foundation skills amended Performance Evidence revised Knowledge Evidence clarified	Not equivalent

Mapping of units of competency between *FBP Food, Beverage and Pharmaceutical Training Package* Versions 4.1 and 5.0			
Code and title (previous version)	**Code and title (current version)**	**Comments**	**Equivalence statement**
		Assessment Conditions clarified	
FBPPHM3007 Operate a separation process using chromatography	FBPPHM3019 Operate a chromatography manufacturing process	Title changed Foundation skills table updated Range of Conditions deleted to remove duplication Minor change to performance criteria and assessment requirements for clarity	Equivalent

d. Credit arrangements

Credit arrangements for *FBP Food, Beverage and Pharmaceutical Training Package Version 5.0*		
Qualification Code	**Qualification Title**	**Credit Arrangement Details**
FBP30820	Certificate III in Pharmaceutical Manufacturing	At the time of endorsement of this training package, no national credit arrangements exist.

Appendix 2: Industry support

Consultation activities

A range of strategies were used for consultation with stakeholders during development of the *FBP Food, Beverage and Pharmaceutical Training Package Version 5*.

Consultation activities included:

- Project page on the Skills Impact website - throughout project lifecycle https://www.skillsimpact.com.au/pharmaceutical-manufacturing-industry-reference-committee/training-package-projects/pharmaceutical-bioprocessing-project/
- Attendance at:
    - BioProcessing Network 2019 Annual Conference - 22 – 24 October 2019
    - PharmAus19 – Medicines Australia forum in Canberra -15 October 2019
    - AusBioTech19 - 1 Nov 2019
- News articles and stories in Skills Impact newsletters and other external publications – throughout project
- Site visits and face-to-face and online meetings – throughout project
- Consultation draft 1 – feedback hub, webinars - 15 May – 14 June 2020
- Validation survey and validation meetings - 06 – 19 July 2020.

There have been three site visits:

- CSL Behring Broadmeadows – 23 May 2019, met with HR Team to discuss the project and request assistance in identification of SMEs for the project. Toured the facility and looked at various job roles in action which included the tasks involved in conducting the roles.
- University of Technology Sydney – 16 October 2019, met with the Facility Manager at the Biologics Innovation Facility at University of Technology Sydney (UTS). This new facility simulates all bioprocessing stages and several RTOs and industries are now partnering with UTS to train students. UTS representatives discussed the lack of actual manufacturing in the pharmaceutical industry in Australia (costs are very prohibitive) now. However, they believe that by having skilled and job ready individuals there will be a desire for big pharmaceutical companies to begin large scale bioprocessing in Australia.
- Pfizer Adelaide – 14 January 2020, met with the Training Manager and Production Lead to discuss roles involved in bioprocessing at Pfizer and how they aligned to existing units of competency for the project.

Other site meetings have included:

- CSIRO Manufacturing – 19 August 2019, meeting with Team Leader - Industrial Biotechnology - Discussed project and possible SME participants for future meetings
- Seer Pharma Pty Ltd – 18 September 2019, met with Partner to discuss project and possible participants for future meetings
- CSL Behring Broadmeadows – 29 October 2019, met with HR Manager and Production Manager to further discuss roles within that organisation and how they aligned to the units of competency
- AdAlta – 31 October 2019, met with the Chief Operating Office to discuss project and bioprocessing manufacture in Australia.

Stakeholders engaged during the project are described in the matrix below, with a full list of all engaged stakeholders available . Skills Impact reached out to RTOs who were delivering existing qualifications for their input.

	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 Industry Training Advisory Bodies confirmed few to no relevant stakeholders in the boxes marked with an asterisk*

Project page on the Skills Impact website

A project page was set up on the Skills Impact website at the start of the project with information about the project together with progress updates. The project page remained on the website throughout the project. Visitors were invited to register their interest to receive email alerts about the project including notification and registration for public consultation workshops and opportunities to provide feedback on draft materials.
Pharmaceutical Bioprocessing Project page: https://www.skillsimpact.com.au/pharmaceutical-manufacturing-industry-reference-committee/training-package-projects/pharmaceutical-bioprocessing-project/

Publications

As part of communication activities to inform stakeholders of the project's progress and opportunities for input and feedback, news articles, social media posts and newsletters were published. Skills Impact newsletters and website news articles were published on the Skills Impact website and distributed to the database of subscribers. External publications were distributed to the relevant publisher's subscriber lists.

Skills Impact newsletters and website news articles

Distributed to the Skills Impact database of subscribers.

- New Project in Pharmaceutical Bioprocessing 24 September 2019
- Reminder: New Pharmaceutical Bioprocessing Project 18 October 2019
- Register Your Interest: Pharmaceutical Bioprocessing Project 19 December 2019
- Get Involved with Defining Skills Standards in Pharmaceutical Bioprocessing 4 February 2020
- Capturing Skills Standards in Pharmaceutical Bioprocessing 26 February 2020
- Capturing Skills Standards in Pharmaceutical Bioprocessing 16 March 2020
- Capturing Skills Standards in Pharmaceutical Bioprocessing 19 March 2020
- Pharmaceutical Bioprocessing Project Draft Units Available – 15 May 2020
- Updated Units for Pharmaceutical Bioprocessing Available for Review 18 May 2020
- Pharmaceutical Bioprocessing Available for Validation Soon 24 June 2020
- Pharmaceutical Bioprocessing Available for Validation 6 July 2020
- Draft Skills Standards Still Available for Feedback: Pharmaceutical Bioprocessing Project 14 July 2020
- Validate Pharmaceutical Bioprocessing Units 16 July 2020

- Thank You for Validating Pharmaceutical Bioprocessing Skills Standards 22 July 2020.

In addition to these publications, an *Update on Skills Impact Projects* Newsletter was distributed to State and Territory Training Authorities, Industry Training Advisory Boards and Councils, Victorian Curriculum Maintenance Managers and TAFE NSW Industry Liaison people each month, providing updates on all Skills Impact projects, including the Pharmaceutical Bioprocessing project.

External publications

- BioMelbourne Network 21/10/2019 https://biomelbourne.org/have-your-say-in-defining-national-skills-standards-for-pharmaceutical-bioprocessing-national-project-identifying-unique-skills-and-standards/
- VETinfoNews – 'Pharmaceutical bioprocessing' – February 2020
- Food, Fibre & Timber Training Industries Training Council (WA) Nimble News – 'Pharmaceutical bioprocessing' – 3 February 2020.

Subject Matter Expert consultations conducted between 23 May 2019 and 5 May 2020

Name	Organisation	Position	Organisation Type / Size	State
David Azzopardi	CSL Behring	Talent Development	Industry	VIC
Dr Geoff Dumsday	CSIRO	Team Leader – Industrial Biotechnology	Industry	VIC
Lachlan Senior	Melbourne University	Biomedical Sciences Department	Education	VIC
Louise White	SeerPharma	Partner	Industry	VIC
Andrew Groth	University of Technology Sydney	Science faculty Business Development Manager	Education	NSW
Edwin Hoang	Biologics Innovation Facility University of Technology Sydney	Facility Manager	Education	NSW
Ashley Bates	Ashley Bates Consulting	Director	Industry	VIC
Michael Song	Dept of Industry, Innovation and Science	Biologics Engineer	Government	ACT
Rebecca Hayes	CSL Behring	Production Manager, Packaging	Industry	VIC
Dallas Hartman	AdAlta	Chief Operating Officer	Industry	VIC
Carol Senn	Pfizer	Training Manager	Industry	SA

Consultation Webinar Participants 9 June 2020 via Zoom

Name	Organisation	Position	Organisation Type / Size	State
Louise White	Seer Pharma	Partner	Industry	NAT
Paul MacLeman	AdAlta	Chair PM IRC	Industry	VIC
Charles Ross	Vaxxas	Clinical Operations	Industry	QLD

Consultation Draft Feedback Contributors 15 May – 14 June 2020 via Feedback hub

Name	Organisation	Position	Organisation Type / Size	State
Paul Saunders	Chisholm Institute	CMM Curriculum Maintenance Management Service General Manufacturing	Education	VIC
Anne Donnellan	AMWU	National Organiser	Union	NAT
Charles Ross	Vaxxas	Clinical Operations	Industry	QLD
Leah Simmons	TAFE NSW	Industry Relationship Lead, Innovative manufacturing, Robotics and Science	Education	NSW
Louise White	Seer Pharma	Partner	Industry	NAT

Validation Meeting Participants 16 and 20 July 2020 via Webinar

Name	Organisation	Position	Organisation Type / Size	State
Ashley Bates	Ashley Bates Consulting	Director	Industry	VIC
Edwin Hoang	Biologics Innovation Facility University of Technology Sydney	Facility Manager	Education	NSW
Charles Ross	Vaxxas	Clinical Operations	Industry	QLD
Leah Simmons	TAFE NSW	Industry Relationship Lead, Innovative manufacturing, Robotics and Science	Education	NSW
Dr Michael Kimber	Health Star Training	Principal	Education	QLD
Paul MacLeman	AdAlta	Chair PM IRC	Industry	VIC
Louise White	Seer Pharma	Partner	Industry	NAT

Letters of Support

Bioprocessing Units of Competency

Michael Kimber <mbk@healthstar.edu.au>

Hi Cathy,

I would like to advise my support for the following revised units of competency. I have reviewed the units and believe that they are comprehensive and fit for purpose in the Pharmaceutical/Bioprocessing industry:

FBPPHM3005 Operate a concentration process (minor changes not for endorsement)

FBPPHM3006 Operate an extraction process (minor changes not for endorsement)

FBPPHM3008 Operate an aseptic fill and seal process (minor changes not for endorsement)

FBPPHM3009 Operate an aseptic form, fill and seal process (minor changes not for endorsement)

FBPPHM3011 Dispense pharmaceutical raw materials (minor changes not for endorsement)

FBPPHM3014 Operate a liquid manufacturing process (minor changes not for endorsement)

FBPPHM3018 Operate a sterilisation process using an autoclave (with new code)

FBPPHM3019 Operate a chromatography manufacturing process (with new code and title change)

FBPPHM4003 Facilitate contamination control (minor changes not for endorsement)

Kind regards,

Michael

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AdAlta
next generation protein therapeutics

17th August 2020
15/2 Park Drive
Bundoora 3083 Victoria
Australia

To Whom It May Concern:

As the foundational Chair of the Pharmaceutical Industry Reference Committee I was involved in the development of the Futures Skills Forecast that led the application for support, gaining of support and subsequent development of the Bioprocessing Technologies training units that are to form part of the Food Beverage and Pharmaceuticals National Training Package.

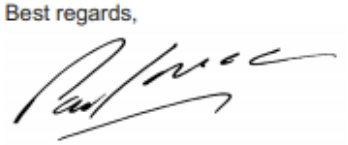
While these units were being developed, I provided input based upon my current experience with bioprocessing as Chairman of ASX listed antibody development company AdAlta Ltd and through bioprocessing knowledge and experience gaining in other organisations I have led and general biotechnology and pharmaceutical industry knowledge. These skills are an essential and growing part of the pharmaceutical industry, with seven out of the top ten drugs by sales value globally requiring such skills for the manufacture.

I therefore know from personal experience that such skills are needed, now and in the future, in order for our pharmaceutical manufacturing sector to grow and flourish. In my capacity as Chair of AdAlta Ltd and through contacts with other companies, I was also to gain positive feedback regarding the need for these skills and also to provide Skills Impact with other contacts with whom they could refine and validate these skills and units.

The recent pandemic crisis has underlined this need, not just globally but with Australia, for increased pharmaceutical manufacturing capacity in order for the country to meet current future needs more self-sufficiently. The Australian government is therefore planning to expand the sovereign capacity for production in this area in order to increase our responsiveness to the current and any future similar crises. This will necessarily require more personnel to staff new and expended bioprocessing facilities to make products such as antisera, vaccines and diagnostics, increasing the country's resilience and ability to respond to changing world health situations.

For the reasons above, I therefore wholeheartedly support the endorsement of the Bioprocessing Technologies training units.

Best regards,



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17 August 2020

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 Bioprocessing Technologies Project.

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 2020, recognising that the Pharmaceutical industry was changing from a focus on chemical molecules to biological substance, SeerPharma has developed a new postgraduate subject titled "Biotech Processing" to be included in the Master of Good Manufacturing Practice Degree. This subject utilises the new Biologics Innovation Facility (BIF) based at the University of Technology, Sydney. BIF "aims to drive the development of the biotech industry by offering a platform for innovation in biopharmaceutical research, as well as providing professional training in bioprocessing techniques in a GMP-lite environment." (https://open.uts.edu.au/uts-open/faculty/science/Biologics_Innovation_Facility/utsnibrt-introduction-to-bioprocessing/).

The biopharmaceutical industry is providing novel and targeted treatments that are life changing for many patients. This is not going to change. Several companies across the Asia-Pacific region such as CSL, Thermo Fisher (Patheon), Tessa Therapeutics, Biocon, Kalbe, Samsung Biologics, Celltrion, WuXi and Lonza are investing heavily and expanding operations across the region. In Australia we are seeing many small to medium sized biopharmaceutical organisations entering this space, looking to scale up from their research & development activities. Two examples of Australian companies that are developing and manufacturing next-generation vaccines for unmet medical needs are Vaxmed (https://www.vaxmed.com.au/about) and Vaxine (http://vaxine.net).

The Irish government recognised the need to "support the growth and development of all aspects of the biopharmaceutical manufacturing industry" some years ago when they funded the National Institute for Bioprocessing Research and Training (NIBRT) (https://www.nibrt.ie/about/). NIBRT has now partnered with the Biologics Innovation Facility (BIF) based at the University of Technology.

If Australia is to take full advantage of the growth and expansion of the biopharmaceutical industry, it must invest in infrastructure and, to meet the demand for a pool of skilled workers, human resources. However, bioprocessing skills are not easy to learn and master. And, as there will be competition in the market for these positions, employers are likely to face ongoing difficulties in filling and holding onto qualified and experienced personnel.

While many of the jobs in a bioprocessing 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 credential is needed to fill these roles and to provide an alternate pathway to employment for our secondary students.

I fully support the Bioprocessing Project.

Yours sincerely

Louise White

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Appendix 3: Minor updates

Mapping of units of competency

Mapping of units of competency between *FBP Food, Beverage and Pharmaceutical Training Package* Versions 4.1 and 5.0			
Code and title (previous version)	**Code and title (current version)**	**Comments**	**Equivalence statement**
FBPPHM3005 Operate a concentration process Release 1	FBPPHM3005 Operate a concentration process Release 2	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to performance evidence and assessment conditions for clarity	Equivalent
FBPPHM3006 Operate an extraction process Release 1	FBPPHM3006 Operate an extraction process Release 2	Minor changes to application, knowledge evidence and assessment conditions for clarity Foundation skills table updated Range of conditions deleted to remove duplication	Equivalent
FBPPHM3008 Operate an aseptic fill and seal process Release 1	FBPPHM3008 Operate an aseptic fill and seal process Release 2	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to assessment requirements and assessment conditions for clarity	Equivalent
FBPPHM3009 Operate an aseptic form, fill and seal process Release 1	FBPPHM3009 Operate an aseptic form, fill and seal process Release 2	Foundation skills table updated Range of conditions deleted to remove duplication	Equivalent

Mapping of units of competency between *FBP Food, Beverage and Pharmaceutical Training Package* Versions 4.1 and 5.0			
Code and title (previous version)	**Code and title (current version)**	**Comments**	**Equivalence statement**
		Minor changes to assessment conditions for clarity	
FBPPHM3011 Dispense pharmaceutical raw materials Release 1	FBPPHM3011 Dispense pharmaceutical raw materials Release 2	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to assessment conditions for clarity	Equivalent
FBPPHM3014 Operate a liquid manufacturing process Release 1	FBPPHM3014 Operate a liquid manufacturing process Release 2	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to assessment requirements for clarity	Equivalent
FBPPHM4003 Facilitate contamination control Release 1	FBPPHM4003 Facilitate contamination control Release 2	Foundation skills amended Minor updates to Knowledge Evidence and Performance Evidence	Equivalent

Appendix 4: Quality assurance report

Quality Report Template

Section 1 – Cover page

Information required	Detail
Training Package title and code	**FBP Food, Beverage and Pharmaceutical Training Package V5.0**
Number of new qualifications and their titles[1]	**0**
Number of revised qualifications and their titles	1 FBP30820 Certificate III in Pharmaceutical Manufacturing
Number of new units of competency and their titles	0
Number of revised units of competency and their titles	2 FBPPHM3018 Operate a sterilisation process using an autoclave FBPPHM3019 Operate a chromatography manufacturing 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 compliance 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 evidence, provided in the Case for Endorsement (CfE) and verified on the Skills Impact project page of the website, of the consultation and validation processes undertaken by the developer are fit for purpose and commensurate with the scope of the CfE.** **It is also the panel member's view that the estimated impact of the proposed changes will be positive in:** • **enabling broader utilisation of the revised units, as suggested in the CfE:** *It is expected the changes that have been made to the components will assist in making them useable in broader contexts, and more appealing to industry and RTOs*, **and** • **the inclusion of the most current versions of endorsed imported units.**
Name of panel member completing Quality Report	**Maree Thorne**
Date of completion of the Quality Report	**Amended 24 September 2020**

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 comprising one revised qualification and two revised units of competency, each with associated assessment requirement, in the *FBP Food, Beverage and Pharmaceutical Training Package V5.0* meet the requirements of Standard 1. The CfE and FBP Food, Beverage and Pharmaceutical Companion Volume Implementation Guide (CVIG) V5.0 specify that no credit arrangements exit at time of endorsement. The FBP CVIG Parts 1 and 2 have been updated to include the components proposed for endorsement, as well as minor changes, and 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 Standard 2 - Compliance with the Training Package Products Policy (TPPP). Supporting evidence includes: • Compliance with changes to coding and/or titling of components proposed for endorsement. Qualification FBP30820 Certificate III in Pharmaceutical Manufacturing was recoded due to endorsement of a recoded core Business Services imported unit. Minor changes to seven units of competency and associated assessment requirements have been reflected in release versions • Foundation skills are explicit and recognisable in units of competency and/or are stated in the Foundation Skills field of the unit of competency template. The CVIG outlines how Foundation Skills have been address in units of competency, and emphasizes that RTOs must consider them part of the training and assessment for each unit • Neither of the two units of competency proposed for endorsement have pre-requisite requirements, and both include unit mapping in the form of an equivalence table with information on the extent of the changes made, and the equivalency status of each unit, which is also included in the CVIG • As identified in the Equity Report 'the *FBP Companion Volume Implementation Guide, Version 5.* (FBP CVIG*)* includes guidance to ensure that learners are not discriminated against, and guidance around reasonable adjustment to accommodate learners with disabilities or particular needs. Reference has been made to *Disability Standards for Education, 2005*.'

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 CfE provides information about the Pharmaceutical Manufacturing Industry Reference Committee's (IRC) and Skills Impact's development processes for this Bio Processing project, and compliance with the Key Characteristics of the *Training Package Development and Endorsement Process Policy (TPDEPP)* including: • promotion through a variety of channels of consultation and validation strategies and opportunities for participation and compliant timeframes for each phase of consultation • contributing personnel including state-based employers and national industry organisations, unions and registered training organisations • flexible communication and engagement strategies, as required by nature of the industry and current national health crisis restrictions on travel and face to face events • summaries of feedback, responses and actions available on the website for each stage of the project, which were examined in the quality assurance process to confirm stakeholder engagement and developer actions. The CfE details very limited Australian pharmaceutical bioprocessing manufacturing, and commercial-in-confidence limitations in the pharmaceutical bioprocessing industry in Australia, which impacted the original scope of the project Activity Order which was approved in June 2018. Qualification FBP30820 Certificate III in Pharmaceutical Manufacturing was recoded and is submitted for endorsement without the full endorsement process due to the endorsement of a core imported unit, a process that the developer advised is supported by the AISC Secretariate, with the imported units approved as suitable by the Pharmaceutical Manufacturing IRC.
Standard 4 Units of competency specify the standards of performance required in the workplace	Yes	Both units of competency, as well as the seven units with minor changes, were reviewed in the QA process. Skills Impact has indicated that all aspects of the units of competency were supported by stakeholders and the IRC through validation.

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 5 The structure of units of competency complies with the unit of competency template	Yes	The structure of the two revised units complies with the unit of competency template specified in the TPPP. The QA process confirms the Editorial Report that: • the coding and titling of the units comply with the unit of competency template and policy. • all units include a statement in the Application field relating to legislative and regulatory requirements: *No licensing, legislative or certification requirements apply to this unit at the time of publication.* • foundation skills are described in the appropriate field utilising skills described in the Australian Core Skills Framework (ACSF). • the equivalence of each unit to the previous version is stated in the unit mapping information table.
Standard 6 Assessment requirements specify the evidence and required conditions for assessment	Yes	All 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. Reference to frequency of Performance Evidence is stated, as are Assessment Conditions in relation to how evidence may be gathered and provision of necessary resources for meeting assessment requirements. Skills Impact has indicated that all aspects of the assessment requirements were supported by stakeholders and the IRC through validation.
Standard 7 Every unit of competency has associated assessment requirements. The structure of assessment requirements complies with the assessment requirements template	Yes	Both units of competency proposed for endorsement, and the units with minor changes, have associated assessment requirements, and the structure of these comply with the assessment requirements template. The performance evidence specifies frequency of the tasks to be performed. The assessment conditions have been updated to provide clear, mandatory conditions.

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 8 Qualifications comply with the Australian Qualifications Framework specification for that qualification type	Yes	The proposed FBP30820 Certificate III in Pharmaceutical Manufacturing complies with the AQF specification for a Certificate III, with no changes to packaging rules.
Standard 9 The structure of the information for the Australian Qualifications Framework qualification complies with the qualification template	Yes	The structure of information for the FBP30820 Certificate III in Pharmaceutical Manufacturing complies with the qualification template requirements.
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 CfE and CVIG both clearly specify that no credit arrangements exist: *At the time of endorsement of this training package, no national credit arrangements exist.*
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 *FBP Food, Beverage and Pharmaceutical Training Package Companion Volume Implementation Guide V5.0* in two parts (Part 1: *Overview and Implementation* and Part 2: *Component Details*) was quality assured in this process, is available at the time of endorsement of the proposed components, and complies with the companion volume implementation guide template.
Standard 12 Training Package developers produce other quality assured companion volumes to meet the needs of their stakeholders as required.	N/A	An additional companion volume produced by the developers (Companion Volume User Guide: *Artisanal Food and Beverages*) is not relevant to this project.

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	The CfE clearly outlines why the project outcomes are not aligned to the AISC Activity Order approved in June 2018, which was confirmed and clarified with the developer in the QA process. As detailed in the CfE, the project reflects the IRC recommendation which defers to current industry feedback indicating that qualifications and skills sets in vocational education and training would not be industry supported or utilised at this time, but suggests that the current health crisis may impact Australian pharmaceutical manufacturing in the future, which may also shift the industry demand and desire for the uptake of vocational education and training skills and credentials over higher education qualifications in the industry.
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	Yes	The endorsed components respond to the COAG Industry and Skills Council's (CISC) training package reforms, specifically: • **improve the efficiency of the training system by creating units that can be owned and used by multiple industry sectors** As noted in the CfE and Equity Report: *It is expected the changes that have been made to the components will assist in making them useable in broader contexts, and more appealing to industry and RTOs. (p10)* In particular, unit of competency *FBPPHM3018 Operate a sterilisation process using an autoclave* has undergone significant change and can be used broadly including outside of the pharmaceutical manufacturing sector. The '*change enables the unit to be utilised across several industries who use autoclaves in their laboratories but are not required to adhere to GMP requirements. It also prevents the need to duplicate this unit in other training packages'.* Updated endorsed imported units of competency have been updated in the FBP30820 Certificate III in Pharmaceutical Manufacturing to minimise component

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 • 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		releases for users and ensure the most current versions of imported units, endorsed by industry, are applied.
Reflect contemporary work organisation and job profiles incorporating a future orientation	Yes	The CfE details the consultation and validation processes that have been conducted to ensure the revised units of competency reflect contemporary work organisation and job profiles incorporating a future orientation. Evidence includes seeking industry input regarding use of generic statements about regulations/standards rather than directly referencing specific manufacturing and distribution standards to enable more extensive inclusion of a range of regulatory requirements and/or standards across different facilities/organisations.

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	Updated endorsed imported units of competency have been updated in the FBP30820 Certificate III in Pharmaceutical Manufacturing to minimise component releases for users and ensure the most current versions of imported units, endorsed by industry, are applied.

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*
Promote national and international portability	Yes	The CfE indicates national consensus in the development of the proposed components. Reference is made in the CfE that revised units of competency intentionally retain references to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) international standards, whilst enabling flexibility in unit application wording for industries who do are not required to meet these requirements.
Reflect regulatory requirements and licensing	Yes	Neither proposed component has licencing or regulatory requirements. As required by the Unit of Competency template, the Application field specifies that '*No licensing, legislative or certification requirements apply to this unit at the time of publication'.*

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	Whilst there was not national consensus in relation to the need for a qualification and/or skill set in pharmaceutical bioprocessing, the CfE does reflect national consensus in relation to the two units proposed for endorsement. The CfE (and the Skills Impact project website) evidences the consultation and validation processes providing stakeholders with opportunities to participate via a number of communication channels (telephone, email and online, direct engagement via site visits, newsletter alerts inviting feedback) to capture input on the endorsed components throughout the duration of the review. Appendix 2 details the range of respondent stakeholders including industry participants, government representatives and training practitioners.
Recognise convergence and connectivity of skills	Yes	The Certificate III in Pharmaceutical Manufacture includes imported units from the MSL, MSM, MSS, SIR, BSB and HLT Training Package, with the BSB and HLT units recently endorsed updated in the qualification to ensure use of most current units.

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 QA process confirms the statement in the Equity Report that: 'The following statement in the Case for Endorsement relates to the changes made to the units of competency: *It is expected the changes that have been made to the components will assist in making them useable in broader contexts, and more appealing to industry and RTOs. (p10)* The assessment requirements for *FBPPHM3019 Operate a chromatography manufacturing process* and the seven updated/release 2 units specify that assessment must take place in a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions, allowing the assessment to occur in a range of different contexts. FBPPHM3018 Operate a sterilisation process using an autoclave has undergone significant change and can be used broadly including outside of the pharmaceutical manufacturing sector'.
Support equitable access and progression of learners	Yes	Neither of the two components proposed for endorsement have pre-requisite requirements, and there are no entry requirements for the Certificate III in Pharmaceutical Manufacturing to limit accessibility.

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	The QA confirms the Equity Report statement that: The Case for Endorsement states that there is "… *a tendency in pharmaceutical bioprocessing activities in Australia, to hire university graduates or postgraduates*". The revised units of competency provide practical skills, relevant to individuals following a university pathway and to meet future demand to upskill individuals selecting a vocational pathway.

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	Confirming the review comments in the Equity Report, the *FBP CVIG V5.0* ‘includes comprehensive information about access and equity issues and training pathway information. Guidance is provided to ensure that learners are not discriminated against, and about reasonable adjustment to accommodate learners with disabilities. The FBP CVIG also provides detailed information about Foundation Skills and the frameworks adopted, namely: • the Australian Core Skills Framework (ACSF), and • the Core Skills for Work Developmental Framework (CSfW). It is noted that the two revised units (and 7 units with minor changes/Release 2) have all had updates to the Foundation Skills mapping table to reflect Skills Impact’s current policy to include references to the ACSF only. The foundation skills identified appear to be reasonable and not exceed the skills required in the workplace’.
Support sound assessment practice	Yes	The draft Units of Competency and associated Assessment Requirements proposed for endorsement include references to frequency of Performance Evidence and include Assessment Conditions specifying how evidence must be gathered. Knowledge and Performance Evidence requirements in the Assessment Requirements aligns well to the unit of competency Elements and Performance Criteria.
Support implementation	Yes	The CfE states that ‘All components have been created to comply with the National Register requirements for publication’. The proposed components contain links as required by the templates to the FBP CVIG 5.0 which has been updated to include the components being endorsed, has been quality assured in this process and is ready for publication at the same time as the Training Package components.