



Enterprise Information Guide

To support the Pharmaceutical Manufacturing Operator Induction Skill Set (FBPSS00051)

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Introduction

This resource is for pharmaceutical manufacturing enterprises thinking about employing a trainee or embarking on a skills development program for staff to meet the requirements of the *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*. The Enterprise Information Guide assists employers to:

- Understand their role in providing learning and practice opportunities as part of training new workers
- Highlight the skills and knowledge that an employee undertaking this skill set could learn and practice in the workplace.

What's in this Guide

The Enterprise Information Guide outlines how the training and delivery process works, answers many of the questions an enterprise might have, provides a checklist for commencing a skills development program, and points the enterprise towards further resources. At the end of this resource is also a form that the enterprise can use to monitor and record a learner's progress and track supporting evidence and skills obtained.

Note: The Enterprise Information Guide addresses only the requirements of the units of competency within the *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*, and does not consider issues relating to industrial arrangements, state or territory funding arrangements for vocational training programs, legal requirements or individual arrangements with Registered Training Organisations (RTOs).

Acknowledgements

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Dr Michael Kimber of HealthStar Training is acknowledged as a significant contributing author and compiler of these materials.

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While these materials have been developed with the guidance and assistance of industry experts, trainers and assessors are encouraged to utilise their industry expertise in the use of these materials. Skills Impact will be pleased to receive feedback on any improvements or changes via inquiries@skillsimpact.com.au

For further information about this document or any other work being undertaken by Skills Impact, please visit: www.skillsimpact.com.au

Frequently Asked Questions

Why put employees through an accredited VET course?

By providing an employee with an opportunity to achieve a VET qualification or skill set, you are:

- Assisting employees to obtain or maintain up-to-date work skills
- Building the skill base of your organisation through accredited training (accredited training has been shown to increase overall productivity more quickly than non-accredited training)
- Building the skill base of the industry in general
- Providing a structured and recognised approach to professional development
- Building stronger workplace relationships.

The Australian Vocational Education and Training system is industry-led, skills-based and focused on providing the skills and knowledge that Australian workplaces need to grow stronger, resilient and innovative industries.

Qualifications and skill sets achieved through this system are recognised in all states and territories across the country, have been designed by the industry, reflect current practices and skills required by Australian industries and are delivered and assessed by only qualified, regulated trainers and assessors working with authorised RTOs.

What will the employee learn?

The *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set* is designed to address the skills and knowledge required of pharmaceutical manufacturing operators, for workers entering the pharmaceutical manufacturing industry. This skill set may provide an induction to work in that setting and is also designed to support ongoing professional development for experienced pharmaceutical manufacturing operators.

There are 4 units of competency in this skill set, which require the learner to be able to demonstrate the following skills:

- **FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements**
 1. Identify requirements of GMP related to own work
 2. Prepare for work
 3. Follow GMP requirements when carrying out work activities
- **FBPWHS2001 Participate in work health and safety processes**
 1. Plan and prepare to work safely
 2. Conduct work safely
 3. Respond to hazards
 4. Participate in work health and safety consultative activities
 5. Follow emergency response procedures
- **FBPPHM3002 Operate a pharmaceutical production process**
 1. Receipt materials and components
 2. Set up the production process for operation
 3. Dispense materials
 4. Operate and monitor the production process
 5. Hand over the production process
 6. Shut down the process
- **FBPPHM3003 Work in a controlled environment**
 1. Prepare to enter a controlled environment
 2. Work in a controlled environment
 3. Maintain a controlled environment
 4. Exit a controlled environment

Full descriptions of these skills, and the conditions in which they are to be applied and assessed are available for each unit of competency on training.gov.au:

- [FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements](#)
- [FBPWHS2001 Participate in work health and safety processes](#)
- [FBPPHM3002 Operate a pharmaceutical production process](#)
- [FBPPHM3003 Work in a controlled environment](#)

How much time away from work is required?

This depends on your organisation and your needs. There are dozens of ways to adapt a learning program, and the right solution will meet the needs of your organisation, your employees, your location/facilities/resources, the industry, and the people performing the training.

Options include, but are not limited to:

- releasing employees, and paying them while they attend class
- inviting a trainer on site to run lessons during scheduled workplace training
- training employees yourself, but using an RTO for assessments.

All of these arrangements are legal and valid, and need to be negotiated and agreed.

Depending on the options provided by the RTO, the employee may undertake all, some or none of the learning at the workplace. They may require no time off, a few hours, a few days, or more. Talk to the RTO and see what is possible and what might best suit your needs.

How Training is Delivered and Assessed

Learning online, in a classroom, in a workplace – or a blend of all three

Training providers offer online courses, classroom-based courses, courses undertaken at a learner's workplace – or a mixture of all three. Depending on the delivery options offered by the RTO, you may need to discuss and agree to:

- Where and when classes are scheduled
- How much of the course is conducted online
- Whether learners are expected to undertake training activities at the workplace.

The purpose of assessments

Assessments are designed to formally confirm that an individual (usually called a 'candidate' during assessment) can apply all aspects of the skills and knowledge in the Skill Set in an industry context. To confirm a candidate's competency, a qualified, regulated assessor working with an authorised RTO will collect evidence of competency. This is done through formal assessment tools, which contain things like on-the-job observations, questioning, scenarios, simulated tasks, written tasks, projects and portfolios.

When assessments are delivered

Assessments can be delivered during a training program, after a training program has been completed, or without any training program at all. If the candidate believes they are already competent, they may undertake the assessment without any formal training. If the candidate feels they have enough experience and evidence, they may also prove their competency to an assessor through Recognition of Prior Learning (RPL) or other pathways of assessment.

Assessment and learning on-the-job

Some learning and assessment activities, such as on-the-job observations as part of assessment, are best completed in the workplace. A real work environment can better allow a candidate to learn about and demonstrate competence in the workplace and industry, instead of merely the ability to apply theoretical knowledge based on classroom learning.

The Trainer Guide and the Assessor Guide

The Trainer Guide and the Assessor Guide, published by Skills Impact, are sample resources for trainers, RTOs and assessors of *FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set*. These guides are a good place to learn more about the skills and knowledge of the skill set, as well as the kind of assessments that will be undertaken by candidates.

Choosing a Registered Training Organisation (RTO)

The RTO you select can offer the best options for training delivery and assessment, based on your enterprise and your learner's needs and experience. Before agreeing to arrange for your employees to be trained by a Registered Training Organisation (RTO), check that:

- The RTO is registered to deliver the course you want them to deliver:
 - You can search on training.gov.au to see which RTOs are authorised to deliver the qualification, skill set or units of competency
- The RTO has access to the equipment, knowledge and other resources required to teach the learners in the method you have agreed. (For example, are online training resources available? If face-to-face off-site, is there a classroom/meeting room with resources, equipment, etc?)
- The RTO has clearly explained the cost to you, the cost to the learner and/or other funding arrangements.
- The RTO has provided you with a plan for how they will deliver and assess the learners.
- The RTO will provide a formal certificate of attainment to employees who complete the requirements of the skill set, or of one or more units within it.
- Note: Some states and territories provide services through Industry Training Advisory Bodies (ITABs) that may help you identify appropriate RTOs.

The Enterprise Checklist

The following checklist is a good starting point for enterprises wishing to embark on a VET skills development program for staff.

| | |
|---|--|
| <p>Decide on your requirements:</p> <ul style="list-style-type: none"> • Training program or assessment only? • Online, classroom, on-the-job or mixed training? • How many employees? • Locations/times/cost requirements | |
| <p>Choose an RTO:</p> <ul style="list-style-type: none"> • Discuss requirements • Discuss costs and funding options • Discuss timeline | |
| <p>Decide on details:</p> <ul style="list-style-type: none"> • Training – who/where/when • Assessment – who/where/when | |
| <p>Arrange support for employees:</p> <ul style="list-style-type: none"> • Enrolment support • Funding support and arrangements • Points of contact and monitoring requirements • Time out of work and HR support | |
| <p>Commence training and assessment!</p> | |

Further Resources about the Skills Needed in the Industry

Print resources

The Pharmaceutical Operator, by Dr Michael Kimber, published by HealthStar Training: healthstar.edu.au / The Pharmaceutical Operator: <https://pharmaceuticaloperator.com>
[Good Pharmaceutical Manufacturing Practice: Rationale and Compliance](#), by John Sharp, ISBN 9780429205446. Publisher: CRC Press
[Aulton's Pharmaceuticals: The Design and Manufacture of Medicines](#) by Kevin M.G. Taylor and Michael E. Aulton, ISBN: 0-7020-7003-3. Publisher: Elsevier
Work Health and Safety: A complete course for the CIV and Diploma Courses BSB41412 and BSB51312, by Michael Stol, Caroline McGill, James Ritchie, ISBN: 9781743077467, Publisher: [McGraw-Hill Education](#)

Online resources

Therapeutic Goods Administration (TGA), Good manufacturing practice - an overview: <https://www.tga.gov.au/good-manufacturing-practice-overview>
World Health Organization (WHO). Essential medicines and health products, Quality and Safety: Medicines teaching resources: https://www.who.int/medicines/training/qsm_training/en/
Pharmaceutical Inspection Co-operation Scheme (PIC/S), GMP Guide: <https://picscheme.org/en/publications?tri=gmp#zone>
U.S. Food & Drug, Current Good Manufacturing Practice (CGMP) Regulations: <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>
International Society for Pharmaceutical Engineering (ISPE): <https://ispe.org>
International Pharmaceutical Federation (FIP): <https://www.fip.org>
Medicines Australia: <https://www.medicinesaustralia.com.au>
SeerPharma: <https://www.seerpharma.com/about-us>
PharmOut: <https://www.pharmout.net>
Safe Work Australia: <https://www.safeworkaustralia.gov.au>
Normal body flora: <https://www.scq.ubc.ca/microbes-and-you-normal-flora/>

Newsletters

Pharma in focus: <https://www.pharmainfocus.com.au> (signup for the free 2 week trial)
Pharmaceutical Online (free newsletter): <https://www.pharmaceuticalonline.com>
ISPE SmartBrief (free newsletter): <https://ispe.org>
PharmTech (free newsletter): <https://www.pharmtech.com>

Keeping Track of Your Employee's Progress

Use the following worksheet to monitor and record a learner's progress and track supporting evidence and skills obtained. Check employee's work and understanding. Be particularly vigilant as the employee will have had little experience. Be prepared to go over a procedure with constructive feedback as the employee gains confidence. Once you feel the employee is doing OK use the criteria checks in the sections that follow. Aim to do at least 3 checks so you can be confident the employee has gained the skills and understanding required.

When you are satisfied the employee has mastered the tasks, organise the RTO Trainer to do a final check and sign off on the candidate's competency.

Training and Assessment Record

| | | | |
|------------------|---|-----------|--|
| Employee Name | | Signature | |
| Training Program | FBPSS00051 Pharmaceutical Manufacturing Operator Induction Skill Set | | |

| Unit and Element | Training off the job undertaken | Training in the workplace undertaken? | Formal assessment undertaken? | RTO decision (Competent/Not Yet Competent) |
|---|---------------------------------|---------------------------------------|-------------------------------|--|
| FBPPHM2001 Follow work procedures to maintain Good Manufacturing Practice requirements | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | C / NYC |
| Identify requirements of GMP related to own work | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Prepare for work | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Follow GMP requirements when carrying out work activities | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| FBPWHS2001 Participate in work health and safety processes | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | C / NYC |
| Plan and prepare to work safely | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Conduct work safely | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Respond to hazards | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Participate in work health and safety consultative activities | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Follow emergency response procedures | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| FBPPHM3002 Operate a pharmaceutical production process | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | C / NYC |
| Receipt materials and components | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Set up the production process for operation | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Dispense materials | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |

| Unit and Element | Training off the job undertaken | Training in the workplace undertaken? | Formal assessment undertaken? | RTO decision (Competent/Not Yet Competent) |
|--|---------------------------------|---------------------------------------|-------------------------------|--|
| Operate and monitor the production process | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Hand over the production process | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Shut down the process | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| FBPPHM3003 Work in a controlled environment | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | C / NYC |
| Prepare to enter a controlled environment | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Work in a controlled environment | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Maintain a controlled environment | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Exit a controlled environment | Yes / No Date: .../.../... | Yes / No Date: .../.../... | Yes / No Date: .../.../... | |
| Further Comments | | | | |
| | | | | |

I am satisfied <<employee>> has met the skill development requirements in the workplace.

Workplace Supervisor (signature) _____ Date _____

I am satisfied <<employee>> has met all the requirements set out in the units of competency for this skill set.

RTO Trainer (signature) _____ Date _____



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