Queensland Health

Competency requirements for medicines manufacturers

Purpose of this guideline

The *Medicines and Poisons Act 2019* (MPA) regulates the manufacture of medicines, poisons and prohibited substances in Queensland. The manufacture of medicines, and products containing medicines, presents particular risks to public health and safety. Medicinal products must be manufactured so as to ensure that they are safe, homogenous, of high quality and efficacy, and are fit for purpose.

Manufacturing supervisors play a critical role overseeing the manufacturing process to ensure that these high standards will be met. For this reason the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) requires that the holder of a manufacturing licence for medicines must appoint an appropriately qualified person (or persons) to supervise manufacturing under the licence and that the licensee must take all reasonable steps to ensure the medicine is manufactured under the supervision of that person.

This guideline establishes the minimum competency requirements for persons supervising the manufacture of medicines under a Queensland manufacturing licence. Persons who have qualifications and experience that meet these minimum requirements may be considered 'appropriately qualified'. Qualifications and experience that are deemed to satisfy the necessary competencies, subject to the conditions, have been provided to assist licensees.

Medicated feed versus other medicines

Due to the nature, scale and method of production, there are significant differences between the manufacture of **medicated feed** (being feed for an animal that contains an S4 medicine) and **other medicines** that are for human or veterinary use. For this reason, the competency requirements have been split into two parts, the first are the competency requirements for manufacturing supervisors of medicated feed and the second are the competency requirements for manufacturing supervisors of all other medicines.

Further information

For further information, please see additional guidelines and factsheets:

- Initial application for a medicines manufacturing licence – Form MPA75MME
- Factsheet – Medicated feed
- Factsheet – Commonwealth law manufacturers

To apply for or renew a medicines manufacturing licence, please complete the relevant application form and submit to medicines.applications@health.qld.gov.au.

For additional information on this guideline, contact the Healthcare Approvals and Regulation Unit (HARU): HARU@health.qld.gov.au.

Part 1 – Competency requirements for manufacturing supervisors (medicated animal feed)

Necessary competencies
A person supervising the manufacture of medicated animal feed must have the capability to do the following:
1. Plan for successful feed milling through consideration of the milling environment
2. Follow safe work practices to minimise risks to animals, self and others
3. Manage quality of raw, bulk and packaged ingredients from receival to storage and handling
4. Determine and carry out appropriate milling technique according to type of medicine and feed, and species, size and number of animals
5. Successfully weigh, batch and mix ingredients to desired quantity or concentration avoiding errors and cross-contamination
6. Manage pelleting systems and maintain pellet quality during and post-pelleting
7. Decontaminate, clean and store medicines, equipment and materials or dispose of accordingly
8. Assure quality of finished feed
9. Package or load finished feed for dispatch and delivery
10. Access and use management systems to keep and maintain accurate records of medicines usage

Qualifications and experience that are deemed to satisfy the necessary competencies for supervision of the manufacture of medicated feed, subject to the conditions

Acceptable qualifications/experience	Conditions
Stock Feed Manufacturers' Council of Australia (SFMCA)/University of Queensland Certificate in Advanced Feed Milling completed in past 2 years	

Acceptable qualifications/experience	Conditions
SFMCA/UQ Certificate in Advanced Feed Milling completed over 2 years ago	Must have a minimum of 160 hours of supervising stock feed manufacture in previous 12 months
5 years of experience as a stock feed manufacturing supervisor, with a minimum of 160 hours supervising stock feed manufacture in the previous 12 months	Only considered acceptable until 1 October 2026

Part 2 – Competency requirements for manufacturing supervisors (other than medicated animal feed)

Necessary competencies[1]
A person supervising the manufacture of medicines (other than medicated animal feed) must have the capability to do the following:
1. Knowledge of the requirements of Good Manufacturing Practice applicable to the dosage forms for which they are responsible
2. A comprehensive understanding of the manufacturing methods and controls for the specific dosage forms for which they are responsible
3. Knowledge of the regulatory requirements relevant to the dosage forms manufactured by their site. In particular, knowledge of the marketing authorisation requirements for the specific products for which they are responsible
4. Working knowledge of the Pharmaceutical Quality System (i.e. the design elements and requirements for a quality system used to manage the manufacture of medicinal products) implemented at their manufacturing site

Qualifications and experience that are deemed to satisfy the necessary competencies for supervision of the manufacture of medicated feed, subject to the conditions

Acceptable qualifications/experience	Conditions
Bachelor of Science or Applied Science (majoring in chemistry, biochemistry or medical laboratory science)	Must have a minimum of 640 hours supervising manufacture in the previous 12 months
Bachelor of Chemical or Process Engineering	Must have a minimum of 640 hours supervising manufacture in the previous 12 months
Bachelor of Pharmacy	Must have a minimum of 640 hours supervising manufacture in the previous 12 months

[1] These competencies adopted from *PE009, the PIC/S guide to GMP for medicinal products: TGA interpretation and expectations for demonstrating compliance* v2.1 September 2020

Acceptable qualifications/experience	Conditions
5 years of experience as a manufacturing supervisor, with an average of at least 960 hours supervising manufacture per year for the past 5 years	Only considered acceptable until 1 October 2026