

Minimum Qualifications and/or Experience Necessary to Supervise the Manufacture of Controlled and/or Restricted Drugs; and/or Poisons under the *Health (Drugs and Poisons) Regulation 1996*

This information has been prepared to assist with completing the following;

- Application for a Licence to Manufacture Controlled Drugs (CDM)
- Application for a Licence to Manufacture Restricted Drugs (RDM)
- Application for a Licence to Manufacture Poisons (PM)

Each application requires that particulars concerning the identity and qualifications and/or experience of all persons who will personally supervise the manufacture of the substances be provided. The information contained in this fact sheet aims to provide a benchmark for the minimum qualifications and/or experience necessary.

Controlled Drugs and/or Restricted Drugs

Sections 42 and 136 of the *Health (Drugs and Poisons) Regulation 1996* require that the manufacture of controlled drugs and/or restricted drugs be supervised at all times by a person who 'has the qualifications and experience necessary to effectively supervise the manufacture.'

The person nominated to personally supervise the manufacturing of controlled drugs and/or restricted drugs under a 'CDM' licence and a 'RDM' licence respectively, shall hold the following minimum qualifications:-

- (1) B Pharm; or
(2) B App Sc - Chemistry; Bio Chemistry; Med Lab Tech; or
(3) B Sc - Chemistry; Bio Chemistry; Microbiology; or
(4) Associate Diploma in Applied Chemistry; or
(5) Certificate in Chemistry, (from a recognised tertiary institution).
- Appropriate experience in the manufacturing field for which the licence is requested. Preferably, the person should have attended a course in Quality Management, conducted by the National Association of Testing Authorities (NATA).
- The applicant will have both a formal tertiary qualification, as detailed in a., together with relevant experience, as listed in b., and be interviewed and assessed prior to approval/licensing.
- Where the applicant does not meet the criteria required in c. but has had experience in Good Manufacturing Practices acceptable to the Therapeutic Goods Administration (TGA), then their application will be individually assessed for approval. (The TGA contact number for this matter is (02) 6232 8628).
- OR** the person shall hold qualifications/experience to the satisfaction of the Chief Executive, Queensland Health.

NOTE: Applications may be viewed on a case-by-case basis to ensure that the applicant is not disadvantaged.

Poisons

Section 225 of the *Health (Drugs and Poisons) Regulation 1996* requires that the manufacture of poisons be supervised at all times by a person who 'has the qualifications and experience necessary to effectively supervise the manufacture.'

The person nominated to personally supervise the manufacturing of poisons under a "PM" licence shall hold qualifications to the satisfaction of the Chief Executive, Queensland Health.