# Fact Sheet
Health Protection Directorate

Queensland Government
Queensland Health

## Application Guide for a Licence to Manufacture Poisons

1. This information has been prepared to assist you in applying for a *Licence to Manufacture Poisons*. Following this advice will enable your application to be processed quickly.

2. When you complete the form, please print clearly and answer all questions in full.

3. Applications are processed only when all the information requested is provided. You will be notified by mail if the licence is granted.

4. All forms requiring a signature must bear the original signature in ink. **Queensland Health is not able to accept a photocopy, facsimile (fax) or emailed copy of the completed form. Applications must be forwarded by POST to the address provided below.**

## How to complete an application

Please cross ☒ each checkbox below as you complete the application form to ensure that you have provided the necessary particulars.

### Question 1

☐ *Sole Trader*: Names are to be advised *in full* and exactly as they appear on each applicant's birth certificate. If you have ever been known by any other name, attach any copies of documentation that provides for formal changes of name ie. deed poll, marriage certificate etc.

☐ *Business Partnerships*: Advise the details of *all* partners in the business. Names are to be advised *in full* and exactly as they appear on each person's birth certificate. If either person has ever been known by any other name, attach any copies of documentation that provides for formal changes of name ie. deed poll, marriage certificate etc.

### Question 2

☐ *Incorporated Companies:* Advise the name that appears on the *Certificate of Incorporation* issued by the Australian Securities and Investment Commission (ASIC). Attach a copy of the document to the application only if you have not previously done so.

☐ Provide the Australian Company Number (ACN) as it appears on the *Certificate of Incorporation*.

☐ Provide the details of at least two (2) directors of the company. Names are to be advised *in full* and exactly as they appear on each applicant's birth certificate. If you have ever been known by any other name, attach any copies of documentation that provides for formal changes of name ie. deed poll, marriage certificate etc.

### Question 3

This information refers to the address of the business' head office in Queensland. If a business office is not located in this State, advise the address of the head office where correspondence is to be sent.

☐ Attach a copy of the *Business Names Extract* issued under the *Business Names Act 1962* if you have not previously done so.

☐ Provide the name and contact telephone number of the person responsible for licence processing.

### Question 4

☐ This information refers to the physical premises located in Queensland from where scheduled drugs and poisons are intended to be manufactured. Do not advise a post box address or a mobile telephone number.

### Question 5

If you have answered YES, attach copies of the following documents –

☐ Certificate of conviction / court or tribunal order / police records search.

☐ ASIC order preventing individual from managing a corporation.

**Do not return this fact sheet with the application**

### Question 6

☐ Payment of the prescribed fee is attached. Payment can be made by cheque or money order made payable to Queensland Health. Credit card transaction is also acceptable using Mastercard, Bankcard or Visa card only. American Express cannot be processed.

### Question 7

☐ The form is signed and dated by all persons named at either section **1** or **2**.

### Question 8

☐ Please indicate the schedule of poisons to be manufactured.

### Question 9

Refer to attached information regarding minimum qualifications and/or experience necessary to supervise the manufacture of controlled and/or restricted drugs; and/or poisons.

☐ All details for each supervisor are provided.
☐ Certified copies of all evidentiary documentation are attached.

### Credit card payments

Use this sheet only if payment is being made by this method. Do not return this page if payment is made by cheque or money order.

☐ The card no. is accurate and legible[1]. Do not overwrite any digits.
☐ The expiry date is completed and the card has not lapsed[1]. Do not overwrite any digits.
☐ The cardholder has signed and dated the form.

[1] If an error is made, cross through the digit using a single line, write the correct digit above and initial the change.

## General information

1. It is unlawful for any person, business partnership or incorporated company to possess, manufacture or sell *Schedule 2, 3 and/or 7* poisons in Queensland unless that person, business partnership or incorporated company is the holder of a current *Licence to Manufacture Poisons* issued by Queensland Health in respect of the premise(s) located in Queensland from where those substances are being manufactured or are intended to be manufactured.

2. A person, business partnership or incorporated company must lodge a separate application and correct payment of the prescribed fee for each premise located in Queensland from where *Schedule 2, 3 and/or 7* poisons are being manufactured or are intended to be manufactured.

3. Refunds

   Queensland Health can only provide a refund if:

   (a) the application is refused by the Chief Executive
   (b) the application is withdrawn prior to a decision being made.

4. Further information, as it applies to medicines and poisons, may be available from Queensland Health's Drugs & Poisons Policy & Regulation website at www.health.qld.gov.au/ph/ehu/drugs_poisons.asp.

**The application must be returned to –**

Senior Licensing Officer
**Drugs & Poisons Policy & Regulation Unit**
Environmental Health Branch
PO Box 2368
FORTITUDE VALLEY Q 4006
Tel: (07) 3328 9310

**Do not return this fact sheet with the application**

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# 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:-

a. (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).

b. 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).

c. 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.

d. 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. (TGA contact details can be obtained from their website at www.tga.gov.au.

e. **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.