# Submitting Effective GMP Licence Applications

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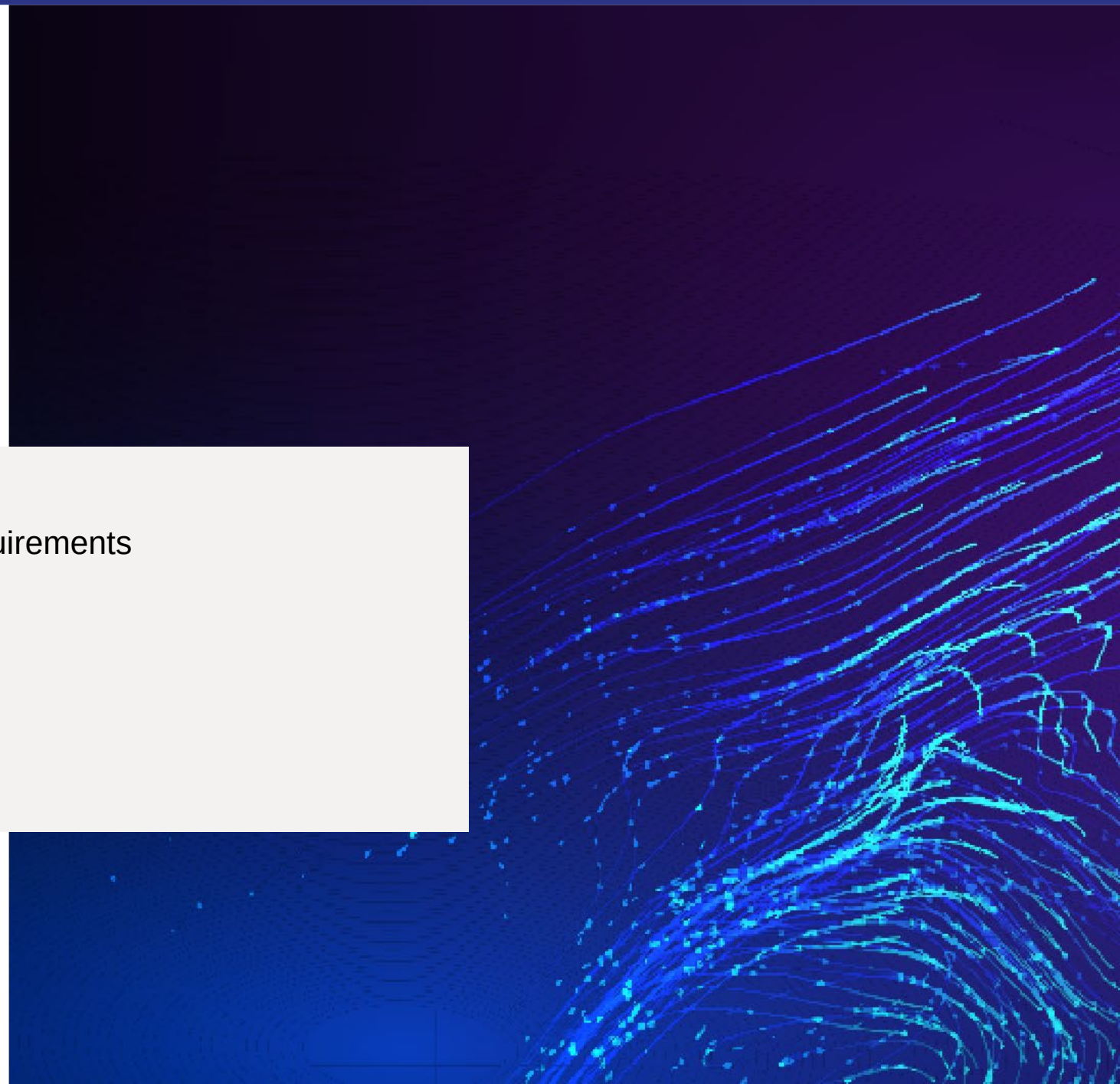
GMP FORUM 2024

# Agenda

Common Pitfalls
Licence Application Types and Evidence Requirements

- Initial (new) GMP Licence
- Variation to an existing GMP Licence
- Suspend or revoke a GMP Licence
- Transfer a GMP Licence

Secondary Manufacturing Sites
Application Effective Date



# Common Pitfalls

## GMP Licence Applications

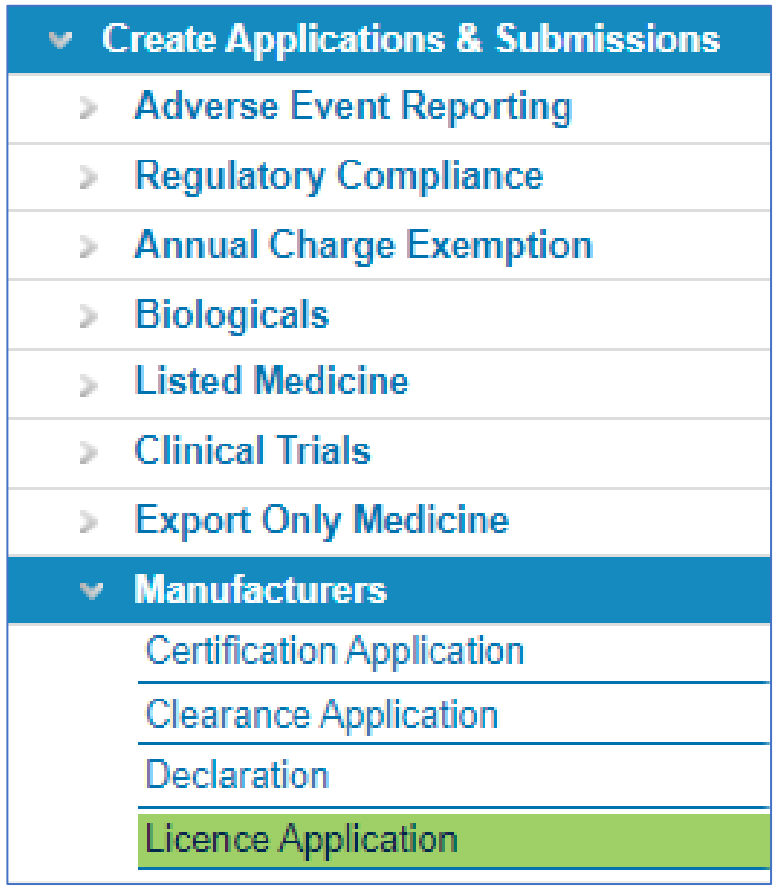
- Incorrect application types being submitted.
- Delays in paying application fees.
- Mandatory evidence not being provided with the application.
- Incorrect or unclear requests in applications.
- Questions from application assessors not being answered.

# Licence Application Types

- Initial Licence Application
- Licence Variation Application
- Voluntary Licence Suspension Application
- Voluntary Licence Revocation Application
- Licence Transfer Requests

# Licence Application Types

## Initial Licence Application

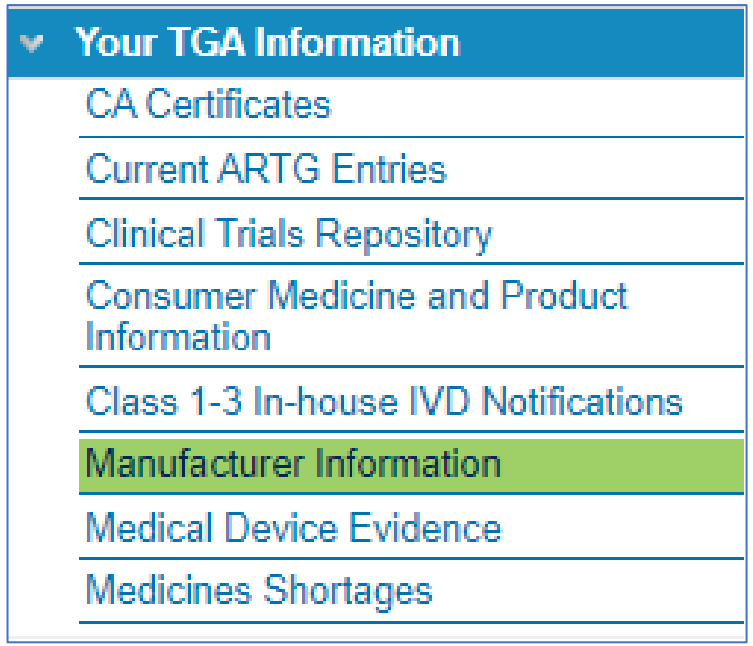


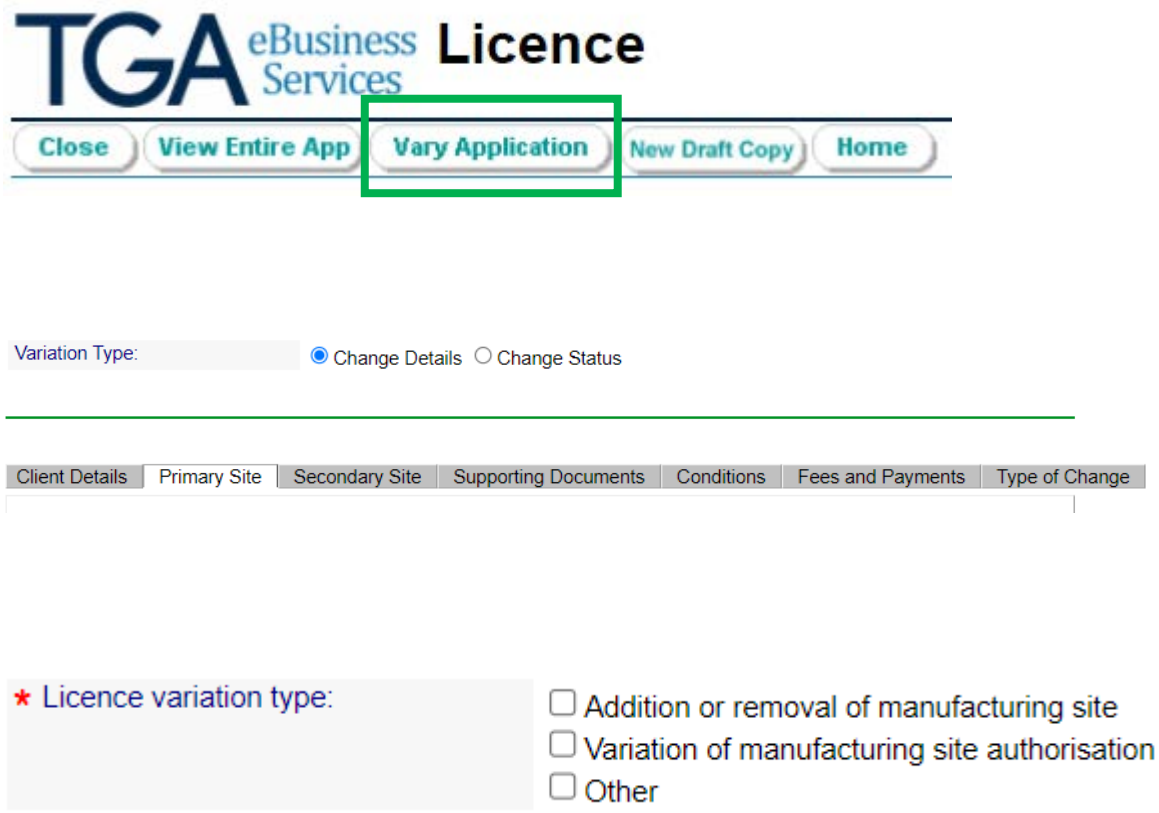

Evidence Requirements:

- Pay the initial licence application fee
- Provide a cover letter
- SMF or Quality Manual
- Curriculum vitae (CV) for licence nominees
- A completed Certificate for subsection 38(1)(g) of the *Therapeutic Goods Act 1989*

# Licence Application Types

## Variation to existing GMP Licence



# Licence Application Types

## Variation to existing GMP Licence

**Addition or removal of (secondary) manufacturing site**
- a cover letter
- a current / draft Site Master File or Quality Manual
- pay the licence variation application fee, if applicable

**Variation of manufacturing site authorisation**
- a cover letter
- a current / draft Site Master File or Quality Manual
- pay the licence variation application fee, if applicable

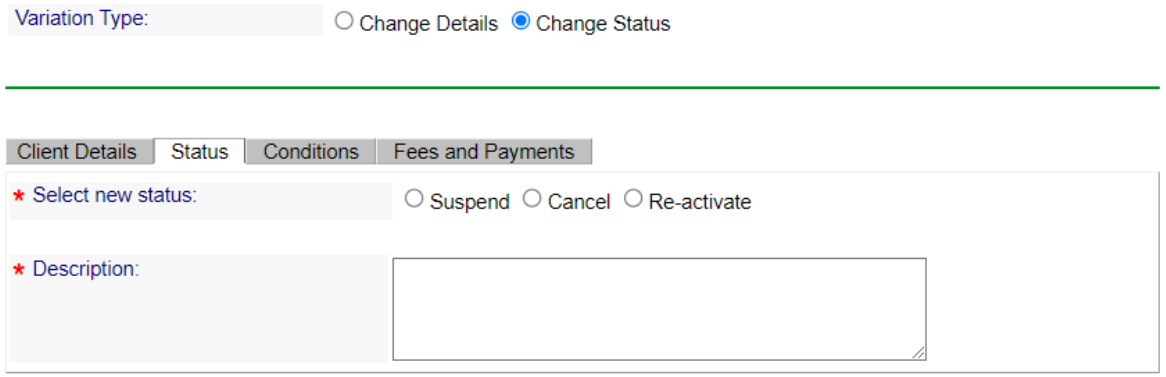
**Other**
- a cover letter
- CV for the new nominee/s, if applicable
- other supporting documents, if applicable

# Licence Application Types

## Voluntary Suspension or Revocation of a GMP Licence

**You are required to provide a notification letter addressed to the Assistant Secretary, Manufacturing Quality Branch.**

**Your letter should address but not be limited to:**




**For suspending your licence:**

• your request to suspend your licence including the site address and licence number;

• the reason why you wish to suspend your licence; and

• the time period for the suspension including the date that you intend to resume manufacture.

**For revoking your licence:**

- your request to revoke your licence including the site address and licence number;
- the reason why you wish to revoke your licence;
- How you will maintain your GMP responsibilities for any product manufactured at the site including the management of:
    - Manufacturing documentation including batch documents
    - Management of any retention samples
    - Information including the contact person/company if a recall were required; and
- the date of the revocation.

# Licence Application Types

## Transfer of a GMP Licence

The acquirer of the business will need to notify us by emailing the Manufacturing Quality Branch within 3 months of acquiring the business.

This notification must be supported by suitable evidence:

- A letter from the Chief Executive Officer (CEO) / Managing Director (MD) from 'the seller'
- A letter from the CEO / MD from 'the acquirer'
- A sales agreement, or other suitable documents, proving the transaction has taken place, which also details the **date the transfer took place.**

The 'acquirer' is also required to completed a Certificate for subsection 40(6) of the *Therapeutic Goods Act 1989.*

# Application Evidence Requirements

## Cover Letter

- indicating the earliest date that you believe you will be ready for an inspection.
- include as much detail in the cover letter to assist the TGA assess your application.
- include the best contact details for the application.

# Application Evidence Requirements

## Site Master File / Quality Manual

**Manufacturers of APIs, medicines, or biologicals containing or comprising animal cells, tissues or organs**:

a **Site Master File (SMF)**; or

a **Quality Manual** (however, a SMF is preferred).

- The most up-to-date version of your document should be provided (this includes draft versions).
- The document should include information on the manufacturing authorisations / manufacturing sites included in your application.

# Application Evidence Requirements

## Curriculum vitae (CV) for Licence Nominees

Curriculum vitae (CV) for licence nominees (persons in charge of Production and Quality Control).

## Fit and Proper Persons Declaration

Initial Licence:

A completed Certificate for subsection 38(1)(g) of the *Therapeutic Goods Act 1989*.

Licence Transfer Request:

A completed Certificate for subsection 40(6) of the *Therapeutic Goods Act 1989*.

# Section 38A of the *Therapeutic Goods Act 1989*

## Secondary Site

A manufacturing licence may cover multiple manufacturing sites where all of the criteria are satisfied, as outlined in the S38 guidelines for Australian manufacturing licences covering multiple manufacturing sites.

Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020, sets out the circumstances in which a manufacturing licence may cover two or more manufacturing sites.

Secondary sites are normally ancillary sites that support the primary site — for example, warehouses.

# Section 38A of the *Therapeutic Goods Act 1989*

## Medicines - Secondary Site

***Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020***

Section 5

Circumstances for multi-site licence—manufacture of therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue.

Subsection 5(2)

A licence may cover two or more manufacturing sites where all of the following paragraphs apply:

(a) steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for carrying out the following steps:

(i) the storage of primary packaging materials, starting materials, in-process materials or finished product; or

(ii) the secondary packaging of finished product; or

(iii) the release for supply of packaging materials, starting materials, in-process materials, or finished product; and

(b) all steps in the manufacture of the therapeutic goods are to be covered by a single quality system; and

(c) all sites are capable of being inspected within the relevant period; and

(d) all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes.

## Biological - Secondary Site

***Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020***

Section 6

Circumstances for multi-site licence—manufacture of blood, blood components, haematopoietic progenitor cells or human tissue

Subsection 6(2)

A licence may cover two or more manufacturing sites where all of the following paragraphs apply:

(a) steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for carrying out the following steps:

(i) in relation to a fixed site—the storage of packaging materials, starting materials, in-process materials, or finished product;

(ii) in relation to a mobile (non-fixed) site—the collection of blood or blood components; and

**(**b) all steps in the manufacture of the therapeutic goods are to be covered by a single quality system; and

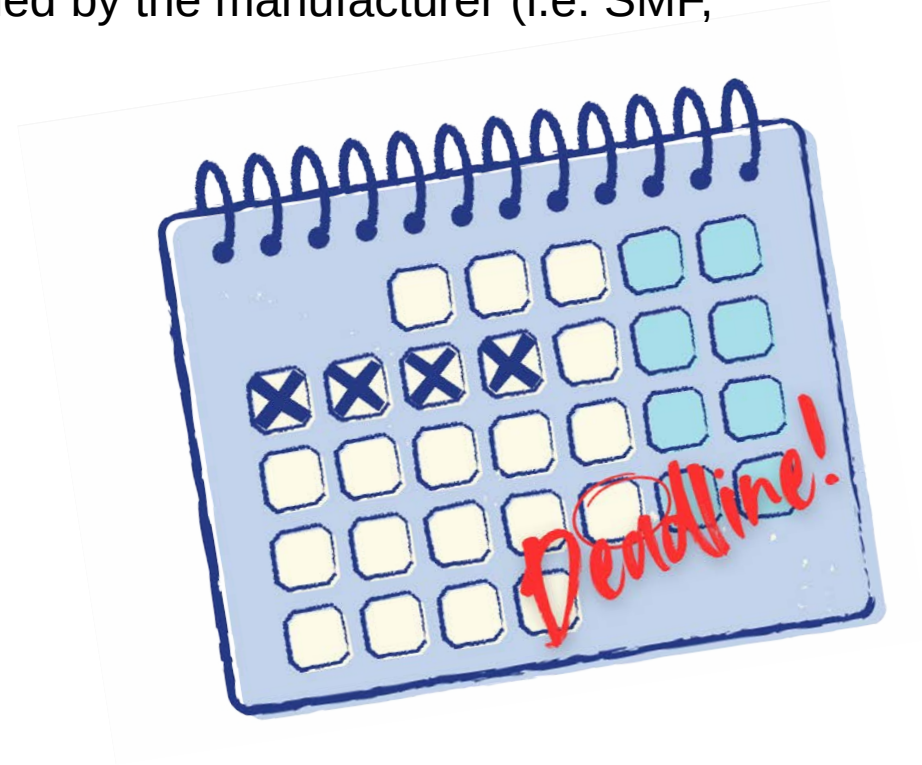
(c) all sites are capable of being inspected within the relevant period; and

(d) all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes

# Application Effective Date

The effective date of the application is the latest date out of:

- The date the application fee was paid (if applicable);
- The earliest date the manufacturing site has indicated that they are ready to host a TGA inspection; and
- The date all mandatory evidence has been supplied by the manufacturer (i.e. SMF, CVs, Cover Letters, etc.).



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# Questions?

**Scan this QR code with your device to submit a question**

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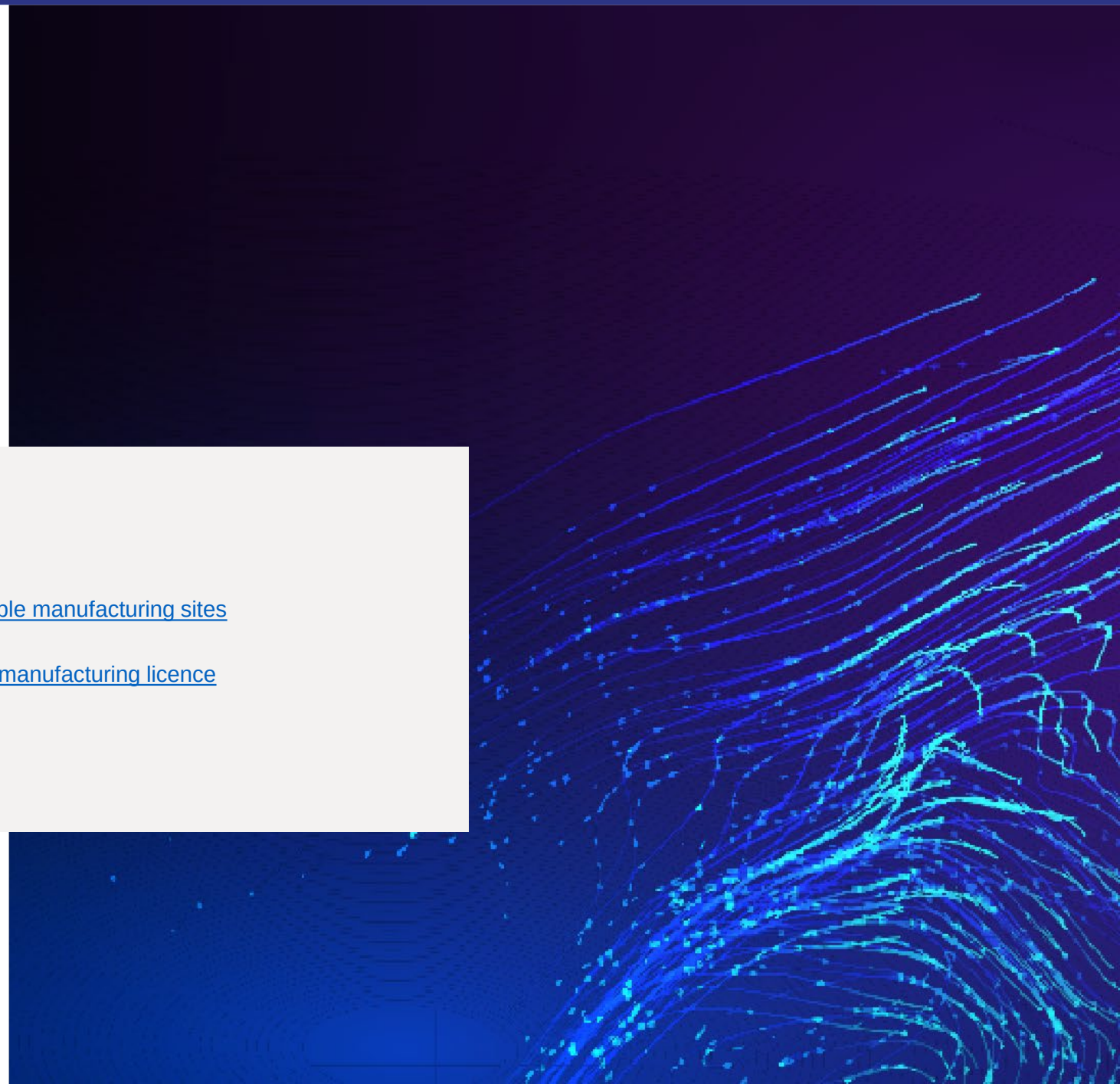
# Useful Online Resources

- Australian manufacturing licences and overseas GMP certification
- Requesting variations to your manufacturing licence
- S38 guidelines for Australian manufacturing licences covering multiple manufacturing sites
- Suspending, revoking and TGA initiated variation of conditions of a manufacturing licence
- Transfer of a manufacturing licence
- TGA Business Services - Questions and answers for administrators

Contact Us

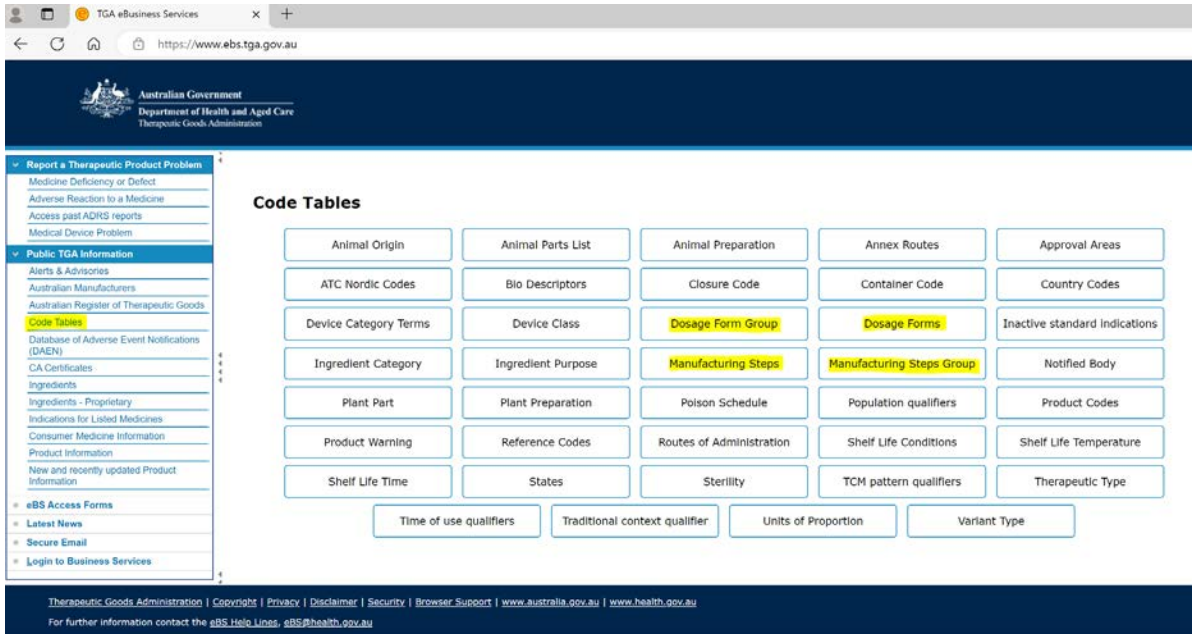
Email: GMP@health.gov.au

Phone: 1800 020 653



# Additional Resources

## Code Table Interpretation
## Dosage Form and Manufacturing Steps




A list of the current manufacturing steps and manufacturing steps groups are found within the Code Tables link under the ‘Public TGA Information’ tab in the TGA Business Services (TBS) page.

Prior to applying for a new GMP Licence or variation to an existing GMP Licence, please consult these code tables and contact GMP@health.gov.au if assistance is required.

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration