



Australian Government
Department of Health
Therapeutic Goods Administration

Australian manufacturing licences and overseas GMP certification

A step-by-step guide

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TGA Health Safety
Regulation

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Contents

| | |
|--|-----------|
| Responsibilities | 7 |
| Supplying manufactured goods to Australia | 8 |
| Confidentiality | 8 |
| Timeframes | 8 |
| APVMA–TGA cooperation | 8 |
| The licensing and certification process | 9 |
| Determining the appropriate process | 9 |
| New applications | 9 |
| Preparing your application | 9 |
| Applying for a licence or GMP certification | 9 |
| Inspections | 9 |
| Preparing for inspection | 9 |
| The inspection | 9 |
| Finalisation | 10 |
| Ongoing compliance | 10 |
| 1: Determining whether licensing or certification is required | 11 |
| The goods must be therapeutic | 11 |
| Medical devices | 11 |
| Goods exempt from manufacturing principles | 11 |
| Persons exempt from manufacturing principles | 11 |
| Country of manufacture | 12 |
| 2: Complying with the manufacturing principles | 13 |
| Manufacturing principles | 13 |
| Medicines and biologicals that contain live animal cells, tissues or organs | 13 |
| Human blood, blood components, Haematopoietic Progenitor Cells (HPCs) and biologicals that comprise, contain or are derived from human cells and tissues, or are specified as a biological by the Secretary, | 14 |
| Therapeutic Goods Orders | 14 |
| Default standards | 14 |
| TGA guidance | 14 |
| Independent advice | 14 |

| | |
|--|-----------|
| 3: Becoming a TGA client | 15 |
| 4: Compiling documentation | 15 |
| Client details | 15 |
| Primary and secondary sites | 15 |
| Primary site | 15 |
| Secondary site | 16 |
| Supporting documents | 16 |
| 5: Making a statutory declaration | 17 |
| 6: Drafting and submitting your application | 17 |
| Readiness for inspection | 17 |
| Meeting with TGA | 18 |
| 6a: Applying for a new TGA manufacturing licence | 19 |
| Applying for a manufacturing licence using TGA Business Services | 19 |
| Selecting the manufacturer name and manufacturing site address in the Client Details tab | 19 |
| 6b: Applying for GMP certification | 23 |
| Applying for GMP certification using TGA Business Services | 23 |
| 7: Application fees | 25 |
| 8: Determining whether your application is effective | 26 |
| Screening your application | 26 |
| Advising us of changes | 26 |
| 9: Scheduling the inspection | 27 |
| Scheduling procedures | 27 |
| Choosing the inspection team | 27 |
| The inspection team | 27 |
| Avoiding conflict of interest | 27 |
| Arranging the onsite inspection | 28 |
| 10: Paying inspection invoices | 28 |
| 11: Preparing for inspection | 29 |
| 12: The onsite inspection | 30 |
| Avoiding improper influence | 30 |
| Purpose of the inspection | 30 |



| | |
|--|-----------|
| What we are looking for _____ | 31 |
| Disputes and complaints _____ | 31 |
| Opening meeting _____ | 32 |
| Manufacturer guides and observers _____ | 32 |
| The translator | 32 |
| Conducting the inspection _____ | 33 |
| Closing meeting _____ | 33 |
| Related information | 33 |
| 13: The post-inspection letter (PIL) _____ | 34 |
| Classifying deficiencies _____ | 34 |
| Unacceptable rating _____ | 34 |
| 14: Addressing deficiencies _____ | 35 |
| Objective evidence _____ | 35 |
| 15: Reviewing your response and closeout _____ | 35 |
| 16: Issuing the inspection report _____ | 36 |
| Compliance rating _____ | 36 |
| Overview of the inspection closeout process _____ | 37 |
| Reinspection duration _____ | 38 |
| 17: Paying your final invoice _____ | 38 |
| 18: Providing feedback _____ | 38 |
| 19: Making a decision _____ | 39 |
| Refusal to grant licence or issue certification _____ | 39 |
| Revocation, suspension or restriction of licence _____ | 39 |
| 20: Granting licences and issuing certification _____ | 40 |
| Licence _____ | 40 |
| Legislation underpinning manufacturing licences | 40 |
| GMP certificate of compliance for licence holders | 41 |
| GMP certification _____ | 41 |
| Extra copies _____ | 41 |
| 21: Conducting follow-up inspections _____ | 42 |
| Routine inspections _____ | 42 |

| | |
|--|-----------|
| Special inspections _____ | 42 |
| 22: Keeping us up-to-date and making requests _____ | 43 |
| Sponsor responsibilities _____ | 43 |
| Requesting recertification | 43 |
| Licence holder responsibilities _____ | 43 |
| Comply with the manufacturing principles..... | 43 |
| Implement corrective and preventative actions as agreed..... | 44 |
| Pay your annual charge | 44 |
| Declarations..... | 44 |
| Variation applications..... | 44 |
| Contacting the Manufacturing Quality Branch _____ | 44 |

This step-by-step guide is for:

- Australian manufacturers of therapeutic goods (medicines, active pharmaceutical ingredients (APIs) and biologicals, human blood and blood components and haematopoietic progenitor cells) applying for a **manufacturing licence** for an Australian manufacturing site
- Australian sponsors of therapeutic goods manufactured overseas applying for **GMP certification** of the overseas manufacturer
- overseas manufacturers **inspected by the TGA**

This guidance is not intended for:

-  medical device manufacturers or sponsors; instead, see [Manufacturing medical devices: where to start](#)
-  obtaining [GMP clearance](#) for overseas manufacturers using the Mutual Recognition Agreement (MRA) or Compliance Verification (CV) pathways; this is a separate process.



Only Australian manufacturing sites can obtain a **manufacturing licence**.

Overseas manufacturers can instead obtain **GMP certification** following a successful on-site inspection by the TGA.

GMP certification applications are required to be submitted by the Australian sponsor or an agent acting on the Australian sponsor's behalf.

GMP certification is usually only requested if it is not possible to obtain GMP clearance via the Mutual Recognition Agreement (MRA) or Compliance Verification (CV) pathways, for example due to lack of evidence. The TGA reserves the right to undertake an audit of an overseas manufacturing site, irrespective of any other evidence supplied. For example, this may be where TGA has other regulatory information, has concerns regarding compliance.

Ensure that GMP clearance cannot be obtained via the MRA or CV pathways before applying for GMP certification.

[Step 1](#) will help you determine if this process is appropriate for you.

Responsibilities

Both manufacturers and sponsors need to be aware of their responsibilities. For more information, see:

- [manufacturer responsibilities](#)
- [sponsor responsibilities](#)

Information about fees and charges can be found in the [Summary of fees and charges](#).

Supplying manufactured goods to Australia

No batch of product (including validation batches) manufactured prior to licensing or certification can be sold or supplied within Australia, or exported from Australia, unless prior approval has been obtained.



Do not commence manufacturing for supply to Australia until a manufacturing licence or certification has been granted, unless prior approval has been obtained.

Confidentiality

We treat information about applications and manufacturers as [official information](#). Find out more about confidentiality at [TGA approach to disclosure of commercially confidential information](#).

We publish a list of [licensed Australian manufacturers](#).

Timeframes

Consider the [timeframes involved in the licensing or certification process](#) to ensure you allow sufficient time to apply for and obtain your manufacturing licence or GMP certification.

From application to completion, the process (including the on-site inspection) can take:

- up to 12 months for a manufacturing licence for an Australian manufacturing site
- up to 15 months for GMP certification of an overseas manufacturing site

APVMA–TGA cooperation

The TGA and the Australian Pesticides and Veterinary Medicines Authority (APVMA) have a [Memorandum of Understanding \(MoU\)](#) for cooperation on medicinal products manufactured in Australia for veterinary use.

Manufacturers holding both TGA and APVMA licences may elect to the APVMA to have routine inspections conducted by the TGA. The licence holder must notify the APVMA of this decision. The TGA will not inspect aspects of the manufacturing facility that are dedicated to veterinary products only.

Australia has a mutual recognition agreement (MRA) with the European Community (EC) and the European Free Trade Association (EFTA). Manufacturers licensed by the APVMA who wish to [export veterinary medicines to Europe](#) must be inspected by the TGA. This inspection must be requested by the APVMA, **not** by the manufacturer. The APVMA will assess the TGA inspection results and can then issue a GMP certificate to the manufacturer. Under the MRA, the EC recognises the TGA as the authority for inspecting veterinary premises in Australia.

The licensing and certification process

Determining the appropriate process

1. [Determining whether licensing or certification is required](#)
2. [Complying with manufacturing principles](#)

New applications

Preparing your application

3. [Becoming a TGA client](#)
4. [Compiling documentation](#)

Applying for a licence or GMP certification

5. [Making a statutory declaration](#)
6. [Drafting and submitting your application](#)
 - a. [Submitting a TGA manufacturing licence application](#)
 - b. [Submitting a GMP certification application](#)
7. [Paying the application fee](#)
8. [Determining your application's effectiveness](#)

Inspections

Preparing for inspection

9. [Scheduling the inspection](#)
10. [Paying inspection invoices](#)

The inspection

11. [Pre-inspection preparation](#)
12. [The onsite inspection](#)
13. [The post-inspection letter](#)
14. [Addressing deficiencies](#)
15. [Reviewing your responses and closeout](#)

Finalisation

16. [The inspection report](#)
17. [Paying your final invoice](#)
18. [Providing feedback](#)
19. [Making a decision](#)
20. [Granting licences and certificates](#)

Ongoing compliance

21. [Conducting follow-up inspections](#)
22. [Keeping us up to date and making requests](#)

1: Determining whether licensing or certification is required

You need a TGA manufacturing licence to manufacture in Australia certain therapeutic goods for supply in or export from Australia under the [Therapeutic Goods Act 1989](#) (the 'Act') and the [Therapeutic Goods Regulations 1990](#).

GMP certification is how we determine that certain therapeutic goods manufactured overseas and intended for import and supply to Australia comply with GMP requirements.

The goods must be therapeutic

TGA only regulates therapeutic goods for human use. For more information, see:

- [What are therapeutic goods?](#)
- [What the TGA doesn't do](#)

Medical devices

The TGA regulates medical devices under Chapter 4 of the *Therapeutic Goods Act 1989*. Medical devices must comply with the [Essential Principles](#).

The TGA manufacturing licence and GMP certification processes are **not applicable** to medical devices. For more information, see:

- [Manufacturing medical devices: where to start](#)

Goods exempt from manufacturing principles

Some therapeutic goods are exempt from complying with the [manufacturing principles](#). Check Schedule 7 of the [Therapeutic Goods Regulations 1990](#) to find out if your therapeutic good is exempt from the manufacturing principles.

We recommend you seek independent legal advice to ensure you comply with the legislation.

Persons exempt from manufacturing principles

Some persons are exempt from the manufacturing principles. Check Schedule 8 of the [Therapeutic Goods Regulations 1990](#) to find out if the person manufacturing the goods is exempt from the manufacturing principles.

We recommend you seek independent legal advice to ensure you comply with the legislation.

Country of manufacture

If your manufacturing site is in **Australia**, you manufacture therapeutic goods (excluding medical devices), and neither you nor the goods are exempt, then you need a **manufacturing licence** from the TGA.

If your manufacturing site is **overseas**, you manufacture therapeutic goods (excluding medical devices), and neither you nor the goods are exempt you need **GMP clearance**. This can be obtained by an **Australian sponsor** who:

- can use the MRA or CV pathways to [GMP clearance](#) instead of requesting TGA certification
- can obtain **GMP certification** from the TGA if the MRA and CV pathways are not appropriate

The MRA and CV pathways to [GMP clearance](#) are only available if the relevant overseas regulator has recently inspected the manufacturing site to a **GMP code** equivalent to the TGA's for the type of therapeutic good produced there.



It is often not possible to obtain GMP clearance using evidence from another regulator because of differences in the regulatory frameworks and GMP standards for:

- listed medicines including sunscreens
- biologicals, blood and blood components and haematopoietic progenitor cells

GMP clearance or certification is not necessarily required unless the manufacturing step is recorded on the Australian Register of Therapeutic Goods (ARTG). If you are unsure whether you need GMP certification or clearance, [contact the relevant product regulatory area](#) before you submit your application.

2: Complying with the manufacturing principles

Manufacturers need to comply with:

- the [manufacturing principles](#) specified in Australian legislation
- relevant [Therapeutic Goods Orders](#)
- relevant [default standards](#)
- any conditions applied when the goods are entered on the ARTG

We provide [information](#) to help you comply with the regulatory requirements. You can also obtain [advice](#) from independent consultants and advisors.

We will monitor your compliance when we conduct the inspection.



Manufacturers need to comply with the manufacturing principles specified in Australian legislation. **We recommend you seek independent legal advice to ensure you comply with all relevant requirements.**

Some countries are not members of the [Pharmaceutical Inspection Co-operation Scheme \(PIC/S\)](#). The manufacturing principles these countries' regulators inspect against may not be the same as those mandated in Australia.

Manufacturing principles

Identify the manufacturing principles that apply to your therapeutic goods.

The manufacturing principles are specified in the current [Therapeutic Goods \(Manufacturing Principles\) Determinations](#). The codes of GMP specified in the manufacturing principles are different for:

- [medicines and biologicals that comprise or contain live animal cells, tissues or organs](#)
- [human blood, blood components, haematopoietic progenitor cells \(HPCs\) and biologicals that comprise, contain or are derived from human cells and tissues, or are specified as a biological by the Secretary](#)

Medicines and biologicals that contain live animal cells, tissues or organs

The [PIC/S guide to GMP](#) (except for annexes 4, 5, 14 and 16) is specified in the legislated manufacturing principles for medicines and biologicals that comprise or contain live animal cells tissues or organs



Every manufacturing step for all medicine product types and dosage forms, at all sites, must be GMP compliant, unless there is an exemption. You can find examples of [GMP compliance deficiencies](#) on our website.

This also applies for biologicals that comprise or contain live animal cells, tissues or organs.

Human blood, blood components, Haematopoietic Progenitor Cells (HPCs) and biologicals that comprise, contain or are derived from human cells and tissues, or are specified as a biological by the Secretary,

The [Australian code of GMP for human blood and blood components, human tissues and human cellular therapy products](#) is specified in the legislated manufacturing principles for:

- [biologicals](#) that comprise, contain or are derived from human cells and tissues, or are specified as a biological by the Secretary,
- [human blood, human blood components and HPCs](#)



Unless there is an exemption, **every manufacturing step must be GMP compliant for all product types and dosage forms, at all sites**, for:

- biologicals that comprise, contain or are derived from human cells and tissues, or are specified as a biological by the Secretary,
- human blood and blood components
- HPCs

You can find examples of [GMP compliance deficiencies](#) on our website.

Therapeutic Goods Orders

Check the [Therapeutic Goods Orders](#) to identify those relevant to your goods.

Default standards

Therapeutic goods that are not medical devices must comply with the applicable standards unless [granted exemption](#). The default standards are the [pharmacopoeias](#) defined in Section 3 of the [Therapeutic Goods Act 1989](#).

TGA guidance

To help you comply with the regulatory requirements, we provide guidance on manufacturing:

- [medicines](#)
- [blood and tissue products that are not biologicals](#)
- [biologicals](#)

Independent advice

If you have no previous experience with manufacturing or sponsoring a therapeutic good in Australia, you may wish to seek the services of a GMP or [regulatory affairs consultant](#).

We recommend you seek independent legal advice to ensure you comply with all relevant requirements.

3: Becoming a TGA client

You need to be a TGA client with access to our e-business portal, [TGA Business Services](#), to apply for a licence or GMP certification. Only Australian manufacturers and Australian sponsors (or their agents) can apply for a licence or GMP certification.

For more information, see [Getting started with the TGA](#).

4: Compiling documentation

To apply for a licence or GMP certification, you will need to collect the following minimum information:

Client details

You will need to provide us with:

- the applicant's details
- the manufacturer's details

Primary and secondary sites

A manufacturing licence or GMP certification 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](#).

Primary site

The primary manufacturing site is the main premises where manufacturing occurs. You will need to provide the:

- manufacturing site address
- contact name and contact details for primary site
- name and resume of the person in charge of quality control
- name and resume of the person in charge of production
- name of authorised person for release for supply
- details of the items manufactured. You can select these from drop-down menus in the application form. They include:
 - manufacturing type
 - sterility
 - manufacturing class
 - dosage form
 - product code
 - manufacturing steps

Refer to the [code tables](#) available on the TGA Business Services page if you need assistance in selecting the manufacturing items.

Secondary site

You can combine your applications for a primary and secondary site provided you satisfy the criteria outlined in the [S38 guidelines for Australian manufacturing licences covering multiple manufacturing sites](#). Secondary sites are normally ancillary sites that support the primary site—for example, warehouses.

You will need to provide the:

- site address(es)
- contact name and contact details for the secondary site
- name of the person in charge of quality control
- name and resume of the person in charge of production
- details of the items manufactured. You can select these from drop-down menus in the application form. They include:
 - manufacturing type
 - sterility
 - manufacturing class
 - dosage form
 - product code
 - manufacturing steps

Supporting documents

To make a valid application you need to provide us with:

- for manufacturers of APIs, medicines, or biologicals containing or comprising animal cells, tissues or organs a [Site Master File \(SMF\)](#) or, if the site is a testing laboratory, a Quality Manual
- for blood, blood components, haematopoietic progenitor cells manufacturing, and biologicals that comprise, contain or are derived from human cells and tissues a copy of the Quality Manual. In addition, the [Technical Master File \(TMF\)](#) must also be lodged prior to, or with, the licence application. The licence application is not considered effective until it is confirmed that the TMF has been submitted to the [TGA biological science section](#) or with the licence application.
- for new **manufacturing licences**, make a statutory declaration on [Certificate 38\(1\)\(g\)](#)
- for **GMP certification applications** where the manufacturer does not currently supply to Australia, the Australian sponsor must submit a [Declaration of intent to supply](#)



All documents supplied to the TGA must be in English or accompanied by an English translation.

Documents should be provided in an electronic format.

We prefer you to attach an electronic copy of each document to the application, but you may also email them to the [Manufacturing Quality Branch](#). Your application will not be considered effective until all required evidence has been submitted to us.

5: Making a statutory declaration

- For **new manufacturing licences**, provide us with a statutory declaration on [Certificate 38\(1\)\(g\)](#). This declaration relates to specific convictions and financial penalties in the 10 years prior to your application. For details, see section 38(1)(g) and 38(1)(h) of the [Therapeutic Goods Act 1989](#). Include the manufacturing licence application tracking number on the declaration form
- If you are unable to certify that the persons mentioned in the certificate meet the criteria, you can ask us to consider any special circumstances before we make a decision

Submit the declaration with your licence application or email it to the [Manufacturing Quality Branch](#) with reference to your application tracking number.

6: Drafting and submitting your application

Submit either:

- an application for a **new** TGA manufacturing licence (for an Australian manufacturer)
- an application for GMP certification (by an Australian sponsor or agent acting on behalf of a sponsor of goods manufactured overseas)

Advise us of the date you expect to be ready for inspection in the cover letter you attach to the application or by email to the [Manufacturing Quality Branch](#).



Take care when you complete your application to ensure the scope of your manufacturing operations, as specified in the Manufacturing Items table, fully reflects the activities you want to licence or certify.

Manufacturing Items

| Manufacturer Types | Sterility | Manufacturing Class | Dosage Form | Product Code | Manufacturing Steps |
|--------------------|-----------|---------------------|-------------|--------------|---------------------|
|--------------------|-----------|---------------------|-------------|--------------|---------------------|

Our inspection will be **limited to the scope** described in your application.

Readiness for inspection

To be ready for an inspection you must have:

- completed constructing or fabricating the premises
- taken functional control of the site (we may ask to see a certificate of occupancy or equivalent)
- documented and implemented a quality system, in accordance with the requirements of the manufacturing principles and specifically tailored to your proposed manufacturing operations, that includes procedures, records and instructions for the management of:
 - quality systems such as deviation, change control, risk management, product quality review systems
 - documentation
 - materials
 - production operations, including master batch records

- personnel matters including training, clothing and hygiene
 - validation and qualification
 - equipment assembly and calibration
 - maintenance, cleaning and sanitisation
 - environmental monitoring
 - pest control
 - complaints
 - recalls
 - returns
 - self-inspection
 - laboratory controls and operations
 - release for supply
- qualified all relevant facilities, utilities and equipment to at least the Operational Qualification (OQ) stage
 - documented and approved protocols for qualification and validation post-Operational Qualification for all facilities, utilities, equipment and processes (including cleaning)
 - validated the manufacturing processes for Class 3 or Class 4 biologicals (given the inherent variation in biological processes)
 - employed, nominated and trained all key staff responsible for controlling manufacturing operations and quality assurance

Meeting with TGA

If you would like to meet with us before you submit your application, [contact the Manufacturing Quality Branch](#) and request a meeting. TGA staff are available to meet with new clients to discuss proposed plans and provide advice on the licensing and inspection process.

6a: Applying for a new TGA manufacturing licence

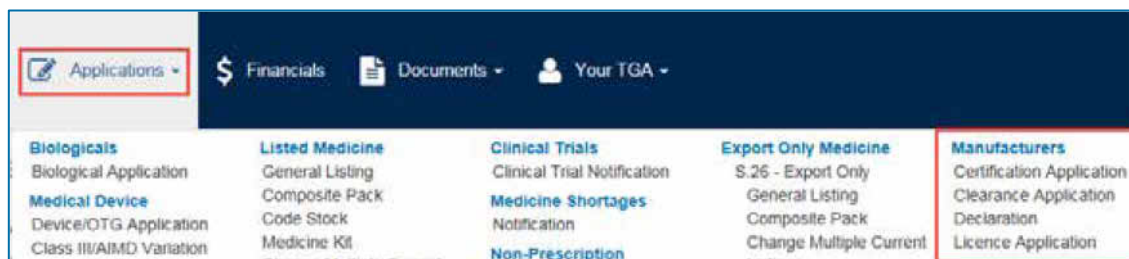
Submit your application for a new manufacturing licence and the necessary supporting documents as soon as possible.

Provide a cover letter as part of your application indicating when you believe you will be [ready for an inspection](#). If you are not going to be ready by this date, notify the Manufacturing Quality Branch by email **as soon as possible**.

Applying for a manufacturing licence using TGA Business Services

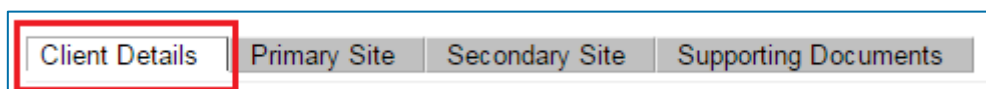
To apply for a manufacturing licence:

1. Log in to [TGA Business Services](#).
2. Go to the **Manufacturers** menu and select **Licence Application**.



This will open a New Licence Application screen.

3. Complete the mandatory fields denoted by a red asterisk (*) on the Client Details tab.



Selecting the manufacturer name and manufacturing site address in the Client Details tab

If you are applying for a new manufacturing licence for an existing manufacturer, select **Search** to open the Manufacturing Information System (MIS) search dialog box.

In the search box, enter a search string by typing the name of the existing manufacturer you wish to obtain a manufacturing Licence for and select **Search**. Only Australian manufacturers should be visible in this search.

If the manufacturer's name is already registered with the TGA, it will appear in the list for selection. Click on the manufacturer and select **OK**.

Important - If the manufacturer name is not already registered with the TGA, you will have to register the manufacturing site prior to proceeding with the application.



Ensure you have thoroughly searched the TGA database for the manufacturer's name before you select New Manufacturer. Duplicate entries created can result in extended delays to application processing times.

If you are unsure whether the manufacturer name you intend to use is available in the TGA database, please contact us prior to proceeding with your application.

If you are applying for a new manufacturing licence for a new manufacturer, select **New Manufacturer** to open the request for entry of a new manufacturer entry form.

Enter all the required information about the manufacturer and the site address and upload at least one piece of evidence to support the request, then select **Send**.

Request for entry of a new manufacturer on the TGA Client database

This email new manufacturer request facility will be sent to the corporate management area of TGA for entry of the manufacturer name and address details into the TGA Client database. The attached or supporting information will be used to help resolve duplicate names or other administrative anomalies. A return email will be used to help resolve any name and address concerns.

The request is for:

Contact person:

Email:

New manufacturer name:

Manufacturer address:

Country:

Please attach documentation containing the name and address details to support the administrative request. Up to three separate attachments can be added to this form, but only one is mandatory.

No file chosen
 No file chosen
 No file chosen

Your manufacturer evidence notification is saved as a draft. Once your new manufacturer has been entered into the TGA Client database you will receive a return email indicating the manufacturer name is available for use in your evidence notification.

Once TGA Business Services have registered the manufacturer and site address, you will be notified and may proceed with the application.

Typically, a new registration is complete within 1-2 business days from the date of request.

4. Complete the mandatory fields denoted by a red asterisk (*) on the Primary Site tab.

Please select the activities intended to be undertaken at the licenced site(s). (Please note, multiple activities can be selected).

* Select the activities intended to be undertaken at the licenced site(s):

Medicine - API & Sunscreens

Blood & Blood Components (not HPC) Primary Site

Blood & Blood Components (not HPC) Secondary Site

Haematopoietic Progenitor Cells (HPCs)

Biological

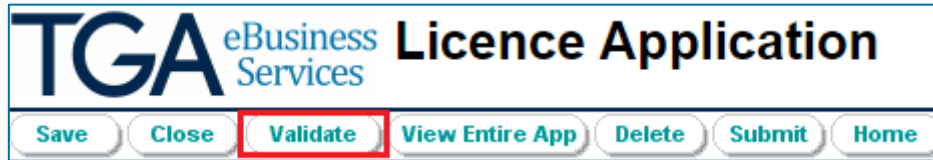
5. If applicable, add a [secondary site](#) using the 'add secondary site button' on the Secondary Site tab. Complete the mandatory fields denoted by a red asterisk (*) in the Secondary Site window.

6. Attach the required [supporting documents](#) on the Supporting Documents tab.

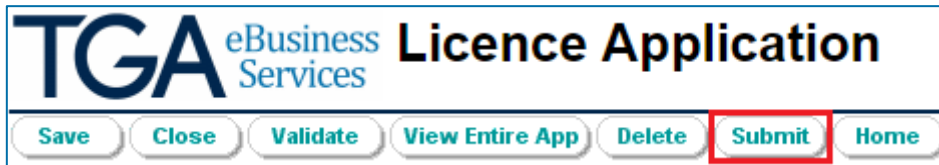
An electronic copy of your Site Master File, Quality Manual or Technical Master File MUST support this application or it will not be valid. However you may also provide a hardcopy of the files if an electronic one is not available.

Electronic Document List

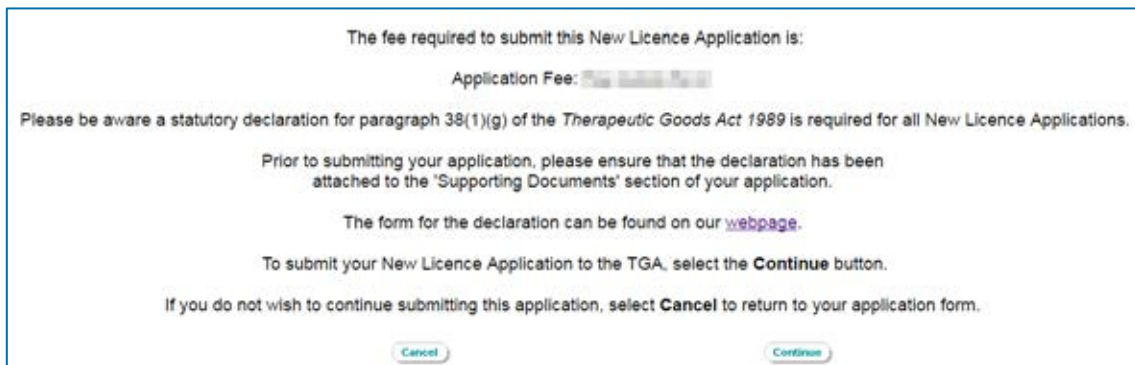
- Click on the **Validate** button to validate your application.



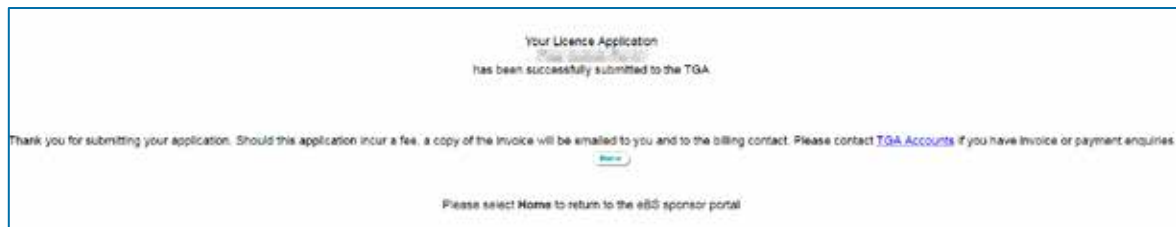
- To submit your application, click on the **Submit** button.



- After submitting your application, the following screen will appear, notifying you of the [fees](#) to be charged. Select Continue to proceed with lodging your application to the TGA or Cancel to return to the form.



- You will receive the following notification of a successful application submission.



6b: Applying for GMP certification

Provide a cover letter as part of your application indicating when you believe you will be [ready for an inspection](#). If you are not going to be ready by this date, notify the Manufacturing Quality Branch by email **as soon as possible**.

We may reject your application if your sites are not ready for inspection.



GMP certification applications must be submitted by:

- **the Australian sponsor**
- OR
- **an agent acting on the Australian sponsor's behalf**

All manufacturing steps are required to be GMP compliant unless they are exempt. However, GMP certification is not necessarily required unless the manufacturing step is recorded on the ARTG.

We offer guidance on the regulatory requirements relating to different types of medicines and biologicals, including:

- [Australian Regulatory Guidelines for Prescription Medicines \(ARGPM\)](#)
- [Australian Regulatory Guidelines for Over the counter \(OTC\) Medicines \(ARGOM\)](#)
- [Australian Regulatory Guidelines for Complementary Medicines \(ARGCM\)](#)
- [Australian Regulatory Guidelines for Biologicals \(ARGB\)](#)

Guidance is also available on [which steps of prescription medicine manufacture require evidence of GMP compliance](#).

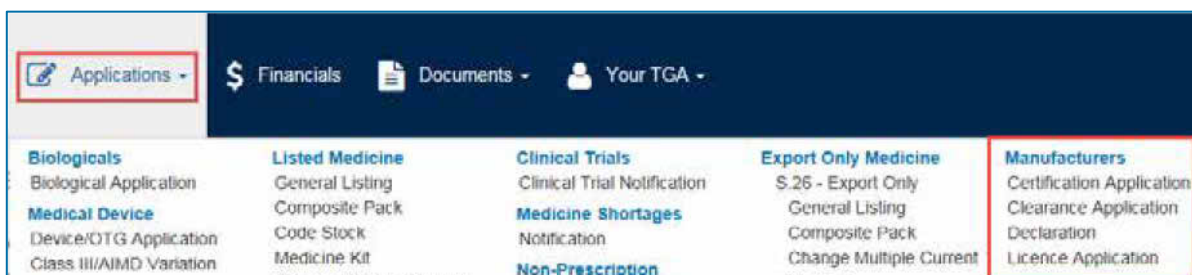
If you are unsure whether you need GMP certification, [contact the relevant product regulatory area](#) before you submit your GMP certification application.

Applying for GMP certification using TGA Business Services

Before you apply for GMP certification, [check you cannot obtain GMP clearance via the MRA or CV pathway](#). We may not accept your application for GMP certification if you can apply for GMP clearance via one of these pathways.

To apply for GMP certification:

1. Log in to [TGA Business Services](#)
2. Go to the **Manufacturers** menu and select **Certification Application**



This will open a **New Certification Application** screen.

- Complete the mandatory fields denoted by a red asterisk (*) on the Client Details tab.

- Complete the mandatory fields denoted by a red asterisk (*) on the Primary Site tab.

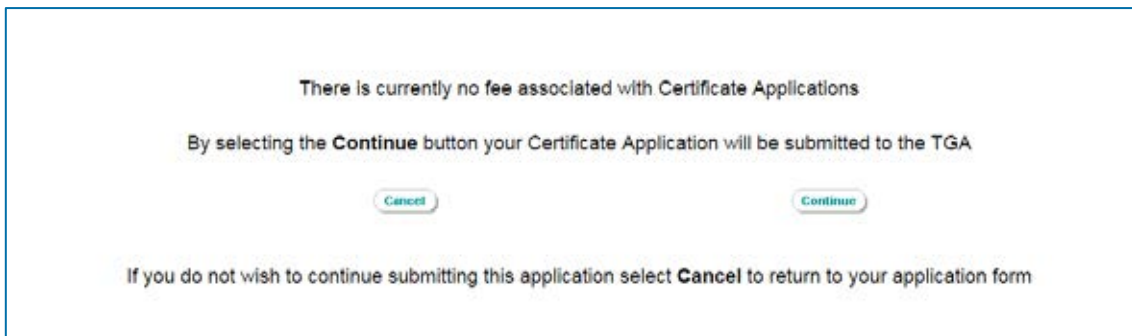
- If applicable, add a [secondary site](#) using the 'add secondary site button' on the Secondary Site tab. Complete the mandatory fields denoted by a red asterisk (*) in the Secondary Site window.

- Attach the required [supporting documents](#) on the Supporting Documents tab.

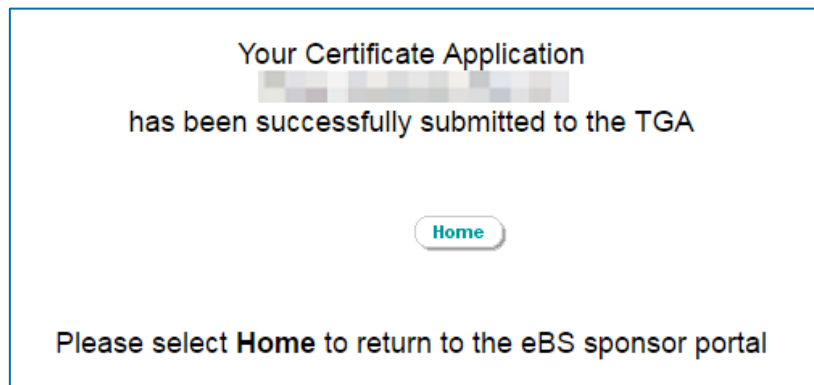
- Click on the **Validate** button to validate your application.

- To submit your application, click on the **Submit** button

- After submitting your application, the following screen will appear. Select Continue to proceed with lodging your application to the TGA.



- You will receive the following notification of a successful application submission.



7: Application fees

The application fee for a new manufacturing licence application is dependent on the manufacturing activities performed at the site. Please refer to relevant areas in the [Summary of fees and charges](#) for details. Where multiple types of manufacturing activities are performed, the highest application fee will be applicable.

When you submit your licence application the system will generate an invoice. We also provide guidance about your [payment options](#).

There is currently no application fee GMP certification applications.

8: Determining whether your application is effective

We will determine whether your application is effective when we have received:

- all necessary [supporting documentation](#)
- the licence application fee

Please note that it may take two to three days to process your payment and release the application for processing.

Our [target timeframes for inspections](#) commence from when we deem the application effective (i.e.: the relevant fees have been paid and that all of the required evidence to support your application has been supplied).

Screening your application

We will review your application after we have received your fees and contact you if we require any clarification or additional information.

If we determine that no inspection is required, we will notify you. This could be because:

- you could obtain [GMP clearance](#) using the MRA or CV pathway
- you selected the wrong type of application
- the goods or the manufacturer are [exempt from the manufacturing principles](#)
- the application was made by an overseas manufacturer or representative acting on behalf of the overseas manufacturer instead of an Australian sponsor or agent acting on behalf of the Australian sponsor

If an inspection is warranted, we will schedule one. This could take up to six months depending on the completeness of the application and inspector availability. It is your responsibility that you submit your application with this timeframe in mind.

Advising us of changes

Once you have submitted your application you cannot change it via TGA Business Services.

If your anticipated timeline changes or you would like to vary the scope of your application, email the [Manufacturing Quality Branch](#). We will review your request and accommodate the changes where possible. However, we may not be able to change the scope or duration of the inspection if you do not give us enough notice.

9: Scheduling the inspection

Scheduling procedures

When scheduling inspections, we take into account the type of product manufactured, the complexity of the manufacturing process, the size of the manufacturing facility et cetera. Based on your application, we will:

- determine the inspection team size
- determine the inspection duration
- select the inspectors and specialists who will conduct the inspection

Choosing the inspection team

The TGA will choose an inspection team. The team has delegated authority under the *Therapeutic Goods Act 1989*.



You may not request or refuse particular inspectors.

The inspection team

Inspection teams are led by a Lead Inspector and supported by appropriately qualified and experienced inspectors and, where required, technical specialists. Technical specialists with current, specialised knowledge of the activities inspected can provide a relevant and practical review of critical aspects of the manufacturing process.

Some inspections may be carried out by an individual inspector.

Avoiding conflict of interest

We will not select inspectors or specialists to inspect manufacturers where there may be a real or perceived conflict of interest. An inspector **cannot**:

- ❏ have been employed by the manufacturer within the three years prior to the date of the inspection
- ❏ have a commercial or financial interest in the manufacturer
- ❏ be a significant shareholder in the manufacturer or the manufacturer's industry
- ❏ have been engaged by the manufacturer as a consultant within the last three years

Generally, no Lead Inspector will lead an inspection of a particular manufacturer on more than two consecutive occasions.

Arranging the onsite inspection

We will:

- liaise with the manufacturer to determine the inspection dates
- schedule the dates for the onsite inspection, although these may sometimes need to be changed
- arrange all travel related to the on-site inspection, including flights and travel allowance, in accordance with Department of Health travel policy

If we need to inspect more than one site overseas, we will attempt to arrange multiple inspections for that trip. This usually results in some costs being shared among sponsors.



You cannot cancel a TGA onsite inspection by submitting a desktop assessment via the MRA or CV pathways if we have confirmed the inspection dates with the manufacturer and begun arranging travel.

10: Paying inspection invoices

Inspection fees will vary depending on the [duration](#) and location of the inspection and the size and composition of the inspection team.

- For overseas inspections, we will issue invoices to the Australian sponsor(s). You need to pay these before the inspection. Final invoices will be issued to the Australian sponsor(s) after the inspection has occurred. If you decline to contribute to an overseas inspection without reasonable justification, you will not be issued a GMP clearance once the inspection has been closed out.
- For inspections in Australia, we will issue invoices to the manufacturer after the inspection occurs. We will not issue an inspection report until all invoices have been paid. For repeat inspections of Australian manufacturers, the inspection hours may be covered by the annual charge. If this is the case, you may not receive an invoice or may receive an invoice for a reduced number of hours.
- For APVMA inspections for exporting to Europe, relevant fees apply. We will issue an invoice before the inspection. You need to pay this invoice before the inspection takes place.

Information about fees and charges can be found in the [Summary of fees and charges](#). We also provide guidance about your [payment options](#).

11: Preparing for inspection

Prior to the inspection, please ensure you confirm your [readiness for inspection](#). An inspector will contact the manufacturing site(s) to discuss:

- the members of the inspection team
- any requests for additional information to support the application, such as:
 - the current Site Master File or Quality Manual
 - details of products manufactured since the last inspection (if relevant, for example for reinspection)
 - details of any significant changes made since the last inspection (if relevant, for example for reinspection)
- any other information the inspector deems relevant

We may request electronic copies of records or other documents, such as Standard Operating Procedures (SOPs), validation plans, lists of products manufactured, any regulatory actions taken (recalls or product alerts) et cetera.

In most cases, we will contact the manufacturing site to arrange the inspection; however, we may also need to contact the sponsor for information relating to the inspection.



All documents supplied to the TGA must be in English or accompanied by an English translation.

Documents should be provided in an electronic format.

12: The onsite inspection

We conduct inspections according to internal procedures based on [PI031-1 standard operating procedure team inspections](#). See our [guidance on manufacturer responsibilities](#) during an inspection.

For general information on inspections, see:

- [Manufacturer inspections – an overview](#)
- [Manufacturer inspection – typical example](#)



Avoiding improper influence

Inspections must be fair and impartial. Manufacturers need to avoid any activity that may cause improper influence including:

- bribes
- threats
- provision of entertainment
- provision of meals (other than simple working lunches where there is no alternative)

If improper influence is attempted, we will:

- take appropriate action
- record all details of attempted improper influence in the inspection file

Purpose of the inspection

The inspection will determine your compliance with the relevant GMP code, standards and regulations in relation to the **scope of your application or the current licence or certification** which is in force (referred to as the extent and boundaries of the inspection).

We will inspect the relevant:

- facilities
- equipment
- staff
- training
- quality management systems

We may also conduct special inspections with a specific purpose, which are more focussed.

What we are looking for

We are looking for your understanding of the requirements for manufacturing therapeutic goods to be supplied to Australia. We will identify any particular areas of concern during our pre-inspection documentation review and inspect all areas relevant to the scope of the application for compliance with:

- the relevant [manufacturing principles](#)
- any other relevant regulatory requirement, such as:
 - the [therapeutic goods orders](#)
 - the [default standards](#)
 - the requirements of the Technical Master File (blood, blood components and biologicals)
 - the conditions of ARTG listing or registration

The emphasis and depth of the inspection depends on the [risk level of the products and the manufacturing processes](#). We will also identify any particular areas of concern during our pre-inspection documentation review.

We expect to find the manufacture of every batch of every product complies fully with the requirements of the marketing authorisation and any other regulatory requirements relevant to the production, control and release of medicines, including the code of GMP. For example, we expect that:

- processes for every product or product group are validated, when validation is required
- every starting material is tested according to GMP requirements and agreed interpretations

We collect evidence by sampling. For example, we do not usually look at the records for every batch, but instead select a small number of batches to examine thoroughly.

We will inform you of all potential deficiencies we observe and give you an opportunity to provide any additional relevant information.

We do not advise how to remedy deficiencies.



If we notify you of an observed deficiency, you can provide additional information for the inspector to review. If you have additional information, we prefer you to provide this **during the inspection**.

Disputes and complaints

We prefer to resolve disputes and differences in views informally during the inspection whenever possible. However, for more serious concerns, follow our [inspection complaint process](#).

Opening meeting

For a general description of the opening meeting, see: [Manufacturer inspection – typical example](#).

At the opening meeting, the inspector or inspection team will:

- clearly describe the inspection objectives, scope and relevant manufacturing principles
- explain the inspection process and how feedback will be provided
- provide you with an inspection plan
- record attendance

Manufacturer guides and observers

Manufacturers have various [responsibilities during an inspection](#).

We conduct the inspection in English. If we need to talk to people who cannot speak or understand English you will need to:

- provide a guide with some technical understanding who can act as a translator
- translate any documents that we request into English



The translator

Please ensure the translator can translate technical language. The translator needs to be able to translate a technical question asked by the inspector in English into your language, as well as translate technical information into English.

- We may terminate the inspection if we cannot communicate effectively.
- If the information cannot be properly translated to the inspector, this may adversely affect the inspection outcome.

The manufacturer's guides should:

- Ü assist the inspection team and act on the request of the inspection team
- Ū not influence or interfere with the conduct of the inspection

Guides are responsible for:

- clarifying information or assisting in collecting information
- ensuring the inspection team understands and respects site safety and security procedures
- witnessing the inspection on behalf of the manufacturer
- translating for the inspection team

The manufacturer can also appoint observers.

Conducting the inspection

We examine actual practices, documentation and records. We collect information during the inspection by:

- interviewing personnel at all levels within the organisation
- observing activities
- reviewing and evaluating systems and procedures for compliance and effectiveness
- taking photographs and copying documents
 - Where an inspector needs to take photographs or copy documents, they will discuss this with you before they do so
 - It is a standard condition that manufacturing licence holders allow inspectors to copy documents and take photographs (section 40(4) of the [Therapeutic Goods Act 1989](#)). Similar expectations apply when we are inspecting overseas.

At the end of each day we may hold a debrief meeting to discuss issues that arose during the day. These will be included in the written closing meeting summary we give you at the end of the inspection. You can provide additional information during the inspection to address any issues raised.

Closing meeting

We will hold a closing meeting at the end of the inspection between the inspection team and your senior management and any other staff nominated by your company.

At this meeting we:

- summarise the findings and present any potential deficiencies
- discuss any divergence of opinion between the manufacturer and the inspectors
- discuss the conditions likely to be applied to the licence or certificate
- explain the inspection close out process
- record of attendance

We will provide you with a written closing meeting summary listing all potential deficiencies we have found. We provide this written summary so you will be aware of the content of the post-inspection letter. This allows you to start remedying any deficiencies immediately.

Do not confuse this written closing meeting summary with the [post-inspection letter \(PIL\)](#) or the inspection report we send you later.

You do not need to formally respond to the closing meeting summary.

Related information

- [Manufacturer inspection – typical example](#)

13: The post-inspection letter (PIL)

We prepare a post-inspection letter (PIL) that records any deficiencies identified during the inspection and categorising them as critical, major or other. The deficiencies reference specific clauses in the GMP code, to identify which compliance requirement was not met.

The PIL is not a comprehensive inspection report.

The purpose of the PIL is to formally notify the manufacturer of the deficiencies identified during the inspection. The content of the PIL should not be a surprise because it will be similar to the written closing meeting summary provided at the closing meeting of the inspection.

The PIL is usually emailed to the manufacturer within four weeks of the inspection; however, it may be sent sooner where serious or significant compliance issues are identified.

Classifying deficiencies

We [classify deficiencies](#) as critical, major or other.

You must respond to all deficiencies listed in the PIL, following the included instructions.

Unacceptable rating

If your site is significantly noncompliant, you may be issued an unacceptable rating. An unacceptable rating means we will consider potential regulatory action to protect public health, including refusing to grant a new licence or suspending or revoking a licence which is in force.

If your compliance is rated as unacceptable, or you receive two consecutive A3 ratings where a licence or certification is in force, we may take the following actions:

- review the inspection findings
- undertake a risk assessment of the manufacturer and any goods manufactured at the site, if applicable
- prepare recommendations to ensure resolution by the manufacturer of any compliance issues
- prepare recommendations for regulatory and/or enforcement action

14: Addressing deficiencies

We normally give you up to four weeks to submit a written response to the inspection findings, which usually equates to a total of eight weeks from the end of the inspection. However, if we identify serious or significant compliance issues, we may give you less time.

You need to complete the manufacturer closeout record following the instructions outlined in the PIL. We will provide you with an electronic template for this record; you do not have to use the template but you may find it helpful.

Your response should clearly outline the actions you will take to correct any deficiencies we have identified. In responding you should:

- develop a corrective and preventative action (CAPA) plan for all critical and major deficiencies identified. This plan must include:
 - an investigation of the root cause of all critical and major deficiencies
 - details of the corrective action(s) to address the root cause
 - details of the preventative action(s) to address the root cause
 - corrections to address the deficiency examples
 - the date all actions will be complete
- for deficiencies classified as 'other', provide the response date, the correction(s) to be applied and when they will be completed

Implement all actions in response to deficiencies as you have described in your response. You need to correct any deficiencies identified at a new manufacturing site before a licence or certification can be granted.

Objective evidence

You must record and review any actions taken to address deficiencies but you do not need to submit objective evidence of these unless expressly requested to. We will assess the effectiveness of the actions taken at the next inspection.

We may request objective evidence where warranted, for example where we find significant noncompliance at an initial inspection, or where we identify chronic noncompliance.

15: Reviewing your response and closeout

The closeout process is intended to ensure the manufacturer commits to perform appropriate CAPAs for each deficiency within an acceptable time period. The closeout correspondence records this commitment as well as our comments and agreement.

The scope of the closeout is limited to the list of deficiencies in the PIL. We will consider closing out the inspection after we have reviewed your responses to the deficiencies in the PIL.

The length of time that it takes to close out an inspection depends on whether you propose suitable CAPAs that address our concerns.

- We will usually review your initial response within four weeks of receiving it.
- If we need additional information, we will notify you and specify a due date.
- You will have up to two opportunities to submit subsequent responses.

If, after your third response, your responses are unacceptable, the inspection may be referred to a review panel.

16: Issuing the inspection report

Once we have reviewed and accepted your responses, we will close out the inspection and issue an inspection report to the manufacturer. The inspection report is a comprehensive account of the inspection, including:

- the scope of the inspection
- the manufacturing, quality control and quality assurance processes and systems inspected
- the list of observed deficiencies
- an assessment of the manufacturer's response to any deficiencies
- the manufacturer compliance rating
- any proposed conditions on the site licence or certification
- proposed reinspection dates
- confirmation of the final outcome and inspection closeout
- any proposed amendments to site authorisations or certifications (only applicable to licences or certifications that are in force)

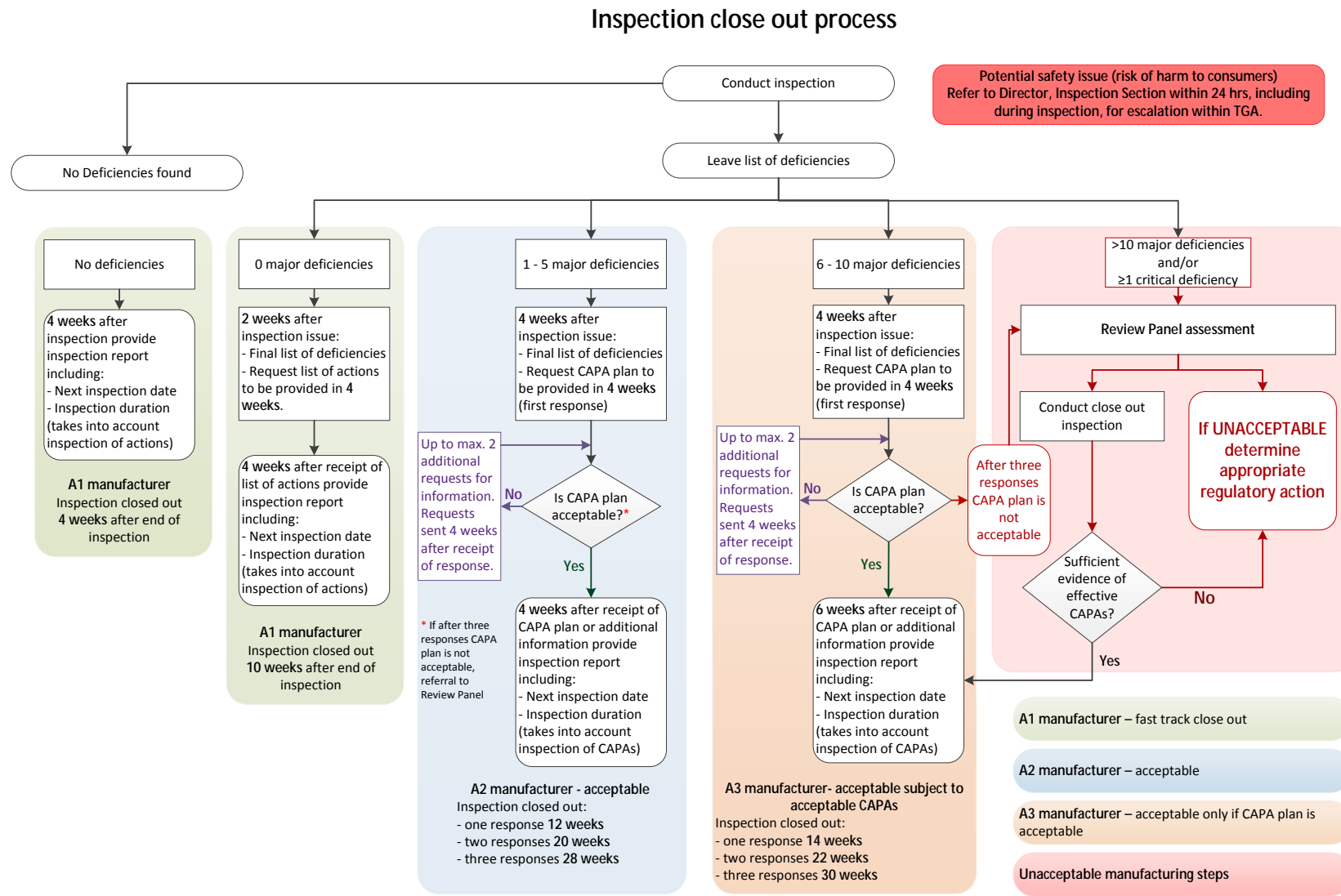
Compliance rating

You will receive a [compliance rating](#) of either:

- A1 (good)
- A2 (satisfactory)
- A3 (basic)
- unacceptable

We consider your compliance rating and the complexity of your operation when we determine the [frequency of follow-up inspections](#).

Overview of the inspection closeout process



Reinspection duration

If necessary, we may extend the next onsite inspection to allow us to assess the corrective actions taken by the manufacturer. This is more effective than requesting objective evidence for assessment offsite. This approach aligns with those taken by our international regulatory partner agencies.

The amount of extra time required for the next inspection will depend on the level of compliance. Where no major deficiencies were identified at the last inspection, an extension will not usually be necessary. However, depending on the number of deficiencies identified and compliance rating, the next inspection could be extended by ½ day for A2 and a full day for A3.

17: Paying your final invoice

After the inspection we will issue you a final invoice. To pay your invoice, follow the guidance at [payment options](#). Pay your invoice within 28 days.

Information about fees and charges can be found in the [Summary of fees and charges](#).



You must pay your inspection fees before we will issue an inspection report and grant your licence, in accordance with section 38 (1)(c) of the *Therapeutic Goods Act 1989*.

18: Providing feedback

This step is optional. However, we would appreciate it if you would provide us with feedback on the inspection process using [one of the two feedback forms provided](#).

19: Making a decision

We will review the findings and recommendations of our inspection report. Following this review, we will make a decision regarding the licence or certification, where relevant.

We need to be satisfied that:

- you have achieved the requirements for a licence or GMP certification
- all deficiencies have been, or are being, satisfactorily addressed
- all fees have been paid

We will decide to either:

- for new applications:
 - [grant a Licence to Manufacture or issue GMP certification](#), with or without conditions
 - [refuse to grant a licence or issue GMP certification](#)
- for licences or certifications that are in force:
 - [reissue a Licence to Manufacture or GMP certification](#), with or without conditions
 - recommend that no changes be made to the licence or certification that is in force
 - [revoke, suspend or vary a licence](#), where relevant
 - recommend an [existing GMP clearance be cancelled](#)

Refusal to grant licence or issue certification

If we decide to refuse to grant a licence or issue certification, we will write to you about:

- our decision
- the reasons for our decision
- how to seek a review of our decision

We can grant or refuse to grant a manufacturing licence under Section 38 of the *Therapeutic Goods Act 1989*.

Revocation, suspension or restriction of licence

Section 41 of the *Therapeutic Goods Act 1989* allows us to revoke or suspend a manufacturing licence. For more information, see [Suspending, revoking and varying conditions of manufacturing licences](#).

We must publish (as soon as practicable) a decision to revoke or suspend a licence [section 41(6), *Therapeutic Goods Act 1989*].

Section 40 of the *Therapeutic Goods Act 1989* allows us to add new conditions to the licence, or to vary or remove existing conditions on a manufacturing licence.

20: Granting licences and issuing certification

Once we have decided to grant your licence or issue your GMP certification, we will send it to you in the mail. If there are changes to your licence we will reissue it, but if there are no changes to the licence there is no need for this.

As a manufacturer with a licence or GMP certification, you have [ongoing responsibilities](#). For GMP certification, the [sponsor also has responsibilities](#).

You shall not in any way use the fact that a licence has been granted or certification has been issued to provide customers with misleading information regarding applicability of the licence or certification outside the scope for which it has been issued.

All licences and certificates remain the property of the TGA. You must return a licence or certificate upon request. This usually happens when we [revoke, suspend or vary a licence](#).

Licence

The Licence to Manufacture includes:

- licence number
- licence holder name
- manufacturing site addresses
- description of the types of products and manufacturing steps authorised

A Schedule of Conditions usually accompanies the Licence to Manufacture. Some of these conditions are common across licences, but some may be specific to a particular licence.

- You must display a copy of the Licence to Manufacture and the Schedule of Conditions where the general public can view them [Regulation 20(a)].
- We must publish (as soon as practicable) the decision to grant a licence [section 38(4), *Therapeutic Goods Act 1989*]. We also publish a [list of licensed Australian manufacturers](#).

A licence commences on the day specified in the licence and remains in force until revoked or suspended.

Legislation underpinning manufacturing licences

| Process | Legislation |
|---|--|
| Application for a licence | Section 37 Therapeutic Goods Act 1989 |
| Granting a licence | Section 38 Therapeutic Goods Act 1989 |
| Term of the licence | Section 39 Therapeutic Goods Act 1989 |
| Conditions of the licence | Section 40 Therapeutic Goods Act 1989 Regulation 19 and 20 Therapeutic Goods Regulations 1990 |
| Variations by the Secretary | Section 40A Therapeutic Goods Act 1989 |
| Variations at the request of the licence holder | Section 40B Therapeutic Goods Act 1989 |
| Revocation or suspension of licence | Section 41 Therapeutic Goods Act 1989 |
| Transfer of licences | Section 41AAA Therapeutic Goods Act 1989 Regulation 22 Therapeutic Goods Regulations 1990 |

GMP certificate of compliance for licence holders

Once you have been granted a licence, you can [request a certificate of GMP compliance](#) if you need one.

GMP certification

Following successful inspection of an overseas manufacturer we issue:

- a GMP certificate to the manufacturer
- GMP clearance to the sponsor who made the application and/or who contributed to the costs of the inspection

The GMP certificate includes:

- the certificate number
- manufacturing site address
- a description of the types of products and manufacturing steps inspected
- the expiry date, which reflects the intended [reinspection frequency](#) and is based on the risk category of the products manufactured and the compliance rating determined at closeout

There may be conditions on a GMP certificate, some of which are common across certificates and some specific to that particular certificate.

Extra copies

We can provide you with notarised copies of manufacturing licences or GMP certificates of compliance for Australian manufacturers if you:

- [request extra copies](#)
- pay an [additional fee](#)

We do not provide notarised copies of GMP certificates issued to overseas manufacturers.

21: Conducting follow-up inspections

Follow-up inspections can be [routine](#) or [special](#).

Routine inspections

We schedule routine follow-up inspections and advise the Australian manufacturer or Australian sponsor shortly before the inspection date. The [frequency of routine follow-up inspections](#) depends on the level of compliance at previous inspections and level of risk of products being manufactured. Generally you do not need to submit applications for routine reinspections or to [request recertification](#); the TGA Business Services will automatically generate an application for re-inspection based on the frequency recommended following the inspection.

Routine follow-up inspections cover the full scope of manufacture. We need to be satisfied that you:

- continue to comply with the relevant codes and standards
- continue to comply with the conditions of the licence or certification
- have paid all fees related to licence or certification

We have [target timeframes for issuing inspection reports](#) following re-inspections.

Special inspections

We may conduct special inspections:

- to complete the closeout of a routine inspection where we need to follow up identified deficiencies on-site.
- as a result of GMP compliance concerns
- for variation applications.

These inspections may focus on specific areas.

We may conduct unannounced inspections when necessary, particularly if we have concerns about GMP compliance.

22: Keeping us up-to-date and making requests

Both [sponsors](#) and [manufacturers](#) have responsibilities. One of your responsibilities as a manufacturer (for licences) or sponsor (for GMP certification) is to notify us of any significant changes in the manufacturer's business or operations. This enables us to evaluate the impact of such changes.

Please notify us **before** making any change, because some changes require prior approval.

- To request changes to the licence, the manufacturer must submit a [variation application](#) via TGA Business Services
- To request changes to GMP certification, the sponsor must email the [Manufacturing Quality Branch](#)

We can usually process any changes to the scope of licence or certification as part of the ongoing inspection program.

Sponsor responsibilities

You can find more information about sponsor responsibilities in [Sponsor responsibilities related to GMP clearance and certification](#). It is the sponsor's responsibility to request recertification, when required.

Requesting recertification

Sponsors should maintain evidence of GMP compliance for all sites used in the manufacture of their registered or listed medicines and are responsible for these nominated sites at all times.

When GMP certification expires, it ceases to have effect. Sponsors do not need to submit applications for routine reinspections—the TGA Business Services will automatically generate an application for re-inspection based on the frequency recommended following the inspection.

If evidence is available from other regulators, or a GMP clearance has been applied for or granted for the same scope for a site, we will consider this. If a GMP clearance has been granted, or evidence is available to support a GMP clearance application, we will not schedule an on-site inspection.

To request recertification, make a GMP certification application using TGA Business Services—for example, where a GMP clearance was obtained via MRA or CV pathway previously, but there is no current evidence available prior to the GMP clearance expiry.

Licence holder responsibilities

Details of licence holder responsibilities can be found in [Responsibilities of manufacturers of medicines and biologicals](#) and include the following.

Comply with the manufacturing principles

Licence holders should maintain an effective quality system and comply with the principles of GMP in the manufacture of therapeutic goods. It is critical that the quality system and resources are appropriate for the manufacturing operations performed.

Implement corrective and preventative actions as agreed

Licence holders are required to implement all corrective and preventative actions as agreed with the TGA. If you are unable to meet a specific commitment or deadline, you should email the Lead Inspector.

Pay your annual charge

Pay the [annual charge](#) for your TGA manufacturing licence.

If you don't pay the annual fee, [we can revoke your licence](#).

Declarations

For TGA licences you need to make a declaration on [Certificate S40\(6\)](#) regarding specific convictions and financial penalties in the 10 years prior to the application when:

- the licence changes hands, such as when the company is sold to a new owner (see [guidance on the transfer of licences](#))

OR

- an individual in your company described in Section 38(1)(g)-(h) of the [Therapeutic Goods Act 1989](#) does not meet its requirements.

Submit the declaration form to the [TGA manufacturing enquiry email address](#).

Variation applications

To make a variation application, refer to the [guidance on making a variation to a manufacturing licence](#).

Contacting the Manufacturing Quality Branch

For enquiries, [contact the Manufacturing Quality Branch](#).

Version history

| Version | Description of change | Author | Effective date |
|---------|--|---|----------------|
| V1.0 | Guidance on licensing/certification inspections | Office of Manufacturing Quality | 29/04/2013 |
| V2.0 | Change in title Reduction in scope (no longer applies to medical device manufacturers) Rephrasing of content Publication following consultation with industry in January 2017 | Manufacturing Quality Branch and the Regulatory Guidance Team | August 2017 |
| V2.1 | Added instructions for selecting manufacturer name and site details, and the manufacturing activities in the New Licence application form. Added clarification for application fees and where declining to contribute to cost of an overseas inspection, the impact on obtaining GMP clearance Minor editorial changes | Manufacturing Quality Branch | March 2019 |

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Reference/Publication #