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Department of Health
Therapeutic Goods Administration

GMP clearance guidance

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TGA Health Safety
Regulation



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This guidance is for sponsors seeking to obtain Good Manufacturing Practice (GMP) clearance for an overseas manufacturing site used in the manufacture of a medicine, or an Active Pharmaceutical Ingredient (API) used in a medicine, intended for supply in Australia.



This guidance is **not** intended for sponsors of:

- **biologicals, human blood and blood components and Haematopoietic Progenitor Cells (HPCs)**, because Australia has its own [manufacturing standard](#) for these product types; however, where the manufacturing site performs only sterilisation of these product types, this guidance may be used
- some **complementary and listed medicines**, including **sunscreens**, because these may not be regulated as medicines in other countries

Further information is available in the [Australian manufacturing licences and overseas GMP certification guidance](#).

GMP clearance basics

What GMP clearance is

GMP Clearance is a non-statutory mechanism used to verify that overseas manufacturing sites comply with the principles of GMP for the products being supplied to Australia. It was introduced as a way to reduce the regulatory burden on industry while maintaining assurance that the suitability of manufacturing processes and quality control procedures are appropriate.

The TGA may issue GMP clearance to sponsors of a medicine or API that is manufactured overseas if there is acceptable evidence demonstrating that the overseas manufacturer complies with the principles of GMP (the [manufacturing principles](#) or equivalent standards).

Why GMP clearance is required

Sponsors are required to obtain GMP clearance for overseas manufacturers of their registered or listed products to satisfy sections 25(1) (g), 26(1) (g) and 26A (3) of the [Therapeutic Goods Act 1989](#). This upholds the main objective of the Act, which is to ensure the safety, quality, efficacy and timely supply of therapeutic goods for Australian consumers.

What manufacturing steps require GMP clearance

All steps of manufacture are required to be **GMP compliant** unless they are exempt. However, **GMP clearance** is not necessarily required unless the product is to be registered or listed **and** the manufacturing step recorded on the [Australian Register of Therapeutic Goods \(ARTG\)](#).

Guidance is available regarding the different types of medicines and their requirements including:

- [Australian Regulatory Guidelines for Prescription Medicines \(ARGPM\)](#)
 - Additional guidance is available on which steps of manufacture require [evidence of GMP compliance for prescription medicines](#)
- [Australian Regulatory Guidelines for Over the counter \(OTC\) Medicines \(ARGOM\)](#)
- [Australian Regulatory Guidelines for Complementary Medicines \(ARGCM\)](#)

Ensure that the manufacturing steps you select are supported by the evidence to be provided with the application and that they align with the details required for product registration or listing.

If you are unsure whether you require GMP clearance for the purpose of registering or listing your product, [contact the relevant product regulatory area](#) **prior** to submitting a GMP clearance application.



If the selections you made result in validation issues with the regulatory submission system, you may be required to submit a [variation application](#) and pay the relevant [fees](#).

How GMP clearance is obtained

GMP clearance can be obtained per manufacturing site via one of three pathways:

- a Mutual Recognition Agreement (MRA) desktop assessment
- a Compliance Verification (CV) desktop assessment
- an on-site inspection by the TGA

This guidance deals with obtaining GMP clearance through the **MRA** or **CV** desk top assessment pathways **only**. The [Australian manufacturing licences and overseas GMP certification guidance](#) provides more information for those obtaining a GMP clearance following a successful TGA on-site inspection.



Letters of Access (LoA) are **not a pathway** to obtain GMP clearance but rather a type of evidence that can be provided when using either the MRA or CV pathways. LoA are explained further in [step 3](#).

How much GMP clearance costs

You are required to pay the relevant [GMP clearance fees](#) to have your application assessed, as we are required to recover the full cost of our regulatory activities.



Separate applications are required to be submitted for API and finished products, even if the evidence is applicable to both.

Similarly, separate applications are required for each unique site address in the TGA database irrespective of whether they are using the same evidence.

Fees for GMP clearance can include:

- **GMP clearance application processing fee:** applies to all GMP clearance applications except extensions and administrative variations
- **obtaining evidence from an overseas regulatory authority ([liaison](#)):** applies to all requests to obtain evidence (GMP certificates) for MRA applications and all CV applications that use US Food and Drug Administration (US FDA) evidence
- **Compliance Verification** (in lieu of an overseas GMP inspection): applies to all GMP clearance applications using the CV pathway unless otherwise stated in the table below
- **reinstatement of an expired GMP clearance:** applies to applications to reinstate expired GMP clearances

Application type	Evidence provided	Application Processing fee	Obtaining evidence fee	Compliance verification fee
MRA	MRA documentation	✓	ⓘ	✗
	LoA to Evidence			
	LoA to Clearance			
CV Sterile/Non-Sterile API	CV documentation	✓	ⓘ	✓
	LoA to Evidence			
	LoA to Clearance			✗
CV Sterile/Non-Sterile finished product	CV documentation	✓	ⓘ	✓
	LoA to Evidence			
	LoA to Clearance			✗
CV Contract testing laboratory or steriliser	CV documentation	✓	ⓘ	✓
	LoA to Evidence			
	LoA to Clearance			✗
TGA Certificate	TGA Certificate	✓	✗	✗
	LoA to Evidence			
	LoA to Clearance			

✓ = Applicable

LoA = letter of access

✗ = Not Applicable

ⓘ = Where requested by applicant or required

The following application types do not incur a fee:

- extensions
- administrative changes
- decrease in scope
- cancellation

How long GMP clearance takes

We provide target processing timelines for GMP clearance applications to assist industry in planning their regulatory activities. However, target processing timelines are dependent on several factors such as the:

- volume of applications received
- available TGA resources
- priority of other applications

The table below outlines the **current** target processing timelines. Any changes to these that occur due to the reasons outlined above will be communicated via the [notices about GMP Clearance webpage](#).

Application type	Target processing timelines
MRA	30 TGA working days
CV Non-Sterile API	60 TGA working days
CV Sterile/Biotech API	75 TGA working days
CV Non-Sterile Finished Product	90 TGA working days
CV Sterile/Biotech Finished Product	120 TGA working days



Target timeframes **do not apply** to any application where:

- liaison or clarification with the overseas regulatory authority is required
- or
- a compliance signal has been received for the site

Prioritisation requests

Generally, applications **will not** be prioritised for assessment. Sponsors are expected to plan their regulatory activities in line with the above processing times.

However, you may still request prioritisation in some circumstances, for example, where there is the potential for a [Medicine Shortage](#) to the Australian market.

What you should provide

If you intend to request that we prioritise your GMP Clearance application over others, you should ensure that you provide the appropriate level of detail and justification upfront via a cover letter submitted with the application and/or an email to [GMP clearance](#).

For example:

- If your prioritisation request relates to the potential for a medicines shortage, you should provide the details surrounding the reporting of that shortage to the Medicines Shortages area along with any other relevant information such as timeframes and supply of existing stock on hand.
- If your request relates to an urgent variation to an existing product on the ARTG, you should provide details of the proposed change including timeframes and impact.

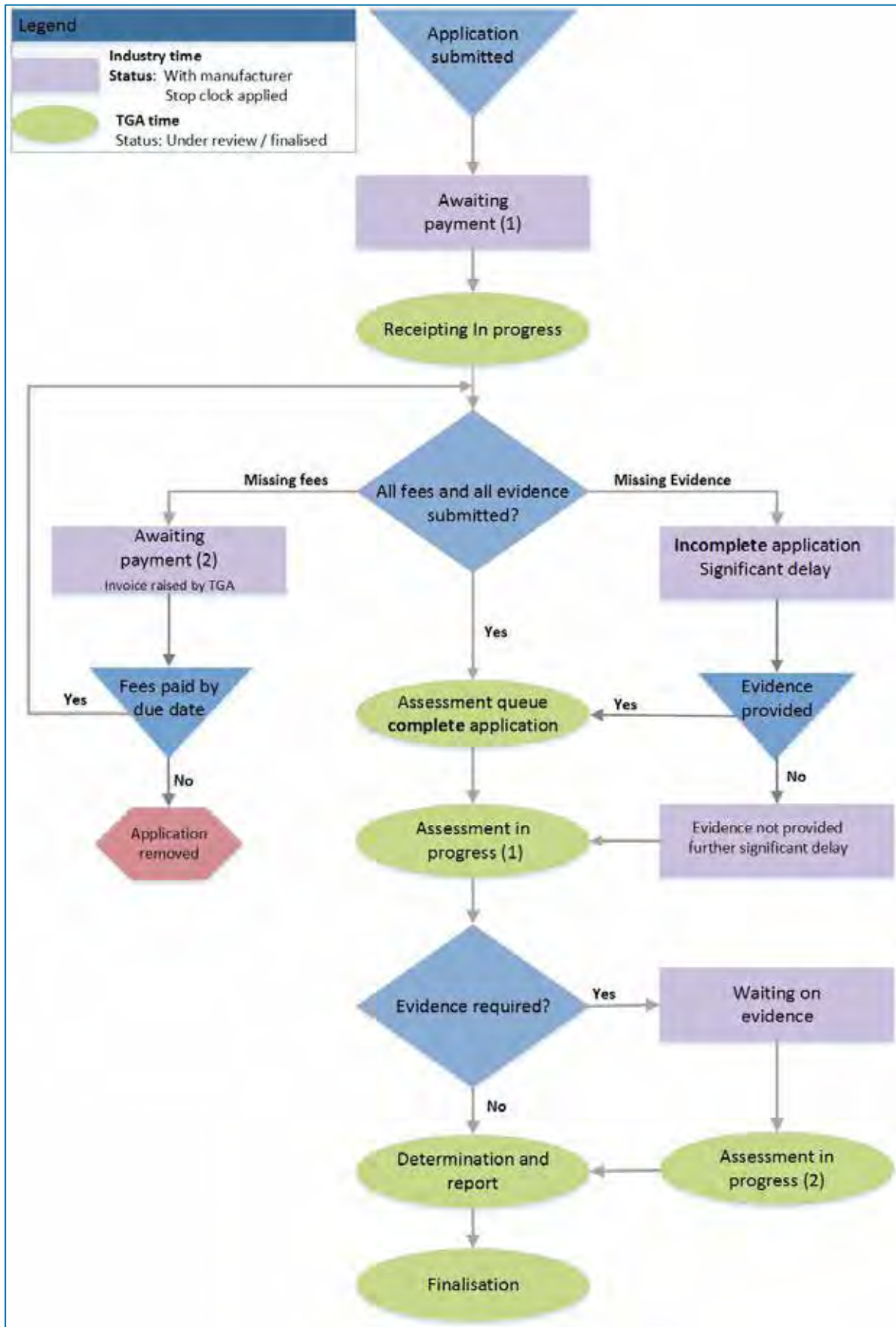
TGA vs Industry time



Due to the combination of various application types, associated [fees](#) and multiple [delivery methods](#) available to provide the required evidence, the CV pathway employs a stop clock process to accurately capture the TGA vs Industry time.

The following flowchart provides an overview of when this stop clock could be applied. Further information on application receipt and assessment are provided in steps [8](#) and [9](#).

Overview of stop clock process for GMP clearance applications using the CV pathway



Once your fees have been paid, processing time (TGA time) will commence. TGA time is defined as the number of TGA working days between the receipting process and the finalisation of your CV application; it does not include industry time. Industry time is when a stop clock is applied. For more information when a stop clock is applied, please refer to steps [8](#) and [9](#).

How to interpret the status of your application

Please login to your TGA Business Services (TBS) portal, and view the current status of your application. The status will help you identify the current stage of your application and whether information is required from you:

- **'Submitted':**
 - Application submitted however not all relevant fees have been paid. 'TGA time' has not commenced
- **'Under review':** This status indicates 'TGA time' has commenced
 - [Receipting in progress](#), or
 - Your application has been placed in the [assessment complete](#) queue, or
 - [Assessment](#) is in progress.
- **'With Manufacturer':** This status indicates a stop clock has been applied ('Industry Time')
 - We identified a [fee](#) is still required during [receipting stage](#), or
 - Your application has been placed in the [assessment incomplete](#) queue or;
 - During assessment, deficiencies identified and/or further clarification is required from the applicant
- **'Finalised':**
 - A [determination](#) has been made on your application. Further details provided in [step 10](#).
- **'Pending withdrawal':**
 - Applications you have identified as no longer relevant, have been withdrawn from TBS
 - Instructions on how to withdraw an application: [Withdrawal of 'under review' GMP clearance applications that are no longer required](#)



To avoid a significant increase in enquiries to the GMP Clearance mailbox, sponsors should contact their manufacturers in the first instance to ensure the required evidence has been provided.

Once you have contacted your manufacturer, if there are still queries in relation to the stop clock, please [contact us](#).

Sponsor responsibilities

Sponsors of therapeutic goods in Australia play an important [role](#) in ensuring the safety, quality, efficacy and timely supply of therapeutic goods for Australian consumers. As a sponsor, you have [responsibilities](#) to maintain GMP clearance for all overseas manufacturing sites used in the manufacture of your registered or listed medicine at all times.



If you do not meet your responsibilities detailed on the [sponsor responsibilities](#) web page:

- you may **not be issued** a GMP clearance
- you may **forfeit any fees** you have paid
- if you have an active GMP clearance, it may be **cancelled**.

The GMP clearance process

This step-by-step guide assists sponsors when applying for a new GMP clearance while also covering the steps for maintaining an existing active GMP clearance.

- [Step 1 - Understanding your supply chain and establishing agreements](#)
- [Step 2 - Identifying the appropriate GMP clearance pathway](#)
- [Step 3 - Identifying what documentation is required](#)
- [Step 4 - Creating your application](#)
- [Step 5 – Selecting your scope](#)
- [Step 6 – Providing your evidence](#)
- [Step 7 – Submitting your complete application and paying fees](#)
- [Step 8 - Application receipt](#)
- [Step 9 - Application assessment](#)
- [Step 10 - Making a determination and assigning expiry dates](#)
- [Step 11 - Maintaining your active GMP clearance](#)

Step 1 – Understanding your supply chain and establishing agreements

Modern supply chains can be complex with multiple manufacturing sites performing various steps of manufacture of a product. You need to:

- understand the activities of every manufacturer in the supply chain of your product
- establish and maintain the relevant [GMP, quality or technical agreements](#) with whom you have a direct relationship with, **including subsidiaries of the same parent company**:
 - The principles of GMP require you to have a GMP, quality or technical agreement with the primary or principle manufacturer of the medicine that clearly outlines the roles and responsibilities for each party
 - Where these manufacturers use subcontractors, this should be clearly specified in the agreement (for example, outsourced testing laboratories).

GMP, quality or technical agreements should be in place between the primary or principle manufacturer and their subcontractors. This should be provided as part of your application where appropriate.

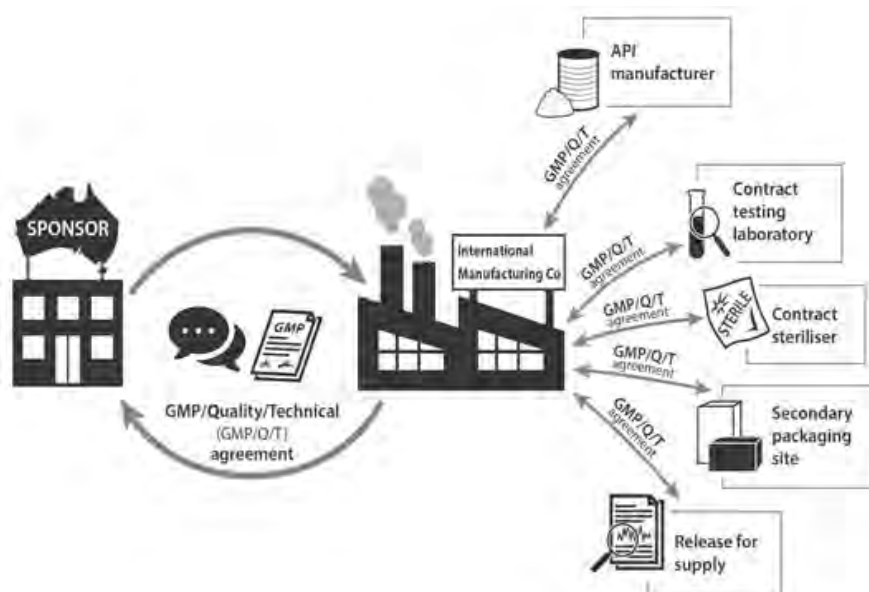
A typical global supply chain

The diagram below illustrates an example of a typical global supply chain and aims to clarify the GMP, quality or technical agreements that need to be in place for the supply of medicines to Australia.



This diagram does not cover every scenario and if you have questions in relation to GMP, quality or technical agreements please [contact us](#) prior to proceeding with your application.

The Australian Marketing Authorisation (MA) holder (the sponsor) has a direct relationship with the primary or principle manufacturer of the product. This relationship consists of a two way communication flow and signed GMP, quality or technical agreement. In addition, the primary manufacturer has a supply chain and contracted manufacturing sites, such as, the API supplier, contract testing lab, contract steriliser, contract secondary packager and contract Authorised Person (AP) performing release for supply.



Step 2 – Identifying the appropriate GMP clearance pathway

The country your manufacturer is located in and which regulatory authority inspected the site will determine which pathway is appropriate for obtaining your GMP clearance.

We have entered into various [international agreements and arrangements](#), some of which allow us to use the evidence from inspections conducted by overseas regulatory authorities as part of the GMP clearance process.

Mutual Recognition Agreements (MRA)

Use the MRA pathway if the manufacturer you are seeking GMP clearance for is located **within the borders** of a [MRA country](#), and has been inspected by that country's regulatory authority.

Compliance Verification (CV)

Use the CV pathway if the manufacturer you are seeking GMP clearance for does not meet the criteria for the MRA pathway and has been inspected by a regulatory authority that has an [agreement or arrangement with the TGA](#).

You can only use the **MRA** and **CV** pathways if the regulatory authority has **physically** inspected the manufacturer to a GMP standard equivalent to that used by the TGA.

🚫 We **do not** accept a regulatory authority's evidence as a result of their own desktop-based assessments.




In many cases, the MRA and CV pathways are **unavailable** because other countries have different regulatory frameworks and GMP standards. For example:

- **biologicals, human blood and blood components and Haematopoietic Progenitor Cells (HPCs)** as Australia has its own [manufacturing standard](#) for these product types. However, where the manufacturing site performs only sterilisation of these products, the MRA or CV pathways may be used
- some **complementary** and **listed medicines**, including **sunscreens**. These may not be regulated as medicines in other countries.

TGA on-site inspection

If the manufacturer produces one of the product types not available to the MRA or CV pathways, or if no acceptable evidence from a recognised regulatory authority is currently available, you may apply to obtain a GMP clearance through the TGA on-site inspection pathway.

 You cannot cancel a TGA on-site inspection by submitting a desktop assessment via the MRA or CV pathways if we have confirmed the inspection dates with the manufacturer and travel arrangements have commenced.



Important - The TGA has the right to inspect an overseas manufacturing site **regardless of what other evidence you supply**—for example, we may:

- have identified issues during the CV assessment
- have received other regulatory information or have concerns about the manufacturer's level of compliance
- be inspecting an adjacent facility.

If you were not using the manufacturer at the time the inspection was scheduled, you may still apply for a GMP clearance via a desk top process. Please refer to TGA certificates in the [Other types of evidence section](#).

Step 3 – Identifying what documentation is required

The documentation required to support your GMP clearance application depends on the pathway you select in [step 2](#) and the type of manufacturer you are seeking GMP clearance for.



Important - If you are unsure what evidence is required, please utilise the [GMP Clearance Application Assistance Tool \(CAAT\)](#) or [contact us](#) before submitting your application.

If your application scope is incorrect, or you do not submit the required or requested evidence, **you may not be issued** a GMP clearance and any fees you have paid **may be forfeited**.

GMP clearance is usually issued for manufacturers of:

- non-sterile APIs, for example:
 - non-sterile APIs manufactured by chemical synthesis
 - non-sterile APIs manufactured by 'classical' fermentation
- non-sterile finished products, for example:
 - tablets or oral liquids
- sterile or biotech APIs, for example:
 - APIs manufactured by biotechnology fermentation/cell culture/cell banking activities
 - APIs that are sterilised
- sterile or biotech finished products, for example:
 - injections or lyophilisates
 - recombinant products
- contract testing laboratories or contract sterilisers.



Consider whether:

- the substance or product in your GMP clearance application is for the purpose of registering a biological medicine
- the processes used to manufacture your product are considered to be biotechnology processes

This could impact your GMP clearance processing times and the documentation required to be submitted.

MRA pathway documentation

If you are using the MRA pathway, the following documentation needs to be provided as evidence for each manufacturer type. Select the evidence in the table to see further information on the requirements.

MRA pathway	Non-Sterile API	Non-Sterile Finished Product	Sterile or Biotech API	Sterile or Biotech Finished Product	Contract Testing Lab or Steriliser
GMP Certificate	✓	✓	✓	✓	✓

CV pathway documentation

If you are using the CV pathway, the following documentation needs to be provided for each manufacturer type. Select each piece of evidence in the table to see further information on the requirements.

CV pathway	Non-Sterile API	Non-Sterile Finished Product	Sterile or Biotech API	Sterile or Biotech Finished Product	Contract Testing Lab or Steriliser
GMP Certificate	✓	✓	✓	✓	✓
Most recent inspection report	✓	✓	✓	✓	✓
Regulatory inspections list	✓	✓	✓	✓	✓
Regulatory action details	✓	✓	✓	✓	✓
Site Master File (SMF), quality manual or equivalent	✓	✓	✓	✓	✓
List of products intended for supply	✓	✓	✓	✓	✗
GMP agreement or equivalent	⚠	✓	⚠	✓	✓
Release procedure(s)	⚠	✓	⚠	✓	✗
Validation Master Plan (VMP)	⚠	⚠	✓	✓	⚠
Latest Product Quality Review (PQR)	⚠	⚠	✓	✓	✗
List of authorised tests	✗	✗	✗	✗	✓

✓ = Required

✗ = Not Required

⚠ = Not required unless requested



[Other types of evidence](#) that are not listed in the tables above may be provided as an alternative to, or to supplement the required evidence for both the **MRA and CV pathways**. For example, a [Letter of Access \(LoA\)](#) or an [API declaration](#).

To avoid unnecessary delays with your application, these should be provided upfront when lodging an application where applicable. Please refer to [step 6 - Providing your evidence](#).

Important – We may request **any additional documentation** or clarification during the GMP clearance assessment process.

General documentary requirements

Any document you provide as evidence in support of a GMP clearance application must be:

- an accurate and complete copy of the original document. As the applicant, you are responsible for the authenticity of documents supplied. Heavily redacted or altered documents will not be accepted
- in English, or accompanied by an English translation by an **independent certified translator** that states it is a true and accurate translation of the original
- the most current and effective version of that document. Draft, expired or superseded documents are not acceptable.

Additionally, to avoid unnecessary delays, any ambiguity or discrepancies in the documentation provided must be clarified upfront via a cover letter submitted with the application.



We may request certified copies of submitted documents **at any time** during the GMP clearance assessment process.

If **any** evidence is to be provided directly by the manufacturer, it is the [Australian sponsor's responsibility](#) to ensure that they meet the requirements of that evidence as detailed below.

GMP certificates

Why we require it

A GMP certificate from an overseas regulatory authority, issued after an on-site inspection was performed, is required because it demonstrates the manufacturer's compliance with the applicable GMP standard.

What you should provide

Provide a copy of the original GMP certificate or EudraGMDP certificate, if available, with your application. Ensure that the:

- certificate is complete, is from a recognised regulatory authority and corresponds to the inspection report provided (where applicable)

- manufacturer's name and site address are correct
- certificate is current—that is, the site was inspected not more than three years ago
- scope of the certificate covers the scope of the application—that is, the sterility, dosage form, and steps of manufacture etc.
- conditions and/or clarifying remarks on the certificate are understood, because these will be applied to the GMP clearance where applicable.

Take particular care

Ensure that the certificate has:

- not been issued as a result of a desk top assessment by an overseas regulator
- not been redacted in any way. Redacted certificates will not be accepted
- been issued for human medicinal products



Veterinary or investigational medicinal product certificates are **not acceptable** to support a GMP clearance to register or list a product on the [ARTG](#).

Alternative evidence (for MRA pathway only)

We **may** accept a Good Laboratory Practice (GLP) or International Standards Organisation (ISO) certificate in lieu of a GMP certificate for some contract laboratories or sterilisers for the MRA pathway.

- GLP certificates for contract laboratories will only be accepted if they are accredited to ISO 17025 (General requirements for the competence of testing and calibration laboratories), relevant to the scope of the application
- ISO certificates for contract sterilisers will only be accepted if they are issued to the specific site and accredited to the relevant sterilisation accreditation—for example, ISO 11137 (Sterilisation of healthcare products – Radiation).



Important - Not all regulatory authorities routinely issue GMP certificates as part of their regulatory framework. For example:

- **Health Canada** issues an inspection 'Exit Notice' or 'certificate of GMP compliance', which is acceptable in lieu of a GMP certificate
- **Singapore Health Sciences Authority (HSA)** issues a 'Letter to attest GMP compliance of a manufacturer', which is acceptable in lieu of a GMP certificate.

Liaison

You may request the TGA to obtain a GMP certificate or equivalent on your behalf for applications made via the MRA or CV pathways. There are some instances where this is a mandatory requirement for the CV pathway.

MRA pathway

If you are unable to obtain the GMP certificate issued by a regulatory authority within an MRA country, you may request that we attempt to obtain it. Please note:

- you will be charged an additional [fee](#) for this service
- we can **only** attempt to liaise for GMP certificates. We **do not** liaise for GLP or ISO certificates
- the evidence may not be available from the regulatory authority for reasons beyond our control. In such cases you will be notified by email and your GMP clearance will **not be issued**.

CV pathway

Where you have provided US FDA evidence to be assessed, we are required to perform a check of the US FDA's compliance status (COMSTAT) database. Please note:

- you will be charged an additional [fee](#) for this service
- as this is a real-time check of the site's compliance status, it is required **for every variation or renewal** of your GMP clearance where USFDA evidence is used, irrespective of the duration between applications.

Most recent inspection report

Why we require it

The most recent inspection report issued after a successful **on-site inspection** is required because it provides detail about the overseas regulatory authority's inspection activities including, but not limited to, which buildings, systems, processes and products were covered during the inspection.

What you should provide

Provide the most recent inspection report. Ensure that the:

- report is from an on-site inspection performed by a [recognised regulatory authority](#) and corresponds to the GMP certificate provided (where applicable)
- manufacturer's name and site address are correct
- report is current—that is, it is not more than three years since the last inspection
- scope of the inspection report covers the scope of your application—that is, the sterility, dosage form, API, steps of manufacture and buildings covered etc.
- inspection was conducted to the equivalent GMP standard, for example, the relevant USFDA compliance program
- time taken to inspect and the size of the inspection team is clearly recorded in the report
- inspection report provided, if from a PIC/S participating authority, aligns to the [standard operating procedure PIC/S inspection report format](#).

Take particular care

Ensure that the:

- inspection report contains sufficient information and detail regarding the inspection activities performed



Insufficient information or lack of detail in the report may be insufficient to issue a GMP clearance.

- inspection report is sufficiently un-redacted so that an assessment can be conducted. Excessively redacted inspection reports will not be accepted
- inspection covered the specific buildings, systems, processes, API or products applicable to the scope of your application
- full inspection report is provided. Inspection cover letters, Post Inspection Letters (PIL), close out letters, observation or deficiency lists etc. are not acceptable.

Regulatory inspections list

Why we require it

The regulatory inspections list is required because it provides information on the compliance history of the site including the frequency and outcomes of past inspections performed by local and/or international regulatory authorities.

What you should provide

Provide a list of inspections performed at the manufacturing site. Ensure you include:

- all on-site inspections conducted within the three years prior to the application submission
- the name of the inspecting authority and the dates, scope and outcomes of the inspections. For example, the observation of critical deficiencies should be specified.

Take particular care

Ensure that the:

- evidence provided is from the manufacturer
- inspections list does not contradict other evidence provided with the application.

Regulatory action details

Why we require it

The regulatory action details are required because they provide additional information about the manufacturer's compliance history, particularly in relation to product alerts, warning letters, import alerts or recalls due to defects applicable to the site.

What you should provide

Provide details of any regulatory actions taken by or against the manufacturing site. Ensure that:

- the details are current and account for three years prior to the date of submission
- where applicable, provide further details about the action or event that occurred. This should include information about the subsequent investigation and root cause analysis conducted, and any resulting corrective or preventative actions that were implemented.

Take particular care

Ensure that the:

- evidence provided is from the manufacturer
- regulatory action details include any actions relating to the entire manufacturing site, not just specific products or dosage forms included in your application.

Alternative evidence

If there have been no product alerts, warning letters, import alerts or recalls due to defects within the past three years for the manufacturing site, provide a declaration from the manufacturer stating this on their company letter head.

Site master file, quality manual or equivalent

Why we require it

The Site Master File (SMF) or equivalent document is required because it provides information about the manufacturer's operations, facilities and quality management system.

What you should provide

Provide the **complete** SMF or equivalent. Ensure that the:

- manufacturer's name and site address are correct
- SMF contains the required information as per the [PIC/S explanatory notes for pharmaceutical manufacturers](#) (if applicable)
- complete document **including all appendices** are provided for assessment. Appendices (including facility drawings) must be legible.

Take particular care

Ensure the SMF contains information regarding cross contamination controls for high-risk or highly sensitising products (if applicable).

Alternative evidence

Depending on the scope of your application, you may instead provide other documents, such as a plant/equipment file or a quality/laboratory manual, which individually or collectively provide the same details.

List of products intended for supply

Why we require it

The list of the sponsor's products is required because it provides additional information about the substances or products intended for supply in Australia.

What you should provide

Provide the product list and ensure that:

- the substances or dosage forms are reflected in the scope of the application
- the AUSTR/AUSTL numbers are provided where relevant.

Take particular care

Ensure that the list of substances or products does not contradict other evidence provided with the application.



For API applications, a separate product list may not be required if the name of the substance has been entered in the application e-form and corresponds to the Australian Approved Name (AAN) in the [ingredients database](#), where applicable.

GMP agreement or equivalent

Why we require it

GMP, quality or technical agreements are required because they provide information about the roles and responsibilities of each party in relation to the critical aspects of GMP and any specific technical aspects related to the product's manufacture. It also provides further information as to the roles and responsibilities of the Australian Marketing Authorisation (MA) holder (the sponsor) in relation to the product's manufacture **and** the relevant post market surveillance obligations.

What you should provide

Provide the **signed** GMP, quality or technical agreement relevant for the scope of your application. Ensure that it:

- meets the full requirements of chapter 7 of the [PIC/S guide to good manufacturing practice for medicinal products – Part I](#).

Take particular care

Ensure that the GMP, quality or technical agreement:

- clearly identifies the products, steps of manufacture (activities) and manufacturing site (where there are multiple sites contained in the one agreement) relevant to the scope of your GMP clearance application
- clearly describes the role of each party subject to the agreement, particularly the communication processes agreed upon
- has been signed by all parties to the agreement.

Additional entities and alternative evidence

Recognising there may be multiple entities involved in the pharmaceutical supply chains, and depending on the timing and scope of your application or the relationship you have with each entity, you may provide:

- For new registrations or New Chemical Entity (NCE) submissions, we will accept a draft GMP, quality or technical agreement between the manufacturer and the sponsor that demonstrates the intended roles and responsibilities will be appropriate along with a declaration/statement from the Australian sponsor that the agreement will be signed by all relevant parties prior to commencing commercial supply to Australia.



A condition will be placed on your GMP clearance to reflect this and the expiry date may be reduced. Your GMP clearance may be cancelled if it is determined that the condition has not been adhered to.

- For contract labs, sterilisers, packagers and/or authorised persons performing release for supply, provide the **signed** GMP, quality or technical agreement between the principal manufacturer and the subcontractor or multiple documents that comprise the same.
- For subsidiaries of the same parent company (either the manufacturer's or sponsor's), provide the equivalent **signed** documentation that clearly outlines the roles and responsibilities of the Australian MA holder (Sponsor) and other entities in the supply chain (i.e. Global Head Quarters). Particular attention should be paid to provide the information as required by PIC/S chapter 7.



- When using a distributor or other intermediary, provide the relevant **signed** GMP, quality or technical agreements you have in place with them **in addition** to the signed agreement they have in place with the manufacturer. Both documents, when assessed together, should provide clear roles and responsibilities between all the entities in the supply chain for Australia.



- For generic medicines, when sourcing product from another Sponsor, provide the **signed** GMP, quality or technical agreement you have in place with them **in addition** to the signed agreement they have in place with the manufacturer. Again both documents, when assessed together, should provide clear roles and responsibilities between all the entities in the supply chain for Australia.



To avoid unnecessary delays with your application, all relevant agreements or documentation should be provided upfront when lodging an application.

Additionally, any ambiguity in terminology or responsibilities should also be clarified upfront via a cover letter. This should include reference to any commercial considerations that may prevent the provision of the required evidence.

Release procedure(s)

Why we require it

The release procedure is required because it provides information about how the authorised person at the site performs the [release for supply \(RFS\)](#) or release for further processing (RFFP) (if applicable) step of manufacture.

We do not routinely require RFFP procedures to be provided however these may be requested.

Guidance is available regarding release for supply of medicines and for releasing medicines that are manufactured across multiple sites:

- [Release for supply of medicines](#)
- [Releasing medicines manufactured at multiple sites](#)

What you should provide

Provide the release for supply procedure(s). Ensure that:

- the procedure is applicable to the product types and dosage forms in your application
- sufficient information about **how** the RFS authorised person ensures each batch has been manufactured and checked for compliance with the relevant Marketing Authorisation (MA) is provided
- all relevant appendices to the procedure are provided—for example, batch release checklists.

Take particular care

Ensure the procedure describes in detail how the RFS process operates, for example, the process for reviewing critical records and verifying compliance with GMP and the MA.

Validation master plan

Why we require it

The Validation Master Plan (VMP) is required as it provides further information about the validation and qualification activities of the manufacturing site and its operations. We need to know that the components and processes used for manufacture of the medicines and APIs are appropriately qualified and validated and have a suitable re-validation schedule.

What you should provide

Provide the VMP and ensure that it meets the requirements outlined in [Annex 15, of the PIC/S Guide to GMP for Medicinal Products](#).

Take particular care

Ensure the VMP:

- includes the relevant equipment and processes applicable to the products intended to be supplied to Australia
- provides a reference to the existing specific equipment or process validation documentation and a re-validation schedule.

Latest Product Quality Review

Why we require it

The Product Quality Review (PQR) is required because it provides information on how effective and consistent the existing manufacturing process of a product is. It also provides information on variations to marketing authorisations and market complaints.

What you should provide

Provide a copy of the most recent PQR of the product you are supplying or intend to supply to Australia. Ensure that:

- the contents meet the requirements outlined in [Chapter One, of the PIC/S Guide to GMP for Medicinal Products](#)
- where the GMP clearance application is for multiple products/dosage forms, provide the most recent PQR available. Please note that additional PQR's may be requested if required.

Take particular care

Ensure that:

- the PQR is complete and does not contradict other evidence in the application.

Alternative evidence

Where the substance or product has not yet been subject to a product quality review, you should state this fact and provide the PQR procedure.

List of authorised tests (for contract testing labs only)

Why we require it

A list of authorised tests is required because it provides further information on the testing capabilities of a contract testing laboratory applicable to the scope of the application.

What you should provide

Provide an accurate list of tests performed by the testing laboratory. Ensure that the information does not contradict any other evidence provided with the application.

For botanical ingredients, provide evidence that authenticated standard reference materials are used.

Take particular care

The list of tests should match your application and the name of test references should clearly indicate the nature and type of testing performed.

Other types of evidence

API declaration

When we require it

An API declaration is required for the MRA or CV pathway when the substances in your application were not specifically covered as part of the most recent inspection provided as evidence. It provides assurance from the manufacturer that the specific APIs in your application are:

- manufactured in the same facility (**specific buildings**) as those inspected and referenced in the inspection report or GMP certificate
- using a similar manufacturing process as those inspected (for example, chemical synthesis)

AND

- controlled under the same Quality Management System (QMS) or Pharmaceutical Quality System (PQS) as those inspected and referenced in the inspection report.

What you should provide

Provide a signed and dated declaration. Ensure that the declaration:

- is provided by the manufacturer on a company letterhead
- has been authorised by an officer of that manufacturer at the senior management level

- confirms that the API(s) listed in the declaration and corresponding GMP clearance application are manufactured:
 - in the same facility (**specific buildings**) as those covered by and referenced in the inspection report provided as evidence
 - using a **similar** manufacturing process (for example, chemical synthesis) as those covered by and referenced in the inspection report provided as evidence

AND

- controlled under the **same** QMS or PQS as those covered by and referenced in the inspection report provided as evidence
- contains details of starting materials for the API(s) and confirmation that all steps of manufacture for each API are carried out in the nominated facility. If any steps of manufacture are carried out at another site or company, details should be provided
- contains details of whether any previous inspection by any other recognised regulatory authorities have covered the API(s) included in the GMP clearance application. If so, a copy of that inspection report should also be provided.

Take particular care

Ensure that the:

- GMP clearance application number is clearly referenced
- declaration does not contradict other evidence provided with the application.



API declarations may not be used in conjunction with a LoA to clearance as these applications are reliant on the original clearance in all aspects including scope.

Letters of access

Each sponsor must obtain their own GMP clearance for a particular manufacturing site for their own specific product registration or listing. However, in an effort to reduce the regulatory burden on industry, you may provide us with a Letter of Access (LoA) obtained from another sponsor or manufacturer, which allows us to access information and/or evidence previously submitted.

There are three types of LoA which can be used for both the MRA and CV pathways:

- **A manufacturer LoA to evidence** grants a sponsor permission to use evidence that has been previously submitted by the manufacturer for another GMP clearance application
- **A sponsor LoA to evidence** grants a sponsor permission to use evidence that has been previously submitted by another sponsor for another GMP clearance application
- **A sponsor LoA to clearance** grants a sponsor permission to use an existing GMP clearance as the primary evidence to allow an additional clearance to be issued on the condition that the scope of the application is identical or smaller. Applications using a LoA to clearance are reliant on the original clearance in all aspects including scope, processing times, determinations made and expiry.



While the use of LoA is intended to reduce the regulatory burden on industry, for the CV Pathway, certain sponsor-specific evidence is still required to be provided (where applicable) along with the relevant [fees](#). These include:

- [GMP, quality or technical agreements](#) between the **sponsor and manufacturer**
- a [list of products intended for supply](#) (specific to the application)
- the [latest product quality review](#) (specific to the products in the application)
- an [API declaration](#).

To avoid unnecessary delays with your application, these should be provided upfront when lodging an application.

For both the MRA and CV pathways, ensure that:

- only **one** LoA is provided per application
- the application it allows access to was **not** issued using another LoA
- the LoA is provided on a company letterhead
- the LoA is signed and dated by the sponsor or manufacturer that is providing it
- it clearly states the **type** of LoA (for example, whether it's for access to **evidence** or **clearance**) and to whom the access is being provided to
- it clearly references the GMP clearance number of the existing application.

TGA certificates

TGA certificates issued as a result of a successful on-site inspection may be provided as evidence to obtain a GMP clearance if you were not using this manufacturer at the time the inspection was scheduled.

If you provide a TGA certificate as evidence, you will still be required to provide the following sponsor specific evidence (where applicable):

- [GMP, quality or technical agreements](#) between the **sponsor and manufacturer**
- a [list of products intended for supply](#) (specific to the application)
- the [latest product quality review](#) (specific to the products in the application)
- an [API declaration](#).



U We will not accept a TGA issued certificate as evidence for a GMP clearance application if you have declined to contribute to the cost of the inspection without justification.

Additionally, you will be expected to contribute to the cost of the next on-site inspection.

Step 4 – Creating your application

Accessing TGA Business Services

You need to be a TGA client to access TGA Business Services in order to submit an application. Only Australian sponsors or agents acting on behalf of an Australian sponsor can submit GMP clearance applications.

Direct any queries related to TGA Business Services to ebs@health.gov.au.

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

Creating a new application

1. Go to [TGA Business Services](#).
2. To limit issues with functionality, distortion or performance, check that the internet browser you are using is compatible with the TGA Business Services system by selecting '**Browser Support**' and following the provided guidance.

Therapeutic Goods Administration | Copyright | Privacy | Disclaimer | Security | **Browser Support** | www.australia.gov.au |
For further information contact the [eBS Help Lines](#), ebs@health.gov.au



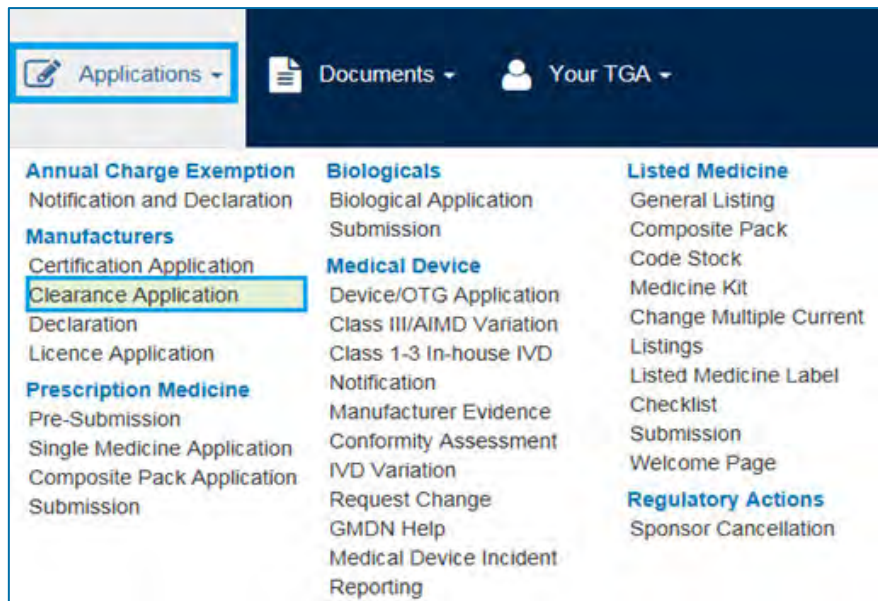
Make sure that your browser allows pop-up windows, or you will be unable to see the dialog boxes and complete the form.

3. Select 'Log in to Business Services'.



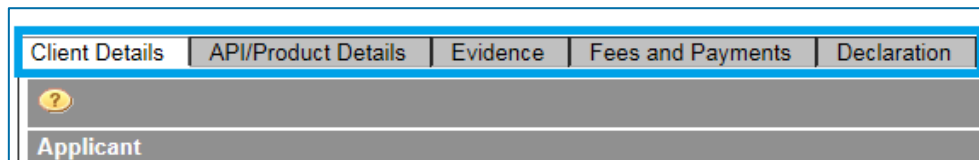
Before you create your GMP Clearance application, ensure you have read the required information contained in this guidance and have utilised the [GMP Clearance Application Assistance Tool \(CAAT\)](#).

- On the homepage, select 'Applications' and from the dropdown menu under the 'Manufacturers' heading, select 'Clearance Application'.




You will be taken to the 'Clearance Application' page which contains the application details section with the following tabs:

- Client Details
- API/Product Details
- Evidence
- Fees and payments
- Declaration



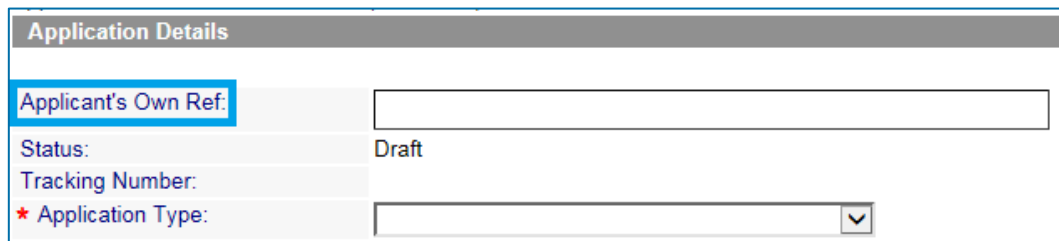
Throughout the e-form tabs, there are **mandatory fields** notated by a red asterisk * that needs to be completed in order to progress your application.

There are also **help icons** notated by a yellow question mark  available to assist you in preparing and submitting the application.

You will be requested to save your progress at various stages prior to continuing.

Completing Application Details

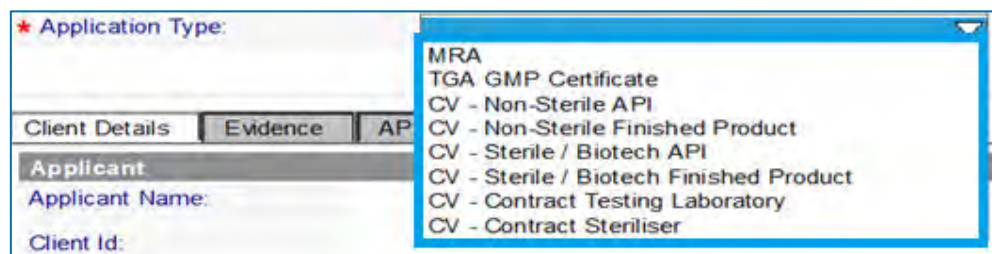
5. Under 'Application Details', you may wish to include your own reference description in the 'Applicant's Own Ref' text box to assist you in identifying your GMP clearance applications. This is a free text field.



The screenshot shows a form titled 'Application Details'. It contains several fields: 'Applicant's Own Ref' (a text input field, highlighted with a blue border), 'Status' (set to 'Draft'), 'Tracking Number' (a text input field), and '* Application Type' (a dropdown menu with a downward arrow).

6. Select the 'Application Type' from the drop down list:

- MRA
- TGA GMP Certificate
- CV – Non-Sterile API
- CV – Non-Sterile Finished Product
- CV – Sterile / Biotech API
- CV – Sterile / Biotech Finished Product
- CV – Contract Testing Laboratory
- CV – Contract Steriliser



The screenshot shows the 'Application Type' dropdown menu open. The list of options is: MRA, TGA GMP Certificate, CV - Non-Sterile API, CV - Non-Sterile Finished Product, CV - Sterile / Biotech API, CV - Sterile / Biotech Finished Product, CV - Contract Testing Laboratory, and CV - Contract Steriliser. The dropdown is highlighted with a blue border.

This selection will determine the subsequent information required for the application.

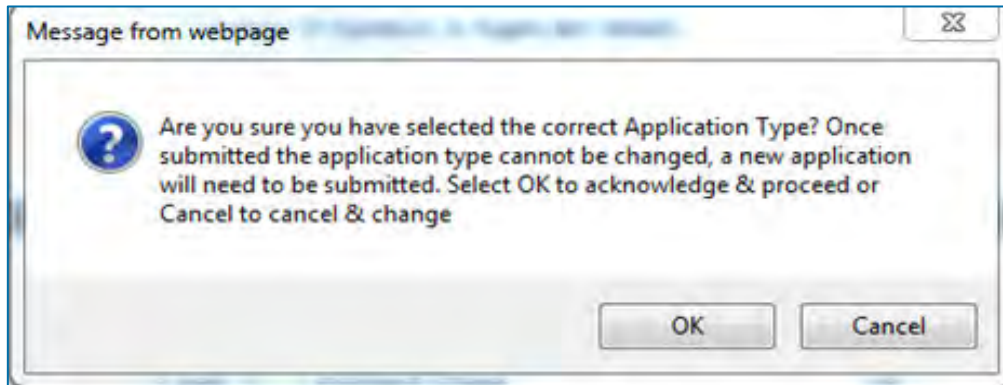


Important – It is crucial you select the correct application type to avoid unnecessary delays with your application. We use the information you enter to assist us in processing your applications and an incorrect selection here may impact your application.

Additionally, once the application is submitted, the application type **cannot be changed**. A new application may be required if an incorrect selection is made.

We urge all applicants to refer to [step 2](#) and [step 3](#) in this guidance and utilise the [GMP Clearance Application Assistance Tool \(CAAT\)](#) for assistance in identifying your application type **prior to submitting** a GMP clearance application.

7. Once you have selected the application type from the drop down list, you will be asked to confirm your selection. Select '**OK**' to proceed or select '**Cancel**' to go back and change the application type.



Completing Client Details tab

In the client details tab, whether you are a sponsor or an agent acting on behalf of a sponsor will determine the required information to be entered.

Some applicant and sponsor information will be pre-populated based on the Client ID you have logged in with. This information is based on the registered client details held by TGA.



If you wish to amend (add or remove) contacts, ask your organisation's nominated TGA Business Services administrator to update these details.

Refer to [TGA Business Services – Questions and answers for administrators](#) or contact ebs@health.gov.au for assistance.

Sponsor

8. If you are the sponsor, you will need to select the address from the drop down menu in both the applicant and sponsor sections and proceed to [instruction 12](#).

Agent acting on behalf of a sponsor

9. If you are an agent lodging an application on behalf of a sponsor, you will need to choose who will be invoiced using the radio buttons.
- Select '**Applicant**' if you (the agent) is to be invoiced for the GMP clearance
 - Select '**Sponsor**' if the sponsor is to be invoiced for the GMP clearance

10. You will then need to choose who should be contacted if we need further information in relation to this GMP clearance using the radio buttons.
- Select '**Applicant**' if you (the agent) is to be contacted about the GMP clearance
 - Select '**Sponsor**' if the sponsor is to be contacted about the GMP clearance

The screenshot shows a form titled 'Contact Details'. At the top, there is a section 'Who to contact for further information' with two radio buttons: 'Applicant' and 'Sponsor'. The 'Sponsor' radio button is selected. Below this are several input fields: 'Contact Name' (with a dropdown arrow), 'Phone', 'Mobile', 'Email', and 'Fax'.

11. Select the '**Contact Name**' from the drop down list. The subsequent mandatory information will automatically populate based on the selection made.

The screenshot shows the 'Contact Details' form with the 'Contact Name' dropdown menu open. The dropdown list is highlighted in blue. Below the dropdown are fields for 'Phone', 'Mobile', 'Email', and 'Fax'.

Note: If the contact is not displayed on the drop down list, your company's TGA Business Services administrator can update these details. Refer to [TGA Business Services – Questions and answers for administrators](#) or contact ebs@health.gov.au for assistance.

Selecting the manufacturer name and manufacturing site address

12. Select '**Search**' to open the manufacturer information system's search dialog box.

The screenshot shows a dialog box titled 'Existing Manufacturer'. It has a search bar with a 'Search' button, a 'New Manufacturer' button, and a 'Manufacturer ID' field.



Important – Ensure you have thoroughly searched the TGA database for the manufacturer's name and address **before** you select New Manufacturer. Duplicate entries created can result in extended delays to application processing times and may require significant updates to your ARTG entry.

If you are unsure whether the manufacturer you intend to use is available in the TGA database, please [contact us](#) **prior** to proceeding with your application.

13. In the search box, enter a search string by typing the name of the manufacturer you wish to obtain GMP clearance for and select **'Search'**.

14. 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'**.

15. If the manufacturer selected has only one manufacturing site registered with the TGA, the existing manufacturing site information will automatically populate. Alternatively select the **'Manufacturing Site'** from the drop down menu.

16. If your manufacturer and manufacturing site are already registered with the TGA, proceed to [step 5 - Selecting your scope](#).



If the manufacturer name or the manufacturing site required is **not** already registered with the TGA you will have to register the manufacturing site **prior** to proceeding with the application.

17. If you need to request a new manufacturer and/or manufacturing site, save your application, then select **'New Manufacturer'**.



Important – Ensure you have thoroughly searched the TGA database for the manufacturer's name and address **before** you select New Manufacturer. Duplicate entries created can result in extended delays to application processing times and may require significant updates to your ARTG entry.

If you are unsure whether the manufacturer you intend to use is available in the TGA database, please [contact us](#) **prior** to proceeding with your application.

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

Once TGA Business Services have registered the manufacturer or 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.

Step 5 – Selecting your scope

Selecting the correct scope of your application is one of the key steps in submitting GMP clearance applications. Incorrect selections here may lead to issues with your product registration or listing activities.

Information on dosage forms and manufacturing steps is available in the TGA code tables ([TGA Business Services](#) > Public TGA Information > [Code Tables](#)).



Ensure you have read the relevant information contained within this guidance regarding [what steps of manufacture require GMP clearance](#).

If you are unsure whether manufacturing step(s) require GMP clearance or aligns with the registration or listing requirements, please [contact the relevant product regulatory area](#) prior to submitting the application.

Ensure the dosage forms and manufacturing steps you select are supported by the evidence to be provided with the application and align with the details related to the product registration or listing.

If the selections you made result in validation issues with the regulatory submission system, you may be required to submit a [variation application](#) and pay the relevant [fees](#).

Completing API/Product Details tab

In the API/Product Details tab, whether you select '[API](#)' or '[Product](#)' will determine the required information to be entered. Once chosen, you will then need to enter the name of the specific substance or dosage forms along with the required steps of manufacture performed at the manufacturing site.



You will need to submit **separate applications** for API and finished product, even if the same evidence is applicable to both.

19. Select if the application scope is for '[API](#)' or '[Product](#)' by selecting the radio button.

API scope

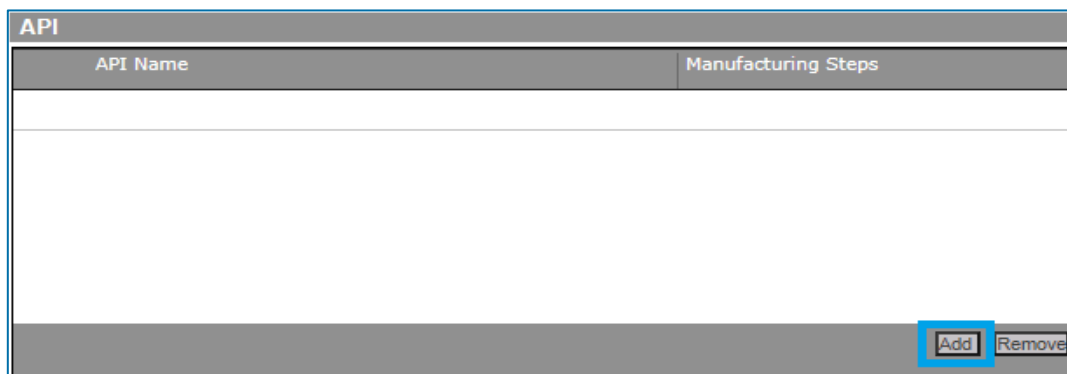
20. If the application is for API, select 'API' and then select the type of APIs you intend to obtain GMP clearance for.
- Select '**Sterile/Biotech**' if all the APIs in your application are sterile or biotech substances
 - Select '**Non-Sterile**' if all the APIs in your application are non-sterile substances
 - Select '**Sterile/Biotech & Non-Sterile**' if the APIs in your application are a combination of both types of substances



API Product

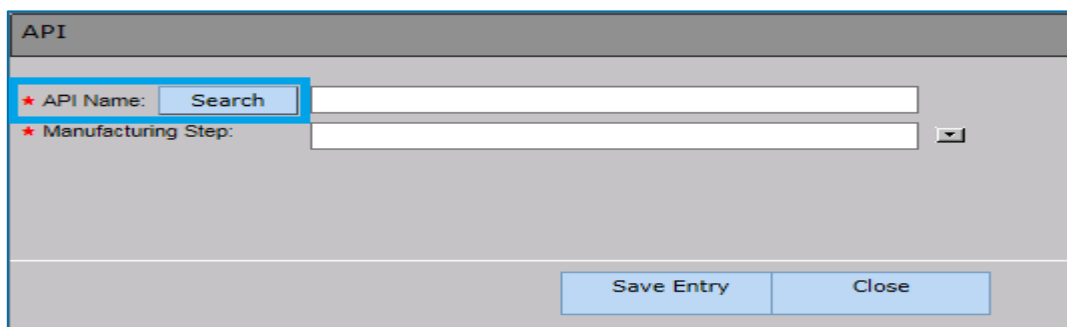
 Sterile/Biotech Non-Sterile Sterile/Biotech & Non-Sterile

21. Select 'Add'.



API Name	Manufacturing Steps

22. You cannot enter the ingredient name directly. Instead, select 'Search' to open a search box of the ingredients database.

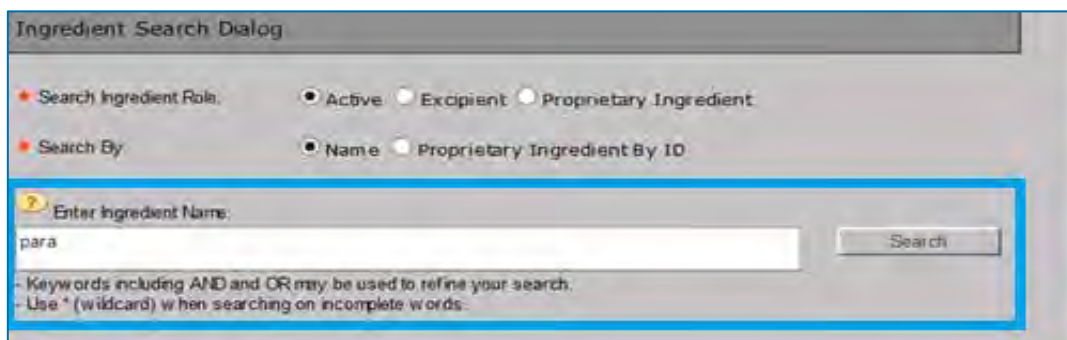


API

★ API Name:

★ Manufacturing Step: ▼

23. Enter the name or partial name of the substance in the Ingredient Search Dialog box and select 'Search'.



Ingredient Search Dialog

★ Search Ingredient Role: Active Excipient Proprietary Ingredient

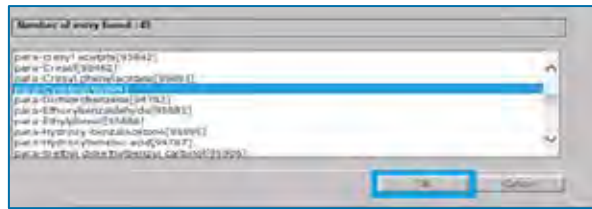
★ Search By: Name Proprietary Ingredient By ID

? Enter Ingredient Name:

para

- Keywords including AND and OR may be used to refine your search.
 - Use * (wildcard) when searching on incomplete words.

24. If the ingredient name is already registered with the TGA, it will appear in the list for selection. Click on the required ingredient and select 'OK'.



If the required APIs are already registered with the TGA, proceed to instruction 26.



If any of the API names are **not** already registered with the TGA and your search returns zero results, information about how to register an ingredient name will be displayed and you will have to manually enter the name of the API to proceed with the GMP Clearance application (instruction 25).

For cell bank manufacturing activities, the name of specific cell lines are not required to be entered in your application and the API name may be entered manually as 'cell bank'.

25. Enter the name of the API in the field labelled 'Enter New Ingredient Name' and select 'OK'.

26. Select the appropriate 'Manufacturing Step' from the drop down menu and click save entry.

To see the entire list of possible manufacturing steps, go to the 'Manufacturing Steps' code table ([TGA Business Services](#) > Public TGA Information > [Code Tables](#)).

27. Repeat instructions 20-26 as required to continue adding APIs and/or manufacturing steps to your application.

Finished Product Scope

28. If the application is for finished product, select 'Product' and then select 'Add'.

29. In the dialog box, make the required selections from the drop down menu for the following manufacturing items:

- **Manufacturing Type** – Generally the selection here would be Medicine Manufacturer or Testing Laboratory
- **Sterility** – Select the sterility of the product
- **Manufacturing Class** – Select either multiple or single manufacturing steps or products
- **Dosage Form** – Ensure when selecting group terms, all the dosage forms contained within the group are supported by the evidence you submit. To see the entire list of possible dosage forms, go to the 'Dosage Form Group' [Code Tables](#).
- **Product Code** – Generally the selection here would be Listed or Registered Therapeutic Good
- **Manufacturing step** - Ensure when selecting group terms, all steps of manufacture contained within the group are supported by the evidence you submit. To see the entire list of possible manufacturing steps, go to the 'Manufacturing Steps' code table [Code Tables](#).

30. Once you have chosen from every drop down menu, select '**Save Item**'.

31. Repeat instructions 27 - 30 to continue adding dosage forms or manufacturing steps to your application.

Step 6 – Providing your evidence

In the Evidence tab, you need to answer some questions about the GMP clearance prior to providing the required evidence. The information you provide will assist us in processing your applications efficiently.

32. Inform us if the GMP clearance application is related to a submission to list or register a product or vary an existing ARTG entry.
- Selecting 'Yes' will require you to choose the submission type from the drop down menu (mandatory) and submission number (if known)

33. Choose whether the application is for the [Compliance Verification pathway](#).

- Selecting 'Yes' will raise the [Compliance Verification fee](#)
- Selecting 'No' will not raise the fee

If you are unsure whether the CV fee should apply, refer to the fee table in [How much GMP clearance costs](#).



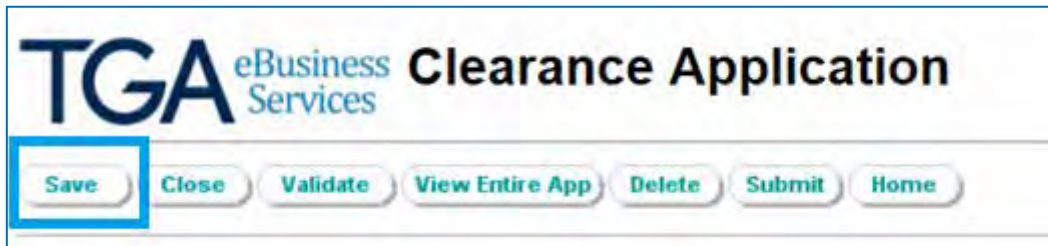
Ensure your selection aligns with the application type selected in [instruction 5 - Completing Application Details](#).

If you have selected 'No' and during [application receipt](#) your application is determined to be a CV, we will raise the fee and your application will not progress until payment is received.

34. Choose whether you intend to use a [Letter of Access \(LoA\)](#) to Clearance or Evidence as part of your evidence. If you select yes then you will need to provide the GMP clearance number in [instruction 43](#) or [instruction 44](#).

Choosing your evidence and delivery method

35. Save your application before proceeding.



You will be required to select a delivery method for each piece of evidence you provide.

Based on the [Application Type](#) selected, this section will display:

- For MRA – [Mandatory Certificate or Letters](#) and [Optional Evidence](#)
- For CV – Mandatory Certificate or Letters, [Mandatory Evidence](#) and Optional Evidence



Ensure you have read the relevant information contained within this guidance regarding [identifying the appropriate GMP clearance pathway](#) and [identifying what documentation is required](#) prior to proceeding.

Mandatory certificates or letters

36. In the mandatory certificates or letters section, select whether you intend to provide a current GMP certificate or a Letter of Access (to clearance or evidence).

 A screenshot of the 'Mandatory Certificates or Letters' section in the application. The title 'Mandatory Certificates or Letters:' is at the top. Below it, there is a dropdown menu with a red asterisk to its left. The dropdown is open, showing three options: '1 Current GMP Certificate', '18 Letter of Access to Clearance', and '19 Letter of Access to Evidence'. To the right of this dropdown is another dropdown menu labeled 'Select delivery method' with a downward arrow.


Letters of Access - If you choose to use a letter of access, you must upload the letter here **and** select the equivalent [delivery method](#) in the [mandatory evidence section](#) for the evidence to be covered by the LoA.

USFDA evidence - If you are using USFDA evidence, you **must** select [TGA to obtain GMP certificate](#) as your delivery method. **Do not** provide the cover letter from the USFDA EIR.

37. Select the required delivery method from the drop down menu.

 A screenshot of the 'Mandatory Certificates or Letters' section. The title 'Mandatory Certificates or Letters:' is at the top. Below it, there is a dropdown menu with a red asterisk to its left. The dropdown is open, showing '1 Current GMP Certificate' as the selected option. To the right of this dropdown is another dropdown menu labeled 'Select delivery method'. This dropdown is also open, showing several options: 'TGA to obtain GMP Certificate', 'Upload Evidence Manufacturer to Provide', 'LOA to Clearance', 'LOA to Evidence', and 'Submit Paper Copy'.

Delivery methods

There are multiple delivery methods available depending on each type of evidence. Additional information specific to the delivery method chosen will be required once selected. These are:

- [TGA to obtain GMP certificate](#)
- [Manufacturer to provide](#)
- [Submit paper copy](#)
- [Upload evidence](#)
- [LoA to clearance](#)
- [LoA to evidence](#)

TGA to obtain GMP certificate


38. If you have selected this delivery method, in the resulting dialog box select:

- the regulatory authority the TGA are to [liaise](#) with from the drop down menu
- the inspection date of the GMP Certificate required

TGA to obtain GMP Certificate

Please note, by choosing this option a fee for obtaining evidence from an overseas regulatory authority will be charged

* Select who TGA to liaise with:

* Enter the Last Inspection Date:  dd/mm/yyyy



For MRA applications, we can only liaise for GMP certificates with regulatory authorities with whom we have a [MRA](#) or equivalent agreement with.

For CV applications, if you are submitting evidence from a US FDA inspection you **must** select [TGA to obtain GMP certificate](#) to ask TGA to confirm the current GMP compliance status from the US FDA COMSTAT database.

You may receive alerts if the inspection date is ≥ 3 years identifying that the GMP clearance may:

- result in a short expiry date (if issued)

OR

- not be issued if the evidence is > 3years from date of inspection.

Manufacturer to provide

39. If you have selected this delivery method, in the resulting dialog box select the expected date the evidence will be provided to us. The delivery date cannot be earlier than the GMP application submission date and should not be later than one month past the date you submit the application.

Manufacturer to provide

When submitting evidence directly to TGA, email GMPclearance@tga.gov.au and quote the GMP clearance application tracking number. Please ensure the manufacturer supplies this evidence as soon as possible. If evidence is not provided by the time TGA review the application, a GMP Clearance may not be issued

* Enter expected delivery date: dd/mm/yyyy

OK Cancel

You should liaise with your manufacturer to ensure the date selected is achievable **prior** to submitting your GMP clearance application.



Evidence should be provided no later than 1 month from the submission of the GMP clearance application.

If we have not received the evidence by the time we perform [application receipt](#), your application will progress to assessment as incomplete. This will result in extended processing times and your GMP clearance may [not be issued](#).

Submit paper copy

40. If you have selected this delivery method, in the resulting dialog box select the expected date the evidence will be delivered to TGA.

Submit paper copy

TGA prefers to receive electronic copies of documents. If you are posting evidence directly to TGA, address it to PO Box 100, Woden, ACT 2606 and quote the GMP clearance application tracking number. Please ensure this evidence is supplied as soon as possible. If evidence is not provided by the time TGA review the application, a GMP Clearance may not be issued

* Enter expected delivery date: dd/mm/yyyy

OK Cancel

We prefer to receive electronic copies of documents. A file size of **100MB** is available and files may be [zipped](#). Paper copies are accepted if they cannot be submitted electronically.



You should liaise with your manufacturer to ensure that the date selected is achievable **prior** to submitting your GMP clearance application.

Evidence should be provided no later than 1 month from the submission of the GMP clearance application.

If we have not received the evidence by the time we perform [application receipt](#), your application will progress to assessment as incomplete. This will result in extended processing times and your GMP clearance may [not be issued](#).

Upload evidence

41. If you have selected this delivery method, in the resulting dialog box select 'Browse' and select the file to upload.



Important: Ensure the document has the [correct naming convention](#).

42. When uploading GMP certificates or inspection reports, you will also need to enter the inspection date relevant to the evidence provided.



You may receive alerts if the inspection date is ≥ 3 years identifying that the GMP clearance may:

- result in a short expiry date (if issued)

OR

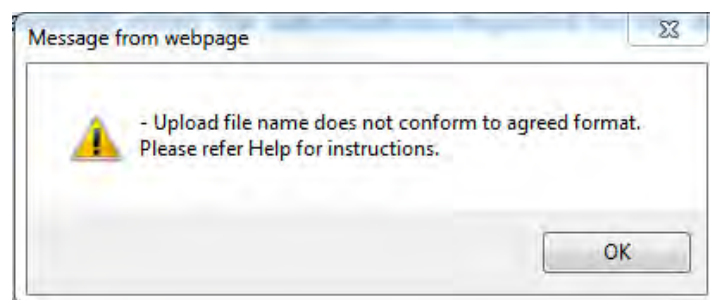
- not be issued if the evidence is > 3 years from date of inspection.



Ensure the document has the [correct naming convention](#).

The maximum file size is **100MB** per piece of evidence. If supplying multiple documents in response to a single item of evidence (for example a SMF and separate appendices) please provide a single [zip](#) file.

43. If the document does not have the correct naming convention, an error message will be displayed. Update the document name as per the [naming convention](#) and upload it again.



Letter of access to clearance

44. If you have selected this delivery method, in the resulting dialog box enter a valid GMP clearance tracking number.



To avoid unnecessary delays and unforeseen outcomes that may impact your regulatory submissions, we strongly recommend you to only use LoA to clearance to access **already issued** GMP clearances.

Letter of access to evidence

45. If you have selected this delivery method, in the resulting dialog box enter a valid GMP clearance tracking number that contains this piece of evidence you wish to access.



If choosing either letter of access delivery methods, the letter must be uploaded in the [Mandatory certificates or letters section](#).

A **valid** GMP Clearance tracking number is a GMP clearance that is currently under review or has been issued.

⚠ Expired or not issued GMP clearances **cannot** be accessed using either type of LoA.

Ensure you have read the relevant information contained within this guidance regarding [Letters of Access](#).

Mandatory evidence

46. If you are submitting a Compliance Verification application, there is a Mandatory Evidence section.

Identify the evidence that is required ([step 3](#)) for your application type:

- Select N/A for the evidence that is not required **and**
- Check the box next to the evidence that is required



If you or your manufacturer do not provide all required evidence, you will experience significant delays in processing times and your GMP Clearance may [not be issued](#).

Mandatory Evidence:			
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 2 Most recent inspection report	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 3 Regulatory Inspections list	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 4 Regulatory Actions Details	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 5 Site Master File / Quality Manual or equivalent	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 6 GMP / Quality / Technical Agreement or equivalent	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 7 List of products intended for supply in Australia	Select delivery method	✗
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 8 Release for supply procedure	Select delivery method	✗
* <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 9 Validation Master Plan	Select delivery method	✓
* <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 10 Latest Product Quality Review	Select delivery method	✓
* <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 11 Authorised laboratory tests	Select delivery method	✓

47. For each piece of evidence, choose the [delivery method](#) and complete the dialog box that appears.

Mandatory Evidence:			
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 2 Most recent inspection report	Manufacturer to provide	✓

48. To **update the information** that you previously entered into a dialog box (for example the delivery date of evidence), **click once** on the dropdown list and the dialog box will be displayed again to update.

Mandatory Evidence:			
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 2 Most recent inspection report	Manufacturer to provide	✓

49. To **change the type of delivery method selected** (for example to change from Post paper version to Upload Evidence), **click and hold** the drop down menu and select the new delivery method and complete the required information in the resulting dialog box.

Mandatory Evidence:			
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 2 Most recent inspection report	Select delivery method Upload Evidence Manufacturer to Provide LOA to Clearance LOA to Evidence Submit Paper Copy	Click & Hold then scroll to your delivery method
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 3 Regulatory Inspections list		
* <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 4 Regulatory Actions Details		

Optional evidence

50. If you wish to supply additional evidence, select the relevant check box in the Optional Evidence section and select the [delivery methods](#) as per instructions 37-44.

Optional Evidence:	
<input type="checkbox"/> 12. Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs)	Select delivery method ▼
<input type="checkbox"/> 13. Certified translation statement	Select delivery method ▼
<input type="checkbox"/> 14. Copy of the certificate of registration or a letter from the registrar in the manufacturer's country confirming the change of name	Select delivery method ▼
<input type="checkbox"/> 15. Cover letter detailing extension request & reason	Select delivery method ▼
<input type="checkbox"/> 16. Cover letter requesting change	Select delivery method ▼
<input type="checkbox"/> 17. Botanical ingredients evidence for authenticated standard reference materials	Select delivery method ▼
<input type="checkbox"/> Other	Select delivery method ▼

Step 7 – Submitting your complete application and paying fees

Fees and Payments tab

51. You will be able to view the itemised fee in addition the total amount before you submit your application.



Please note any applicable fees not selected during the submission of your application will be raised during [application receipt](#) and will result in delays to processing times.

Declaration tab

52. You will need to complete the Declaration tab before you can submit your application by ticking the 'Agree' box. You can then proceed to [validating](#) and [submitting](#) your application.

Validating your application

53. Once you have entered all the required information, you will need to validate your application before submission. Select 'Validate'.

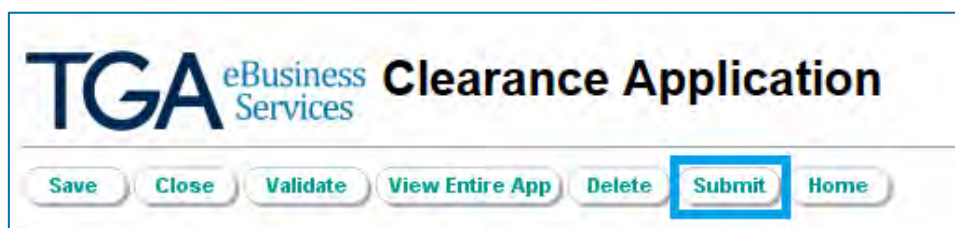
54. If there are areas of the form that have incomplete or incorrect information, an error message will show you what needs to be rectified (example errors below). You will need to address the validation issue before you can proceed.

55. Once your application has validated, you will receive the message below.



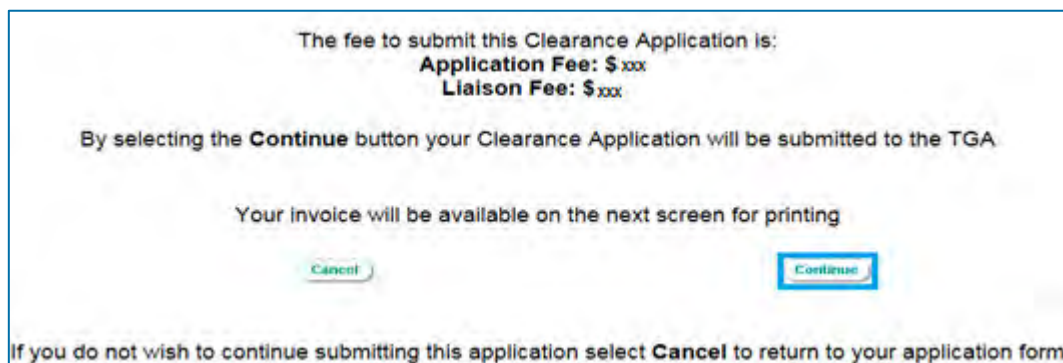
Submitting your application

56. Once all validation issues are resolved, you are ready to submit the application. Select 'Submit'.

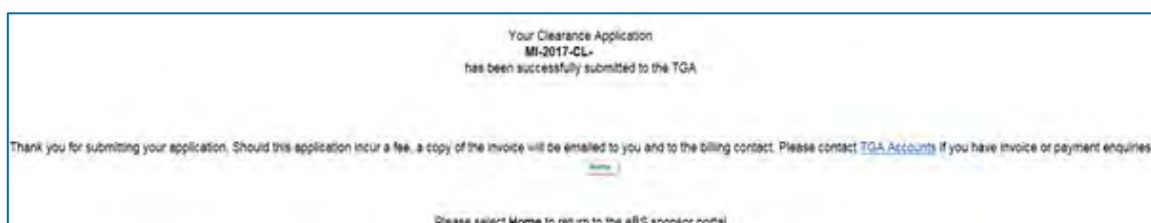


Paying your application fee

57. After submitting your application, the following screen will appear, notifying you of the fees to be charged. Select 'continue' to proceed.



58. You will receive the following notification of a successful submission:



59. The invoice (along with payment instructions) will be emailed to the billing contact. Please direct any queries in relation to invoicing of GMP clearances to accountsrec@tga.gov.au.

Step 8 – Application receipt

Once the application is submitted, it is not available for us to access until all fees have been paid. During this time the application status will be displayed as **'submitted'**. The application processing time has not started at this point until the invoices generated in [step 7](#) have been paid.

Only after your payment has been processed will the application become available to be receipted. The application status will change to 'under review'.

CV pathway

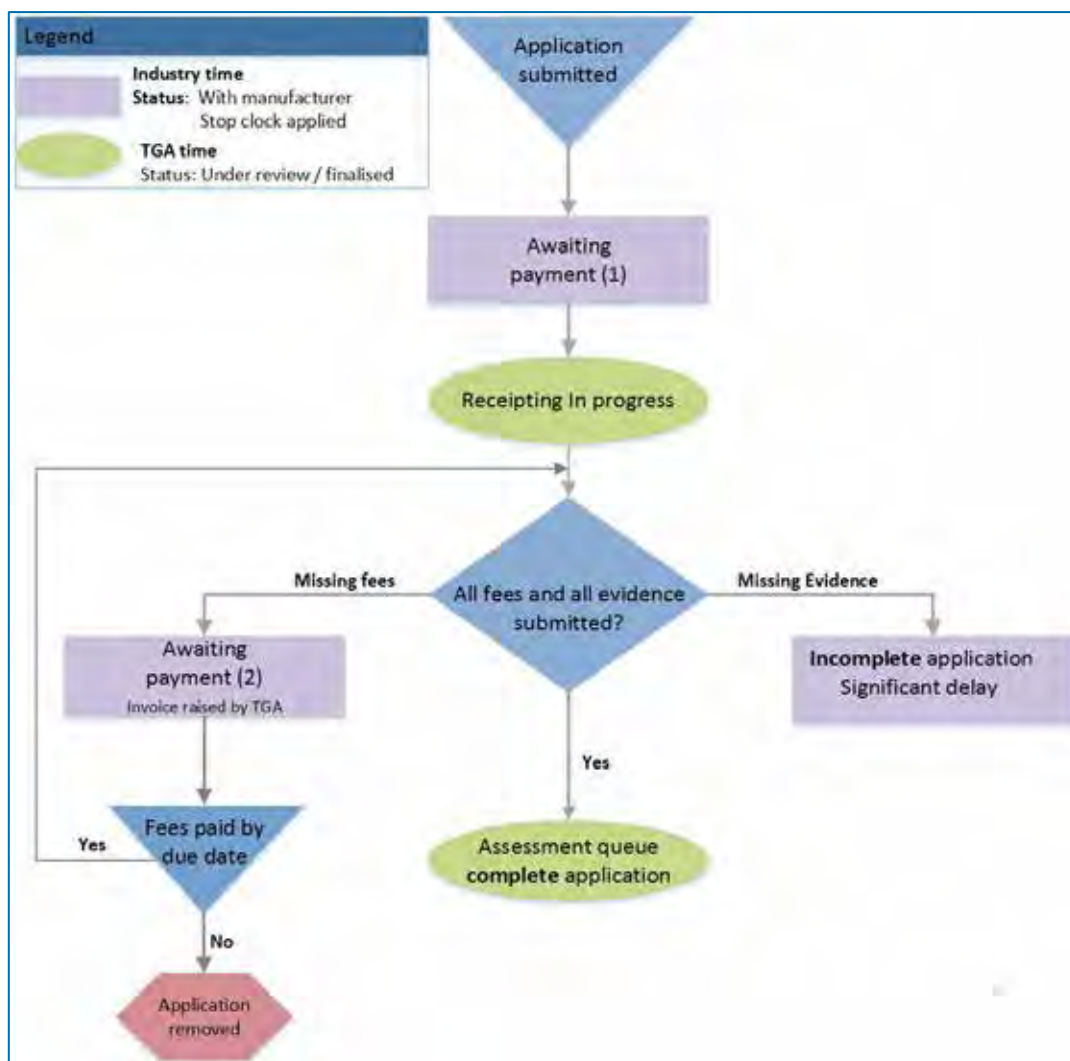
During the receipting process, your application and supporting documentation is filed in our records management system. We then perform a check and if all applicable fees were not selected during the submission of your application, we will raise an invoice and you will receive notification to pay the relevant fees by the specified due date. A stop clock will be applied to your application and the status on your application will change to **'with manufacturer'**.



Where fees have not been paid by the due date provided, your application will be removed from the system and will no longer be visible on your TBS portal.

Any [application processing fees](#) previously paid will not be refunded.

Process overview of CV application receipt



Once all fees have been paid, your application will be placed in the following queues depending on the completeness of your application:

Incomplete Queue – During receipting stage, if we have not received all the evidence required, a stop clock will be applied to your application and the application will be identified as incomplete. The status on your application will change to '**with manufacturer**'. **Applicants will not be contacted regarding evidence requirements at this stage and incomplete applications will experience significant delays.**

In instances where your application is in the incomplete queue and missing evidence is provided to us prior to assessment, your application will be placed in the complete queue, the stop-clock will be removed and TGA time will recommence. The status on your application will change to '**under review**'.

Complete Queue – Applications will be placed in this queue if all relevant evidence has been submitted during receipting stage.



To avoid a significant increase in enquiries to the GMP Clearance mailbox, sponsors should contact their manufacturers in the first instance to ensure the required evidence has been provided.

Once you have contacted your manufacturer, if there are still queries in relation to the stop clock, please contact us.

Step 9 – Application assessment

Once your application has progressed past the receipt process, it will enter the assessment queue. When your application is selected, the supporting evidence you have provided will be assessed against the scope you have applied for. Assessment times vary depending on the:

- risk of the substances or products manufactured
- complexity of the manufacturing steps involved
- number of documents provided for assessment
- level of compliance identified during our assessment.

Once we perform the MRA or CV assessment, taking into account the information and evidence provided with the application, we will make a determination ([step 10](#)).

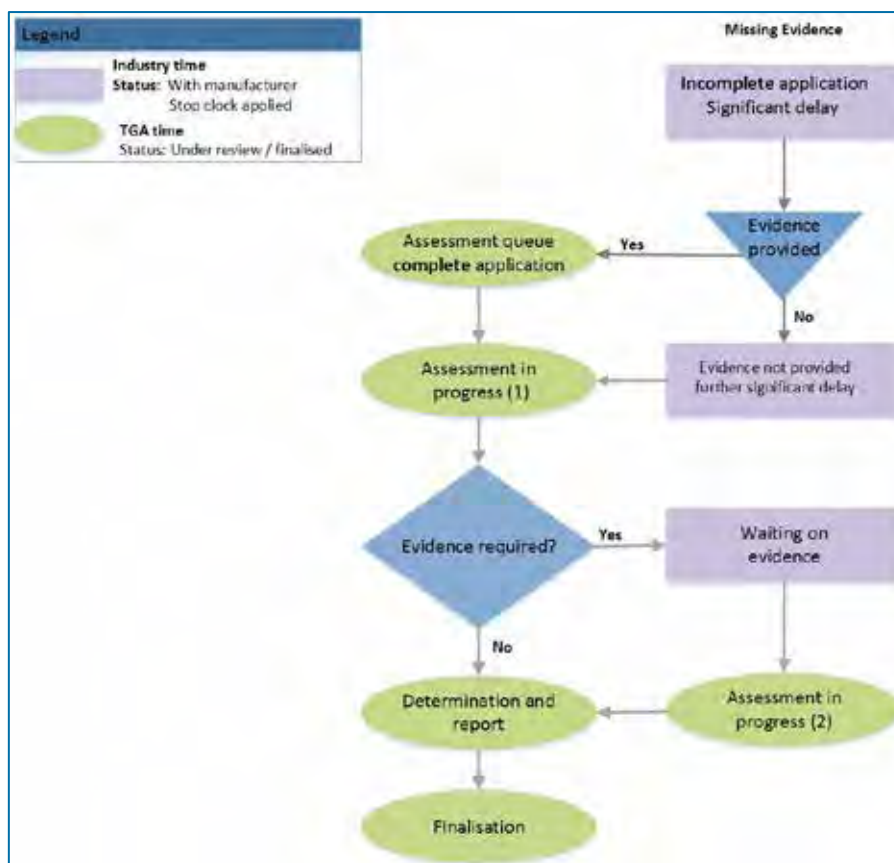
MRA pathway

To ensure we maintain consistent processing times and do not disadvantage applicants who provide the correct information, we will make a determination on the information provided and will not seek clarification from you unless in specific circumstances.

CV pathway

To ensure we do not disadvantage applicants who provide all relevant evidence upfront, applications with missing evidence will be placed in the incomplete queue and will experience significant delays in processing times and your application will be on Industry Time. A stop clock will be applied to your application and the status on your application will change to **‘with manufacturer’**.

Process overview of CV assessment



If we require further information or clarification during the CV assessment, you will be sent **one request** with a specified due date to provide this information. A stop clock will be applied to your application and the application status will change to '**with manufacturer**'.

Where deficiencies have been identified during assessment, these will be included in the request. We may also use this request as a notice of intent to not issue the GMP clearance unless the deficiencies can be addressed satisfactorily.



Your response should address **each deficiency** raised from the assessment.

Where new or updated information is provided as part of your response, you should include specific reference as to **how** it addresses the deficiency.

After the due date has passed, a determination will be made ([step 10](#)) based on the information provided.

Step 10 – Making a determination and assigning expiry dates

Once your application and supporting evidence have been assessed and the due dates provided in the request for information have passed, we will determine whether a GMP clearance can be:

- [issued](#)
- [issued with a condition](#)
- [not issued](#)

GMP clearances that are issued or issued with a condition usually expire after three years plus six months from the date of the site inspection. The additional six months allows us time to process a renewal application or to schedule an on-site inspection, as required.



We may shorten the expiry date of your GMP clearance depending on the level of compliance assessed or due to any restrictions identified in the evidence provided.

Once we make the determination on your application, the status will change to **'finalised'**. Please note that your application may appear like this for several days whilst we complete the GMP clearance process.

Issued

If the evidence you have provided to support your GMP clearance application is acceptable, we will issue the GMP clearance and update your application status to 'approved'. You will be able to view this status and your expiry date via your TGA Business Services portal.

We will notify you by email that your GMP clearance has been issued.

We may issue your GMP clearance with a reduced scope based on the assessment of the supporting evidence you have provided.

For example, where the:



- dosage form selected in the application is a group term which contains several other dosage forms that are not supported by the supplied evidence, the scope will be changed to the dosage forms specifically supported by the evidence
- manufacturing step selected in the application is a group term which contains several steps of manufacture that are not supported by the evidence, the scope will be changed to the manufacturing steps that are specifically supported by the evidence.


Issued with a condition

Depending on the information identified during assessment, we may issue a conditional GMP clearance. The conditions applied can vary and may relate to the scope or the expiry date of the GMP clearance. Existing restrictions or clarifying remarks from the overseas regulatory authority will also be placed on the clearance where applicable.



We may apply a condition which stipulates that the next GMP clearance will only be issued following a successful on-site TGA inspection.

If this condition is applied to your GMP clearance, you should submit a [certification application](#) at least **6 months prior** to your GMP clearance expiry date.

 We will **not** grant an extension to your GMP clearance where you have failed to submit a certification application in sufficient time.

We will update your application status to 'approved' and you will be able to view this status, along with the expiry date and condition placed on your clearance, via your TGA Business Services portal.

We will notify you by email that your GMP clearance has been issued and what condition has been applied.

Not issued

For both the **MRA** and **CV** pathways, the following provides general circumstances in which we are not able to issue you a GMP clearance. Where:

- you have not provided the required supporting evidence for your application type
- the evidence provided does not:
 - adequately demonstrate compliance to the required level or equivalent GMP standard
 - support the scope of the application
- you have not responded to the request for information/proposal to not issue sent during the assessment by the specified due date
- your response does not specifically detail **how** it addresses the deficiencies raised
- your response to the deficiencies raised is insufficient to support issuing a GMP clearance.

MRA pathway only

For the **MRA** pathway, to ensure we maintain consistent processing times and do not disadvantage applicants who provide the correct information, we will make a determination on the information provided and will not seek clarification from you in specific circumstances.

For example, where the GMP certificate:

- is not provided
- has expired (i.e. >3years since the inspection)
- is for the wrong manufacturing site

- has been issued using an inequivalent GMP standard
- does not cover the scope of your application

Once the determination has been made to not issue the GMP clearance, your application will no longer be visible from your TGA Business Portal. You will be notified by email along with the reason for not issuing.

This notification will contain information about the options available to you after your GMP clearance is not issued, for example, how to submit a certification application.

Step 11 – Maintaining your active GMP clearance

You are responsible for maintaining the currency and accuracy of your GMP clearance(s) at all times.



Maintaining your existing GMP clearances by submitting variation applications will allow you to:

- keep the original GMP clearance number
- avoid the need to update your ARTG entries.

You can only vary an existing GMP Clearance.

- If your clearance is expired by more than **30 days** you will not be able to vary it via the TGA Business Services portal.

This means you are required to:

- submit a variation application when there are changes to the manufacturer or manufacturing site which may impact your GMP clearance
- notify us of any significant changes to the manufacturing site, Quality Management System (QMS) or Pharmaceutical Quality System (PQS), products or product range and of any regulatory actions resulting from the outcome of recent inspections
- renew your GMP clearance application by submitting a variation application in sufficient time
- submit an extension application and supply valid reasons and evidence (when requested) in sufficient time.

Variations to in-process GMP clearances

You can request a variation to a GMP clearance currently in-process (**‘under review’**) before the supporting evidence is assessed, by contacting the Manufacturing Quality Branch at GMPclearance@tga.gov.au.

You should detail the specific changes required and provide the relevant evidence to support the change.

If the application has already been assessed and the change or increase in scope was not captured as part of that assessment, you will need to create a variation application once the GMP clearance has been issued. You will need to provide the required supporting evidence and pay the relevant fees.

Renewals, changes and extensions

You can renew, make a change or request an extension to your existing GMP clearance applications by creating a variation application. There are three variation types available on the GMP Clearance variation application form:

- [Change Clearance Details](#): for changes to scope, applicant, sponsor or manufacturers details
- [Change Clearance Status](#): for extension or cancellation requests

- [Renewals](#): to update existing GMP clearances using new GMP evidence: please take processing times into account when submitting your renewal applications.



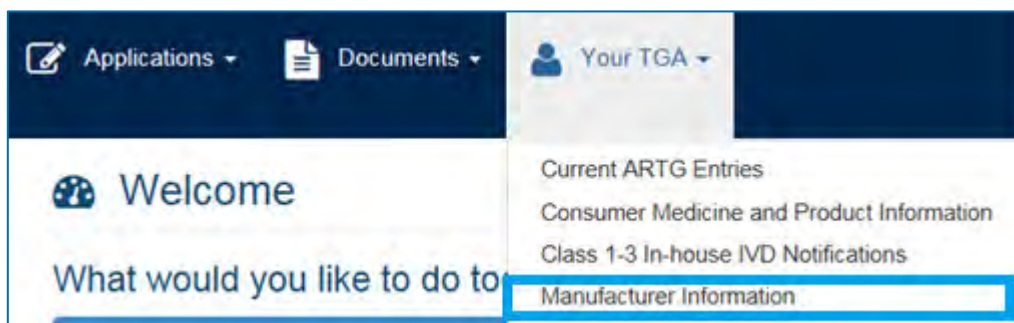
Some variation applications require the same documentary evidence to be submitted and incur the same [fees](#) as submitting a new application. These are:

- [Increases/changes in scope](#)
- [Physical changes to the manufacturing site address](#)
- [Renewals](#)

If the evidence submitted with your original application covers the increase/change in scope, you may provide a [Letter of Access](#) to the original clearance as your evidence. However, if updated evidence is available, this should be provided for assessment.

Creating a variation application

1. Log in to [TGA Business Services](#).
2. On the homepage select **'Your TGA'** and from the dropdown select **'Manufacturer Information'**



3. You will be redirected to a list of all your GMP clearances and licences. Enter **'CL'** as a filter on **'identifier'** and select **'Go'**. This will display a list of your active GMP clearances.

Manufacturer Information

Approval Area:

Manufacturer:

Filter on: for

Approved	Identifier	Site Address	Received	Expiry Date
2016-06-29	MI-2013-CL-		2016-06-29	2016-12-14
2016-06-28	MI-2016-CL-		2016-05-31	2017-10-02
2016-06-14	MI-2016-CL-		2016-05-10	2018-09-17

4. Select the existing GMP clearance you wish to vary.

Manufacturer Information

Approval Area:

Manufacturer:

Filter on: for

Approved	Identifier	Site Address	Received	Expiry Date
<input type="checkbox"/> <input type="info"/>	2016-06-29 MI-2013-CL-		2016-06-29	2016-12-14
<input type="checkbox"/> <input type="info"/>	2016-06-28 MI-2016-CL-		2016-05-31	2017-10-02
<input type="checkbox"/> <input type="info"/>	2016-06-14 MI-2016-CL-		2016-05-10	2018-09-17

5. Select 'Vary Application' from the menu bar at the top of your GMP clearance.



6. Select one of the three variation types:

- [Change Clearance Details](#)
- [Change Clearance Status](#)
- [Renewals](#)



We recommend that for any variation application where multiple changes are required, you provide a cover letter outlining these changes.

For example, where you wish to renew your GMP clearance application in addition to updating the contact details and manufacturer's name or address.

Change clearance details - Scope, applicant or manufacturer changes

7. Select 'Change Clearance Details'

Variation Type: Change Clearance Details Change Clearance Status Renewals

8. In the client details tab, for Variation Requests select the change(s) you wish to make to your GMP clearance from the following options:
- [Change to Manufacturer details – Administrative](#): A change to manufacturer name or a minor change to the manufacturer's address with no physical change to the manufacturing site (rezoning, amending a postcode etc.)
 - [Change to Manufacturer details – Physical](#): A change to the manufacturer's address (adding a building, plot or unit or the relocation of a site to a different address)
 - [Change of Sponsor or Applicant details](#): A change to the applicant or sponsor contact details (e.g. the nominated contact has left the organisation)
 - [Change of scope](#): An increase / change or a reduction to the scope (dosage forms, manufacturing steps, etc.).



When varying your GMP clearance you should:

- consider the impact of the change to your ARTG entries and [contact the relevant product regulatory area](#) if required
- select the applicable variation requests for the changes to be made
- perform a review of all information that exists in the GMP clearance form to ensure the information is both accurate and current.

Change to manufacturer details - Administrative

9. In client details tab select 'Change to manufacturer details – administrative'.

Client Details	API/Product Details	Evidence	Conditions	Fees and Payments	Declaration
?					
* ? Variation Requests:		<input checked="" type="checkbox"/> Change to manufacturer details - administrative <input type="checkbox"/> Change to manufacturer details - physical <input type="checkbox"/> Change of Sponsor or Applicant details <input type="checkbox"/> Change of scope			
* Select application type:		CV - Contract Testing Laboratory			

The manufacturer's information from your existing clearance will be pre-populated in the Manufacturer Details section.

? Manufacturer Details	
Current Manufacturer Name:	ABCD LTD
Current Manufacturer ID:	00000
Current Manufacturer Site Details:	ABCD Road, Ireland
Current Manufacturer Site ID:	00001

The manufacturing site selected in your existing application will be pre-populated. If the minor update to the site address has already been registered with TGA, it will automatically be updated in your application.

* Manufacturer Site Details:	[Pre-populated dropdown]		
Manufacturer Site ID:	[Pre-populated text]		
Suburb:		State:	
Postcode:		Country:	

10. If you are updating the manufacturer name or address, select **'Search'** to perform a search of the TGA database to discover whether the required update has already been registered by another sponsor.

* Manufacturer Name: **Search**
 New Manufacturer
 Manufacturer ID:
 * Manufacturer Site Details:
 Manufacturer Site ID:
 Suburb: State:
 Postcode: Country:

In the search box, enter a search string by typing the updated name of the manufacturer and select **'Search'**.

MIS Search Dialog
 Please enter a search string

 - Keywords including AND and OR may be used to refine your search.
 - Use * (wildcard) when searching on incomplete words.

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

Number of entry found : 1
 ABCO Limited

11. If the manufacturer name or address has not been updated by another sponsor, select the existing site address and request the update to be applied by providing a cover letter in the optional evidence section.
12. Proceed to the Evidence tab where the optional evidence is displayed. Select the evidence you will provide to support the update being applied to your GMP clearance:

Manufacturer Name Changes

Provide:

- a copy of the certificate of registration or;
- a letter from the registrar in the manufacturers country confirming the change of name or;

- a declaration from the manufacturer on its letterhead including the following information:
 - reasons for the name change
 - effective date of the name change.

Manufacturer Address changes

Provide:

- a declaration from the manufacturer on its letterhead including the following information:
 - reasons for the change in address
 - effective date of the change
 - confirmation that there is no physical change to the location of the site.

13. Select the [delivery method](#) for the evidence.

14. Complete the [declaration tab](#).

15. [Validate](#) then [Submit](#) your variation application.

The Manufacturing Quality Branch will update the client database (manufacturer name/address) if the evidence supports the change.

Change to manufacturer details – Physical

16. In client details tab, select 'Change to manufacturer details – physical'.



If your change is to **add a building, plot or unit to an existing site**, you can request the update to be applied by selecting the existing site address and provide the evidence to support this change when completing the evidence tab.

A physical change to manufacturer details will require the same documentary evidence to be submitted and incur the same [fees](#) as submitting a new application.

17. Under manufacturer site details, open the drop down menu to your manufacturer to check whether the new site has been registered with TGA previously. If the new address is in the drop down menu, select it.

18. Otherwise, for the relocation of a site to a different address select **'New Manufacturer'**.



Important – Ensure you have thoroughly searched the TGA database for the manufacturer's name and address **before** you select New Manufacturer. Duplicate entries created can result in extended delays to application processing times and may require significant updates to your ARTG entry.

If you are unsure whether the manufacturer you intend to use is available in the TGA database, please [contact us](#) **prior** to proceeding with your application.

19. Enter all the required updated information about the manufacturing site address, upload a cover letter that explains the request and select **'Send'**.

Once TGA Business Services have made the update to the manufacturer site address, you will be notified and be able to select the details and proceed with the application.

The time required to make changes to an existing manufacturer can vary depending on the impact of the change.

Proceed to complete the remainder of the application from this point as if you were [creating a new GMP clearance application](#).

Change of sponsor or applicant details

20. In client details tab select 'Change of sponsor or applicant details'.

21. Update the relevant sponsor or applicant information in the client details tab by selecting from the available drop down menus.



If you wish to amend (add or remove) contacts, your company's TGA Business Services administrator can update these details.

Refer to [TGA Business Services – Questions and answers for administrators](#) or contact ebs@health.gov.au for assistance.

22. Complete the [declaration tab](#).
23. [Validate](#) then [submit](#) your variation application.

Change of scope

24. In client details tab select '**Change of scope**'.
25. Subsequently, select whether this is:
- an '[increase/change in scope](#)' (for example, addition of dosage form or manufacturing steps) or
 - a '[decrease in scope](#)' (for example, when a site has decommissioned a dosage form manufacturing line).

Client Details | API/Product Details | Evidence | Conditions | Fees and Payments | Declaration

?

* ? Variation Requests:

Change to manufacturer details - administrative

Change to manufacturer details - physical

Change of Sponsor or Applicant details

Change of scope

* Select a change in scope:

Increase / Change in scope Decrease in scope

Increase/Change in scope

26. Your existing scope will be pre-populated. Proceed to complete the remainder of the application as if you were creating a new application by [selecting your scope](#).

Decrease in scope

27. Proceed to the API/Product Details tab. Select the substance, dosage forms or manufacturing steps no longer required and select '**Remove**'.

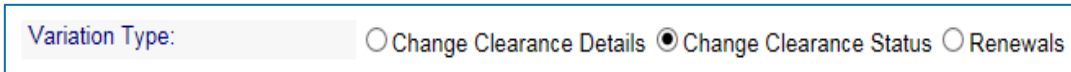
Product Details						
Show Original Entry/s						
Manufacturer Types	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Steps	
<input type="checkbox"/>	Testing Laboratory	Not applicable	Multiple manufacturing steps/Multiple products	All Dosage Forms	Registered Therapeutic Good	Testing Endotoxin
<input checked="" type="checkbox"/>	Testing Laboratory	Not applicable	Multiple manufacturing steps/Multiple products	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical

Add Remove

28. Proceed to the Evidence tab where the optional evidence is displayed. Select the evidence you will provide to support the update being applied to your GMP clearance.
29. Select the [delivery method](#) for the evidence.
30. Complete the [declaration tab](#).
31. [Validate](#) then [submit](#) your variation application.

Change clearance status – Cancel or extend

32. Select 'Change Clearance Status'.

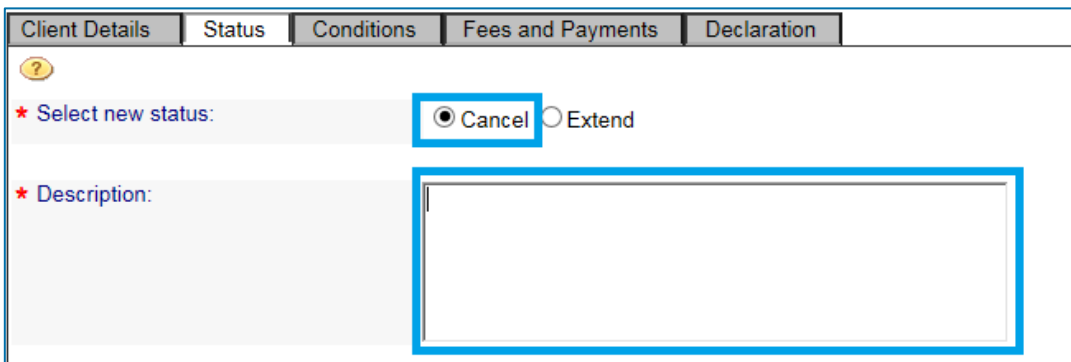


Variation Type: Change Clearance Details Change Clearance Status Renewals

33. Proceed to the Status tab and select whether you want to request to '[Cancel](#)' or '[Extend](#)' your existing GMP clearance.

Cancel your GMP clearance

34. Select '[Cancel](#)' and provide details in the description text box as to the reason for the cancellation request.



Client Details | Status | Conditions | Fees and Payments | Declaration

* Select new status: Cancel Extend

* Description:

35. Complete the [declaration tab](#).
36. [Validate](#) then [submit](#) your variation application.

Extending your current GMP clearance expiry date

You may request a **short-term extension** of your GMP clearance if there are valid reasons to extend it. You may be required to provide evidence of the reason so we can process the extension.

Usually no more than one extension can be given in addition to the six months already applied to an issued clearance. If you cannot provide updated evidence, you will be required to submit a [GMP certification application for a TGA on-site inspection](#).



- ⓘ If your clearance is expired by more than **30 days**, you will not be able to vary it via the TGA Business Services portal.
- ⓘ Extensions may not be given where an existing clearance has been given a shortened expiry date or has previously not been issued.
- ⓘ We may **not** grant an extension without valid reasons and/or evidence (for example, if you submit late renewal applications).

37. Select '**Extend**' and from the resulting drop down menu select the reason for the extension request from the following options:

- **Awaiting TGA inspection**
 - Select this option when TGA is to perform an on-site inspection
- **Awaiting GMP clearance application assessment by TGA**
 - Select this option when a renewal GMP clearance application has been submitted
- **Awaiting inspection by regulatory authority**
 - Select this option when inspecting authority has scheduled for an inspection
- **Awaiting evidence from regulatory authority**
 - Select this option when there has been a recent inspection performed and awaiting on evidence
- **Other** (Note: Selecting 'Other' will generate a heading text box to allow you to enter your reason for extension).
 - Select this option if your reason for the extension is not listed in the drop down menu. Please enter a brief reason in the heading text box. Please enter any additional details about this reason in the Description text box.

The screenshot shows a web interface with tabs: Client Details, Status, Conditions, Fees and Payments, and Declaration. Under the 'Status' tab, there is a question mark icon and a section for 'Select new status:'. Two radio buttons are present: 'Cancel' and 'Extend', with 'Extend' being selected. Below this is a 'Reason for Extension:' dropdown menu, which is currently open and displays the following options: 'Awaiting TGA inspection', 'Awaiting GMP Clearance application assessment by TGA', 'Awaiting inspection by regulatory authority', 'Awaiting evidence from regulatory authority', and 'Other'. There are also fields for 'Is this your first extension request?' and 'Description:'.

38. Select whether this request is the first extension request you have made. If '**No**', provide the previous extension request expiry date.

The screenshot shows a section for 'Is this your first extension request?'. There are two radio buttons: 'Yes' and 'No', with 'No' being selected. Below this is a section for 'Previous request expiry date:'. It features a text input box, a calendar icon, and the format 'dd/mm/yyyy'.

39. Depending on the reason for extension chosen, provide further information in the description text box. For example:
- **Awaiting TGA inspection**
 - In the description text box, please enter the TGA certification (CE) number
 - **Awaiting GMP clearance application assessment by TGA**
 - In the description text box, please enter the GMP clearance (CL) renewal application number
 - **Awaiting inspection by regulatory authority**
 - In the description text box, please enter the inspecting regulatory authority and proposed inspection dates
 - Please also send an email to [GMP clearance](#) referencing the extension clearance number and provide supporting information from the inspection authority regarding inspection dates
 - **Awaiting evidence from regulatory authority**
 - In the description text box, please enter the inspecting regulatory authority and inspection dates
 - Please also send an email to [GMP clearance](#) referencing the extension clearance number and provide supporting information when the evidence will be available
 - **Other**
 - In the description text box, please enter further information. If waiting on evidence, please provide the type of evidence and when this will be available.

Description:	
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40. Complete the [declaration tab](#).
41. [Validate](#) then [submit](#) your variation application.

Renewals

You are expected to submit an application to renew your existing active GMP clearance once new evidence becomes available and preferably **no later than six months** before your clearance is due to expire.

42. Select 'Renewals'.

You may also request to include other changes as part of your renewal application (for example, change of sponsor contact details) by selecting the variation requests below.



i If no other changes are required, do not select a variation request.

The screenshot shows a web form for 'Variation Type' with three radio button options: 'Change Clearance Details', 'Change Clearance Status', and 'Renewals'. The 'Renewals' option is selected and highlighted with a blue box. Below this is a tabbed interface with tabs for 'Client Details', 'Evidence', 'API/Product Details', and 'Conditions'. The 'Evidence' tab is active. Under the 'Evidence' tab, there is a section titled 'Variation Requests' with four checkboxes: 'Change to manufacturer details - administrative', 'Change to manufacturer details - physical', 'Change of Sponsor or Applicant details', and 'Change of scope'. The 'Variation Requests' section is also highlighted with a blue box.



i **Important** – Please take processing times into account when submitting your renewal applications.

i We may **not** grant an extension without valid reasons and/or evidence (for example, if you submit late renewal applications).

43. Proceed to complete the remainder of the application from this point as if you were [creating a new GMP clearance application](#).

Transferring your GMP clearance

If products on the ARTG are transferred between sponsors, the associated existing active GMP clearances may need to be transferred as well.

The new sponsor must contact GMPclearance@tga.gov.au and provide:

- the details of all affected clearances to be transferred
- a letter from the transferring sponsor indicating assent to the GMP clearance transfers; a copy of any sale/transfer agreement may also be acceptable
- current details (Client ID number, contact information).

The new sponsor needs to have a GMP, quality or technical agreement with each manufacturer with whom they have a direct relationship (this may be requested).



⚠ Expired GMP clearances **cannot** be transferred. A new application needs to be submitted by the new sponsor.

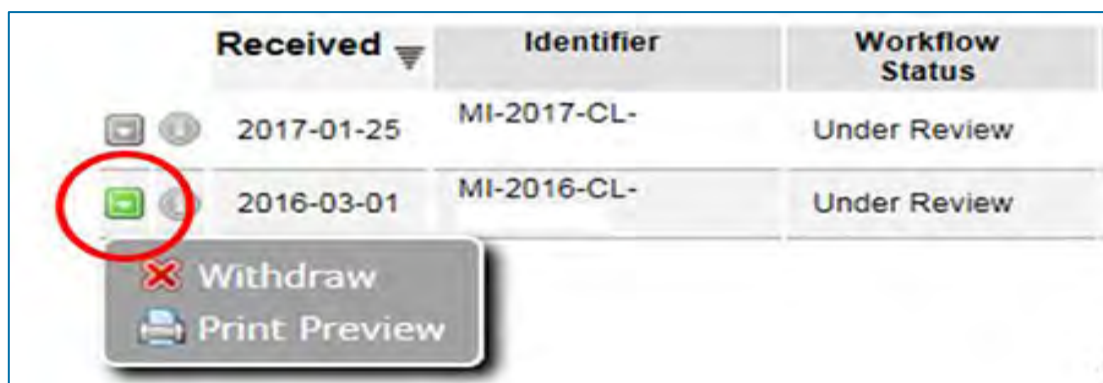
Clearances currently under assessment that have had a transfer of sponsorship processed will not be viewable by the new sponsor until the application has been issued.

Withdrawing GMP clearance applications no longer required

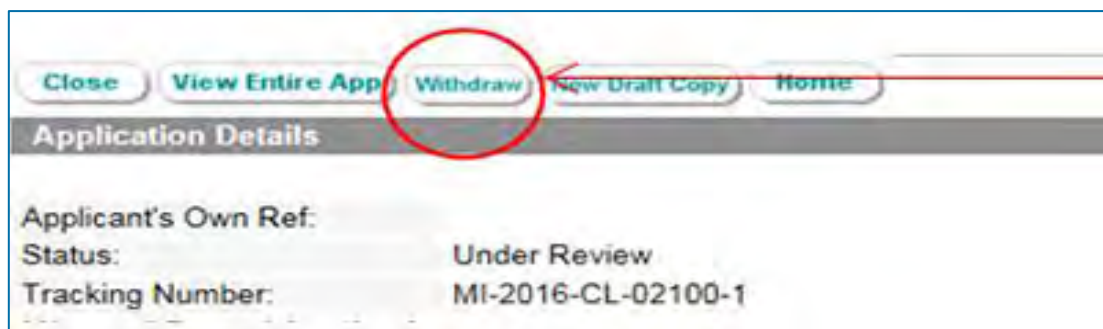
Once your application has been submitted [step 7](#) and the current status of your GMP clearance application is '**under review**', you can still withdraw your application if you have identified the GMP clearance application is no longer required. Any [fees](#) previously paid may not be refunded.

Please withdraw via TBS by following these instructions:

44. Please login to your TBS portal
45. Under "View Lodged Submission", locate the application that is no longer required
46. Click on the drop down next to the application you wish to withdraw. This will bring up an option box



47. Select 'Withdraw' from this box
48. Select 'Print Preview' to preview your application, then select 'Withdraw'.



Cancellation or reduction in scope by TGA

We may cancel or reduce the scope of your GMP clearance where:

- you decline to contribute to the cost of a TGA on-site inspection
- the manufacturer declines a TGA on-site inspection
- the outcome of a TGA on-site inspection is unsatisfactory
- an MRA partner or other regulatory agency withdraws GMP certification, or we receive other compliance signals
- evidence submitted to us is subsequently found to be incorrect.

You will be notified by email of the intention to cancel or reduce the scope along with the reasons for it, and you will be provided the opportunity to respond.

Evidence naming conventions

The table below outlines the naming conventions for evidence being uploaded with your GMP Clearance application.

Each piece of evidence should be provided as a separate file. If supplying multiple documents in response to a single item of evidence (for example a SMF and separate appendices), please provide a single [zip file](#).

You will need to name each file with the document number prefix and the required file name to validate your application, for example:

Ü 8 Release SOP

You cannot add additional text **before the required** naming convention as this will fail validation. For example, the following will fail the validation rule:

Ü 8 Company Name Release SOP

Ü Company Name 8 Release SOP

You can add additional text **after the required** naming convention. For example:

Ü 8 Release SOP Company Name Effective Date



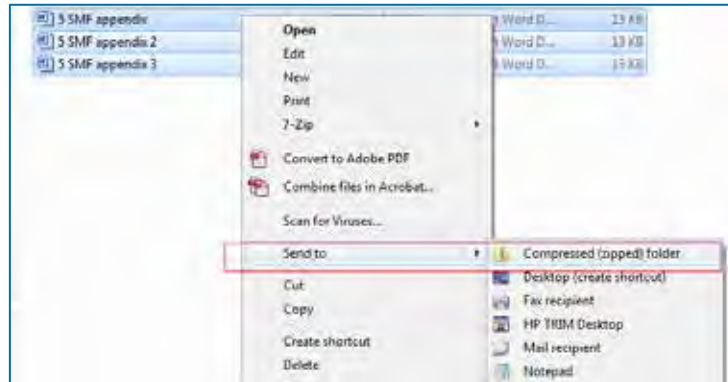
File naming convention table

Prefix #	Evidence name	The beginning of the file name (including the prefix number)
1	Current GMP or GLP or ISO Certificate	1 Certificate
2	Most recent inspection report	2 Inspection Report
3	Regulatory Inspections list	3 Regulatory Inspection List
4	Regulatory Actions Details	4 Regulatory Action Details
5	Site Master File or Quality Manual or equivalent	5 Site Master File or SMF or Quality Manual or QM
6	GMP or Quality or Technical Agreement or equivalent	6 GMP or Quality or Technical or Agreement or TA or QA
7	List of Products intended for supply in Australia	7 Product List
8	Release for supply procedure	8 Release for Supply procedure or Release SOP
9	Validation Master Plan	9 Validation Master Plan or VMP

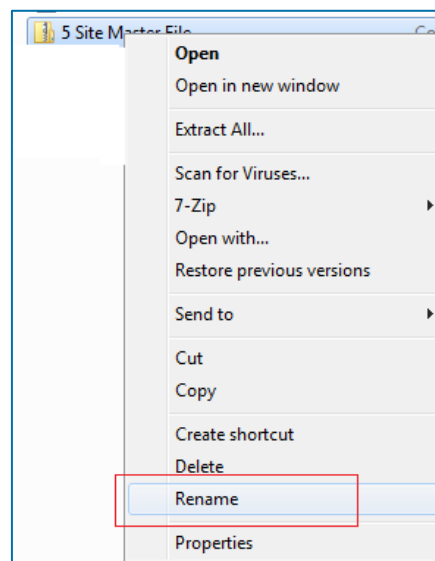
Prefix #	Evidence name	The beginning of the file name (including the prefix number)
10	Latest Product Quality Review	10 Product Quality Review or PQR
11	Authorised laboratory tests	11 Lab test
12	Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs)	12 Declaration
13	Certified translation statement	13 Translation
14	Copy of the certificate of registration or a letter from the registrar in the manufacturer's country confirming the change of name	14 Name or Address Change
15	Cover letter detailing extension request and reason	15 Letter
16	Cover letter requesting change	16 Letter
17	Botanical ingredients evidence for authenticated standard reference materials	17 Botanical authenticated standard reference materials
18	LoA to Clearance	18 LoA Clearance
19	LoA to Evidence	19 LoA Evidence

How to create a zip file

1. Locate the file or folder that you want to zip.
2. Press and hold (or right-click) the file or folder, select (or point to) **Send to**, and then select **Compressed (zipped) folder**.



3. A new zipped folder with the same name is created in the same location. To rename it, press and hold (or right-click) the folder, select **Rename**, and type the new name.



Keep up to date

For further information or associated webpages regarding GMP clearance, please go to the GMP clearance tab on the [Manufacturing medicines](#) web page of the TGA website.

We will continue to keep industry informed of important changes or updates regarding the GMP clearance process on the [Notices about GMP clearance](#) web page.

Troubleshooting

Please see below for common issues raised. If you come across any issues, please use the troubleshooting guide below. However, if you are still unable to rectify the issue, please [contact GMP clearance](#) and include the following:

- GMP clearance tracking number
- Screenshot of the issue (if IT issue related)
- Your username (if IT issue related)

Issue	Suggestion
<p>I am experiencing TBS related issues, such as:</p> <ul style="list-style-type: none"> • I don't have administrator access to submit an application. • I'm not listed as a contact in the application. • I need to reset my password for the TGA Business Services account. 	<p>If the contact is not displayed in the drop down list, your company's TGA Business Services administrator can update these details. Refer to TGA Business Services – Questions and answers for administrators.</p> <p>For TBS related issues, please contact ebs@health.gov.au for assistance.</p>
<p>I can't select a radio button or checkbox in the GMP clearance application form.</p>	<p>Please save your GMP clearance application, refresh your internet browser and try saving again.</p> <p>If you are still experiencing issues, please contact GMP clearance prior to submitting the application.</p>
<p>I am experiencing problems when uploading evidence to the application.</p>	<p>Please save your GMP clearance application, close your internet browser before trying to upload the evidence again.</p> <p>If you are still experiencing issues, please contact GMP clearance prior to submitting the application.</p>
<p>I received notification an invoice has been raised, however I cannot see it.</p>	<p>Please wait for 24 hours from the date GMP clearance sends you an email.</p> <p>If you have not received an invoice by then, please contact GMP clearance.</p>

Issue	Suggestion
I am experiencing validation errors when entering GMP clearance details for my product submission.	<p>Please contact the relevant product regulatory area regarding the validation message shown in the respective lodgement systems.</p> <p>If the selections you made result in validation issues with the regulatory submission system, you may be required to submit a variation application and pay the relevant fees.</p>

Version history

Version	Description of change	Author	Effective date
17th Edition	Australian Regulatory Guidelines Good Manufacturing Practice (GMP) Clearance for Overseas manufacturers	Office of Manufacturing Quality	12/05/2011
V18.0	Updated title to GMP clearance guidance Restructured to be more readable Added instructions for submitting GMP clearance applications	Manufacturing Quality Branch Regulatory Guidance Team	September 2017
V18.1	Added fee table in GMP clearance basics section Clarified that separate applications are required for each unique site address in the TGA database Provided additional information regarding alternative or supplementary information to be provided upfront where applicable and the application receipting process Clarified when applications would be removed from the system due to non-payment and the criteria for immediate not issue of GMP clearances for the MRA pathway Provided additional information and illustrations around GMP agreements Clarified for cell banking activities, names of specific cell lines are not required to be entered in the application Provided additional information for extension applications Added troubleshooting section Minor editorial changes	Manufacturing Quality Branch	January 2019
V18.2	Added information on the stop clock process (TGA vs Industry Time) Added information on application status Added information on how to withdraw applications Minor editorial changes	Manufacturing Quality Branch	March 2019

Version	Description of change	Author	Effective date
V18.3	Provided information on the processing target timelines for CV applications Provided additional information on prioritisation requests	Manufacturing Quality Branch	July 2019

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Reference/Publication #