Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

How to obtain GMP clearance through inspection reliance

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Contents

Purpose of this document

This information is for Australian sponsors seeking to obtain a GMP Clearance to support medicinal product listing and registration activities.

It outlines the processes and documentation requirements relating to GMP Clearance.

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 manufacturing and quality control procedures are acceptable.

The TGA may issue GMP Clearance to sponsors of a medicine or API that is manufactured overseas. Where there is acceptable evidence submitted the Australian sponsor that demonstrates 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), 26A(3) and 26(AB)(4) of the *Therapeutic Goods Act 1989* (the Act). This supports the main objective of the Act, which is to ensure the safety, quality, efficacy and timely supply of therapeutic goods for Australian consumers.

GMP Clearance is not required for medical devices.

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 on the Australian Register of Therapeutic Goods (ARTG) **and** the manufacturing step must be recorded in the product's ARTG entry.

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 Listed medicines and Registered Complementary Medicines (ARGCM)
- TGA Code Tables – Guidance to manufacturing steps and validation

As an Australian sponsor you must ensure:

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

If you are unsure whether the scope of your GMP Clearance application aligns with your product submission or whether you require GMP Clearance, please contact the relevant product regulatory area **prior to** submitting the GMP Clearance application.

You **may not be contacted** prior to finalising the GMP Clearance application and GMP Clearances will be issued for the scope that is supported by the evidence provided.

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.

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 Clearances 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 or suspended**.

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. As a sponsor, you need to:

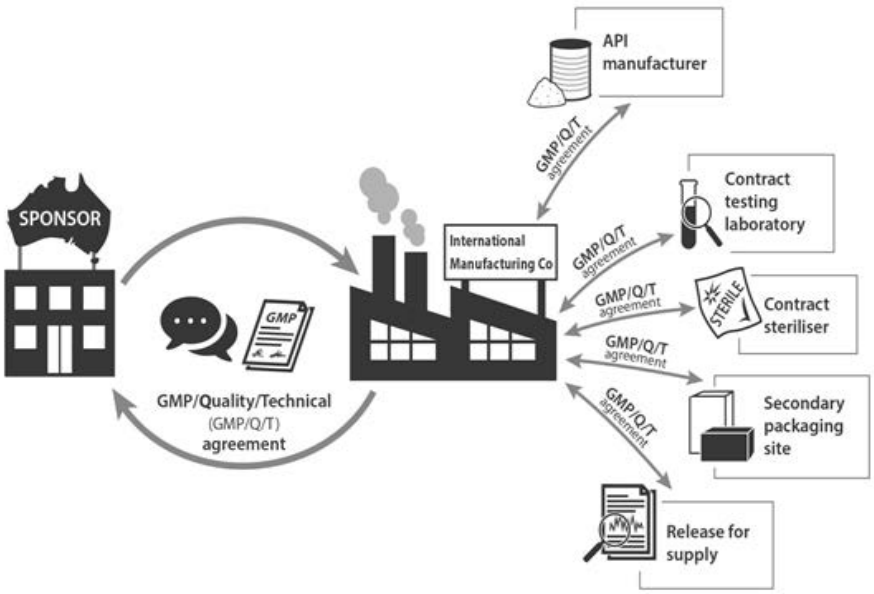
- understand the activities of every manufacturer in the supply chain of your product
- establish and maintain the relevant GMP, quality or technical agreements with whom you have a direct relationship with, **including subsidiaries of the same parent company**:
  - The principles of GMP require you to have a GMP, quality or technical agreement with the primary or principal 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 principal manufacturer and their subcontractors. These should be provided as part of your application where appropriate.

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 principal 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.



How GMP Clearance is obtained

GMP Clearance can be obtained by the Australian Sponsor for the manufacturing site. You can apply for a GMP Clearance for your manufacturing site using one of three pathways:

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

The TGA or the Australian Government has 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 desktop evaluation process. Please refer to International agreements and arrangements for GMP Clearance for a list of regulatory authorities that we have an agreement with, the scope of those agreements and how they are used for GMP Clearance applications.

This information deals with obtaining GMP Clearance through the **MRA** or **CV** desktop evaluation pathways **only**. The Australian manufacturing licences and overseas GMP certification guidance provides more information for those obtaining a GMP Clearance following a successful TGA inspection. If you need a step-by-step guide of how to submit GMP Clearance application in TGA Business Services (TBS) portal, please refer to GMP Clearance: application and submission user guide.

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 pathway.

The location of your manufacturer and which regulatory authority inspected the site will determine which pathway is appropriate for your GMP Clearance application.

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 but has been inspected by a regulatory authority that has an agreement or arrangement with the TGA.

In some 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 and dietary supplements**. These **may not be regulated** as medicines in other

countries. The site must be inspected by a recognised regulatory authority for a human medicinal product against equivalent GMP requirements.

TGA inspection

If the MRA or CV pathways aren't available, for one of the reasons outlined above, you can request a TGA inspection by submitting a certification application via the portal.

If inspection dates have been confirmed with the manufacturer and travel arrangements have commenced, you cannot cancel a TGA inspection by submitting a desktop evaluation via the MRA or CV pathways.

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 evaluation
- have received other regulatory information or have concerns about the manufacturer's level of compliance
- be inspecting an adjacent facility.

Once the TGA inspection is completed and a TGA certificate is issued, the sponsor/s who contributed to the cost of the inspection will receive a GMP Clearance. **You do not need to submit a separate GMP Clearance application for the site**. If you are waiting for a TGA inspection or reinspection to be conducted or finalised, you should **submit an extension application prior to the expiry of your GMP Clearance.**

If you were not using the manufacturer at the time the inspection was scheduled, you may still apply for a GMP Clearance via a desktop process. Please refer to TGA certificates in the Other types of evidence section.

Where a joint inspection has occurred between the TGA and another recognised overseas regulatory authority, the TGA GMP Certificate is the appropriate evidence and should be used to support your clearance application. GMP Certificates issued by other regulatory authorities for the same inspection are not accepted as evidence.

Fees for GMP Clearances

You must pay the relevant GMP Clearance fees before your application can be evaluated.

Separate applications are required 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.

GMP Clearance fees apply to:

- **GMP Clearance application processing**: 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) or Health Canada 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**

Overview of fees for GMP Clearance applications

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	✓	✗	✗
	Health Canada Exit Notice*	✓	✓	✗
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	✓	✗	✓
	Health Canada Exit Notice*	✓	✓	✗
TGA Certificate	TGA Certificate	✓	✗	✗
	LoA to Evidence			
	LoA to Clearance			

*Only applies to certain application scopes. See 'Health Canada extra-jurisdictional inspections'

✓ = **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
- cancellation of the GMP Clearance
- decreases in scope

How long GMP Clearance takes

Processing times for GMP Clearance applications can vary due to several factors such as:

- number of applications received
- the quality of applications including the quality of information provided in the application e-form
- how long it takes your manufacturers to provide necessary evidence
- complexity of evaluations including the extent to which the GMP evidence supports your application
- quality of your responses to Requests For Information (RFI) or Proposals to Not-Issue (PNI)
- prioritisation of applications to address supply, patient access or other national health responses
- availability of trained resources for particular application types

Additional time may be taken to process an application where you have asked us to liaise with an overseas regulatory authority to obtain evidence on your behalf or a non-compliance signal has been identified for the site.

Current processing times

An indication of current processing times for effective applications (all fees paid and all evidence provided) are published on the TGA website to assist industry in planning their submissions and other regulatory activities.

Please refer to the GMP Clearance Sponsor Information Dashboard (SID).

TGA vs Industry time and stop clocks

The number of days shown on the SID is **TGA time** only. TGA time is defined as the number of TGA working days between submission and finalisation of your application; it does not include industry time. Industry time is when a stop clock is applied.

Stop clocks are used to accurately capture TGA vs Industry time and are applied when:

- we are awaiting payment of applicable fees
- required evidence has not been provided at the time of application
- we are seeking additional information or documentation to support your application.

Prioritisation requests

Generally, applications **will not** be prioritised for evaluation as sponsors are expected to plan their regulatory activities using information published on the SID as well consideration of the factors that influence processing times as noted above.

Prioritisation may still be sought in some circumstances, for example, where there is a potential for a Medicine Shortage to the Australian market and you have reported this to the TGA

What you should provide

If you intend to request that we prioritise your GMP Clearance application over others, you **must** 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 medicine shortage, you must provide the details of the notification (typically an MS number) 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 product registration or listing, you should provide the registration or listing details including timeframes and impact.
- 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. The proposed change may need to be considered as part of the GMP evaluation.

- Applications **will not be prioritised** unless sufficient justification with supporting information is provided

The GMP Clearance process

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 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'**.

If the payment has been made and the status does not change within a week, please provide a copy of the remittance advice to GMPclearance@health.gov.au so we can investigate the payment status.

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.

Proactively providing the latest evidence

Sponsors are expected to proactively provide the latest information when it becomes available.

After receipt, applications are placed in a queue for evaluation, when new evidence becomes available this should be provided via email or via GovTeams to assist in the efficient evaluation of evidence.

Where updated evidence is identified as being available during evaluation, this will add significant time to the process.

How to interpret the status of your application

Please login to your TBS portal to 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 evaluation **complete** queue if all relevant evidence has been submitted, or
  - Evaluation 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 evaluation **incomplete queue** as documentation has not been provided during the receipting process or documentation does not meet the documentation requirements outlined in this information, or
  - During evaluation, deficiencies identified and/or further clarification is required from the applicant, the GMP evaluator will advise by email of any deficiencies

- **'Finalised'**:
  - A determination has been made on your application and it is in the final stages of processing.
- **'Pending withdrawal':**
  - Applications you have identified as no longer required and are waiting on removal from the system

If your application is placed in **incomplete queue**, applicants will not be contacted regarding evidence requirements and will experience significant delays.

To avoid a significant increase in enquiries to the GMP Clearance mailbox, sponsors should check the status of the application around the expected delivery date of evidence and 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.

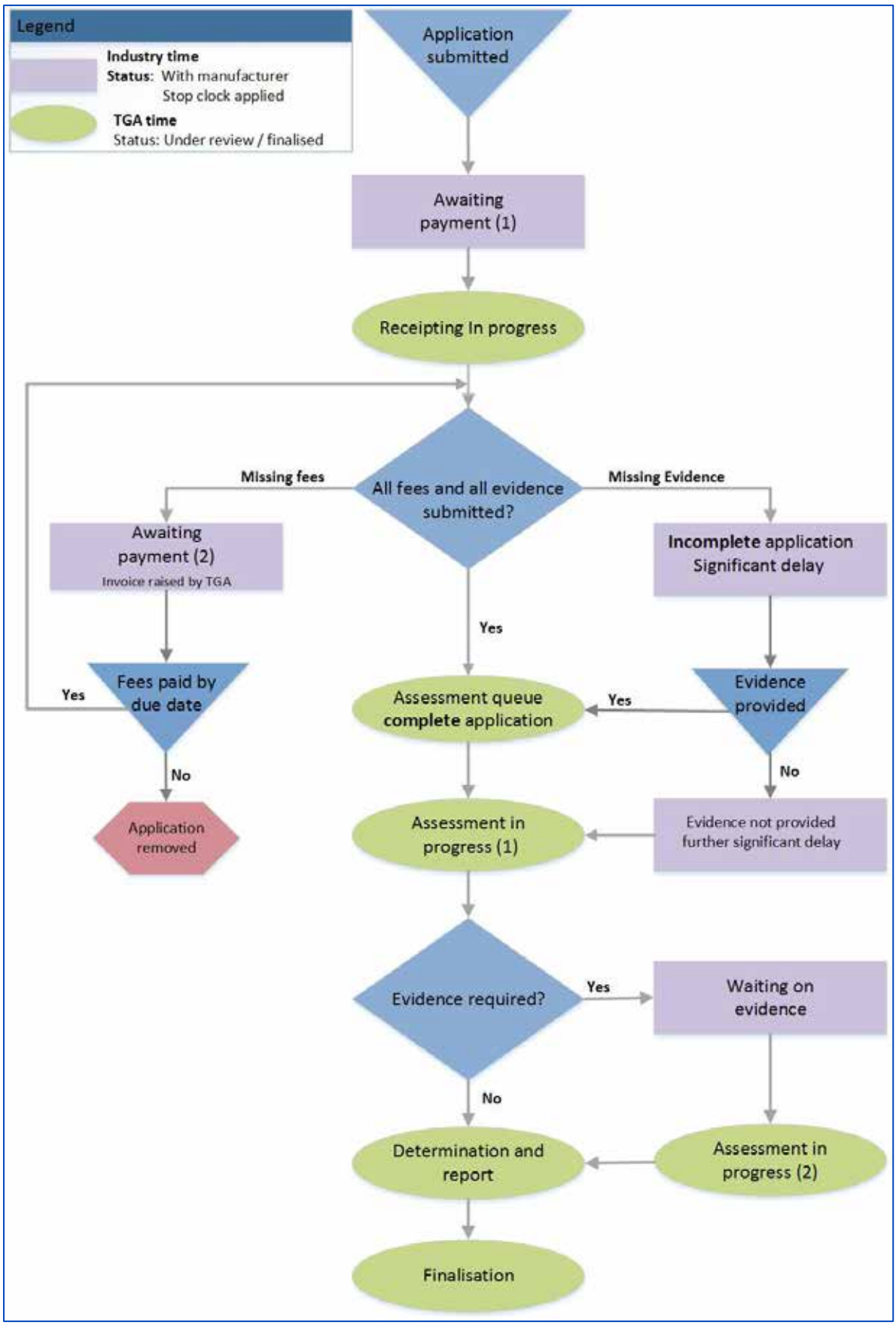
Variations to in-process GMP Clearances

You can request a variation to a GMP Clearance currently in-process ('**under review**') before the supporting evidence is evaluated, by contacting us at GMPclearance@health.gov.au.

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

If the application has already been evaluated and the change or increase in scope was not captured as part of that evaluation, you will need to create a variation application, provide the required supporting evidence and pay the relevant fees.

Overview of the GMP Clearance application process using the CV pathway.



Application evaluation

Once your application has progressed past the receipt process, it will enter the evaluation queue. When your application is selected, the supporting evidence you have provided will be evaluated against your application scope.

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**'.

If we require further information or clarification during the CV evaluation, 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 evaluation, these will be included in the Request For Information (RFI)/Proposal to Not-Issue (PNI).

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

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 based on the information provided.

Making a determination and assigning expiry dates

Once your application and supporting evidence have been evaluated 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

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

Once we make the determination on your application, the status will change to '**finalised**'.

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 TBS 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 evaluation 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

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 TGA inspection.

If this condition is applied to your GMP Clearance, it is a sponsor's responsibility to submit a certification application at least **6 months prior** to your GMP Clearance expiry date.

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

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 evaluation 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 where the GMP certificate:

- is not provided
- is not complete (e.g. missing pages/information, redacted etc.)
- is not a GMP certificate (e.g. Manufacturing license, Manufacturer's Authorisation etc.)
- is not in English or supplied without a translation certificate
- is for the wrong manufacturing site
- has been issued using an inequivalent GMP standard
- is not the most recent applicable GMP certificate
- does not cover the scope of your application and an API declaration has not been provided where required

This is not an exhaustive list. There may be other scenarios where we **will not seek clarification** and will make a determination based on the evidence provided.

Once the determination has been made to not issue the GMP Clearance, your application will no longer be visible from your TBS 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.

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:

ü keep the original GMP Clearance number

ü avoid the need to update your ARTG entries.

You can only vary an existing GMP Clearance.

û If your clearance is expired by more than 30 days you will not be able to vary it via the TBS portal and it will require reinstatement.

This means you are required to:

- submit a new or 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.

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

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 cover letter outlining what information we should be obtaining and the original tracking number of the clearance. However, if updated evidence is available, this should be provided for evaluation.

If the variation application is submitted for increases/changes in scope, ensure the evidence covers the whole scope of the application.

Change clearance details - Scope, applicant or manufacturer changes

You can submit variations to your existing GMP Clearances as below. Please refer to GMP Clearance: application and submission user guide for more information on varying your GMP Clearance in the TBS portal:

- **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.)
  - If part of the site is being divested, please contact GMPclearance@health.gov.au **prior to submitting** your application.
- **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.

What you should provide for administrative changes

Manufacturer Name Changes

- 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

- 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.

Where an application for a manufacturer name change is received, we are required to contact affected sponsors before we can action the request. We do not have set timeframes for actioning name change applications as it will vary depending on the number of sponsors involved and the number of ARTG entries to be updated.

Please note, we are only able to update ARTG entries with current GMP Clearances. If your ARTG entry lists an expired GMP Clearance, you will need to request that this be updated through a product variation application.

Extension

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 inspection.

Extensions will generally be considered a few weeks prior to the expiry date, however priority will be given to those extension requests which have been submitted more than one month prior to the expiry date. If your extension request is submitted closer to the expiry or after the clearance has already expired, you may experience delays in your application being considered.

- If your clearance is expired by more than **30 days**, you will not be able to vary it via the TBS portal. Refer to reinstatement of expired clearances.
- 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).
- Where a Letter of Access has been used to support your GMP Clearance, we are unable to extend your GMP Clearance unless the clearance you have been granted access to has also been extended. You should ensure that the clearance you have sought access to has been extended prior to submitting your extension request.

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@health.gov.au within three (3) months of the transfer of the product and provide:

- a cover letter with the details of all affected clearances to be transferred including GMP Clearance tracking numbers
- a letter from the transferring sponsor indicating assent to the GMP Clearance transfers; a copy of any sale/transfer agreement may also be acceptable, include confirmation regarding whether the whole or only part of the GMP Clearance is to be transferred.
- Provide new sponsor details (Client ID number) and full contact information such as; full name, contact number and email address for the transferred clearances.

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).

There is currently no fee applicable for transfer of clearances between sponsors.

Where the original sponsor is required to maintain the GMP Clearance for other products, we will be unable to transfer the clearance to the new sponsor. The new sponsor will be required to apply for a 'new' GMP Clearance for all applicable sites and pay the associated fees.

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

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

We will endeavour to consider sponsors requested timeframes; however, this may not be possible for transfer requests consisting of a number of sites. Please be aware it may take several months for the transfers to be completed. We encourage sponsors to contact us in advance where a large number of clearances are to be transferred.

Re-instatement of expired GMP Clearance

Where your GMP Clearance has expired beyond 30 days, you will no longer be able to submit variation applications.

Sponsors should request their GMP Clearance be re-instated via email to GMPClearance@health.gov.au. The request should include the reason for allowing your GMP Clearance to lapse beyond the allotted time provided to submit a renewal or variation. Additionally, as there is a separate fee for this process, your request should include acknowledgement and agreement to pay this fee.

Where there is no valid reason stated in the request, we may not consider reinstatement of your expired clearances. Additionally, GMP Clearances which have been expired for more than 12 months will not be reinstated.

Cancellation, suspension, additional conditions or reduction in scope by TGA

We may cancel, suspend, add conditions to or reduce the scope of your GMP Clearance where:

- you decline to contribute to the cost of a TGA inspection
- the manufacturer declines a TGA inspection
- the outcome of a TGA 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, suspend, additional conditions or reduce the scope along with the reasons for it, and you will be provided the opportunity to respond.

GMP Compliance Signals

When a GMP non-compliance signal is identified for a site, GMP Clearance applications will be placed on hold pending investigation by the GMP Compliance team who, as part of their investigation, will reach out to Australian Sponsors.

Enquiries regarding the status of the GMP compliance signal can be sent to directly to GMPCompliance@health.gov.au. Following investigation of the non-compliance signal, the GMP Compliance team will recommend what actions may need to be taken for the manufacturer. This may include:

- requiring a TGA GMP compliance inspection to be performed
- suspension or cancellation of the existing GMP Clearance (where applicable)
- rejection of the in-process GMP Clearance
- adding specific conditions to the existing or in/process GMP Clearance

Further information can be found in the Guidance on the management of GMP compliance signals.

Identifying what documentation is required

The documentation required to support your GMP Clearance application depends on the pathway you have identified and the type of manufacturer you are seeking GMP Clearance for.

Important - If you are unsure what evidence is required, please **use** 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.

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 recent 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 or any mandatory evidence that is not supplied must be clarified via a cover letter submitted with the application.

We may request certified copies of submitted documents **at any time** during the GMP Clearance evaluation 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.

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
MRA GMP Certificate	✓	✓	✓	✓	✓

✓ = 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 example, a Letter of Access (LoA), an API declaration or a complementary medicine declaration.

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

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

MRA GMP certificates

Why we require it

A GMP certificate from a recognised regulatory authority, issued after an on-site, hybrid or remote inspection was performed, is required because it demonstrates the manufacturer's compliance with the applicable GMP standard in the MRA country.

What you should provide

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

- certificate is complete
- manufacturer's name and site address are consistent with your application
- certificate is the most recent
- scope of the certificate covers the scope of your application—that is, the sterility, dosage form, and steps of manufacture etc.
- conditions and/or clarifying remarks on the certificate are understood, as these will be applied to the GMP Clearance where applicable.

Take particular care

Ensure that the certificate has:

- not been redacted in any way. Redacted certificates or missing pages/information of the certificate will not be accepted
- been issued for human medicinal products

- Manufacturing and Importation Authorisations (MIA), Good Distribution Practice (GDP), veterinary or investigational medicinal product certificates are **not acceptable** to support a GMP Clearance to register or list a product on the ARTG.
- We **do not** accept a regulatory authority's evidence as a result of their own desktop-based assessments or from third party consultants.

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

- **Health Canada** issues an inspection 'Exit Notice', which is acceptable in lieu of a GMP certificate. Health Canada Establishment Licence and GMP certificate for exports **are not acceptable** as evidence.

Alternative evidence (Contract laboratories and sterilisers)

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

When an ISO certificate is used, the full schedule of accreditation must be provided. The schedule of accreditation provides further information on the testing activities or types of sterilisation performed at the manufacturing site.

- For laboratories - we will only accept accreditation to ISO 17025 (General requirements for the competence of testing and calibration laboratories), relevant to the scope of the application
- For Sterilisers – we will only accept if the certificate is issued to the specific site and the accreditation is to the relevant sterilisation for the product — for example, ISO 11137 (Sterilisation of healthcare products – Radiation).

Liaison

For MRA applications, 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 on your behalf. Please note:

- a fee is applicable 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**.
- there may be an additional time taken to obtain information from a recognised regulatory authority

API declaration

When we require it

An API declaration is required when the substances in your application were not specifically covered as part of the most recent inspection provided as evidence.

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 authorised person/qualified person of that manufacturer
- confirms that the API(s) listed in the declaration and corresponding GMP Clearance application are manufactured:
  - in the same facility (for example, Building ABC / workshop 123 / Clean room XYZ) as those covered by and referenced in the certificate provided as evidence

    AND
  - confirm if the buildings are multiproduct or dedicated and using a similar manufacturing process (for example, chemical synthesis) as those covered by and referenced in the certificate provided as evidence

    AND
  - controlled under the same QMS or PQS as those covered by and referenced in the certificate provided as evidence

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.

Complementary medicine declaration

When we require it

Sunscreens, dietary supplements and nutritional products are typically not regulated as medicines under equivalent standards as the TGA in MRA countries. Where these products are manufactured in the same facility under the same standard and controls with other medicinal products, a complementary medicine declaration may be accepted along with the most recent GMP Certificate issued by their local regulatory authority for medicinal products.

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 authorised person/qualified person of that manufacturer
- confirms that the products listed in the declaration and corresponding GMP Clearance application are manufactured:
  - in the same facility (for example, Building ABC / workshop 123 / Clean room XYZ) as those covered by and referenced in the certificate provided as evidence

  AND

  - using a similar manufacturing process and equipment as those covered by and referenced in the certificate provided as evidence

  AND

  - controlled under the same QMS or PQS as those covered by and referenced in the certificate provided as evidence

  AND

  - the declaration should include products intended for supply in Australia and GMP Clearance application number

A declaration is **not required** where:

- the application scope covers testing only

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) 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 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.

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

Health Canada extra-jurisdictional inspections

Under the Memorandum of Understanding between Health Canada and the TGA, both parties agreed to increase collaboration and reliance on each other's extra-jurisdictional GMP inspections. Due to differences between the respective regulatory frameworks, further reliance can only be applied to:

- **Active Pharmaceutical Ingredient (API) manufacturers**
- **Contract testing laboratories**
- **Contract sterilisers**

Where relying on a Health Canada inspection for the above, only the following documentation is required. Select each piece of evidence in the table to see further information on the specific documentary requirements.

CV pathway	Non-Sterile API	Sterile or Biotech API	Contract Testing Lab or Steriliser
Inspection Exit Notice	✓	✓	✓
GMP agreement or equivalent	ⓘ	ⓘ	✓
Latest Product Quality Review (PQR)	ⓘ	✓	✗
API declaration*	✓	✓	✗

* An API declaration is required when the substances in your application were not specifically covered as part of the most recent inspection.

✓ = Required ✗ = Not Required ⓘ = Not required unless requested

To ensure the correct fees are raised, please ensure the following options are selected during submission of your application:

- "Is this a Compliance Verification assessment" = No
- Mandatory evidence – 1 Current GMP Certificate = TGA to obtain GMP Certificate

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, EudraGMDP certificate or MHRA GMP 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 the most recent issued following an **on-site** inspection
- 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, as 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 desktop assessment or remote inspection by an overseas regulator
- not been redacted in any way. Redacted certificates will not be accepted
- been issued for human medicinal products

Manufacturing and Importation Authorisations (MIA), Good Distribution Practice (GDP), veterinary or investigational medicinal product certificates are **not acceptable** to support a GMP Clearance to register or list a product on the ARTG.

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

- **Health Canada** issues an inspection 'Exit Notice', which is acceptable in lieu of a GMP certificate. Health Canada Establishment Licence and GMP certificate for exports **are not acceptable** as evidence.

Obtain evidence for US FDA evidence

Where you have provided US FDA evidence to be evaluated, we are required to perform a check of the site's compliance status. Please note:

- a fee is applicable 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 US FDA 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 routine GMP inspection performed by a recognised regulatory authority and corresponds to the GMP certificate provided (where applicable).
- manufacturer's name and site address are correct
- scope of the inspection report covers the scope of your application—that is, the sterility, dosage form, API, steps of manufacture, systems and buildings covered etc.
- inspection was conducted to the equivalent GMP standard, for example, the relevant US FDA compliance program
- 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 reports issued following a veterinary or investigational medicinal product inspection are **not acceptable** to support a GMP Clearance to register or list a product on the ARTG.

- inspection report is sufficiently un-redacted so that an evaluation can be conducted. Excessively redacted inspection reports will not be accepted
- full inspection report is provided. Inspection cover letters, Post Inspection Letters (PIL), pre-approval inspection, close out letters, observation or deficiency lists etc. are not acceptable.

Alternative evidence (Health Canada Exit Notice only)

When using an Exit notice issued by Health Canada (HC), we will be required to liaise with them to obtain further evidence related to the inspection activities performed at the manufacturing site as the document does not contain sufficient information about the on-site inspection on its own.

Given the additional liaising requirement for the TGA to obtain further evidence from HC, the liaison fee will be applicable to all CV clearance applications submitted using HC exit notices.

The CV fee, however, is **not required** for the following scopes:

- Active Pharmaceutical Ingredient (API) manufacturers
- Contract testing laboratories
- Contract sterilisers

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

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 evaluation. 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.

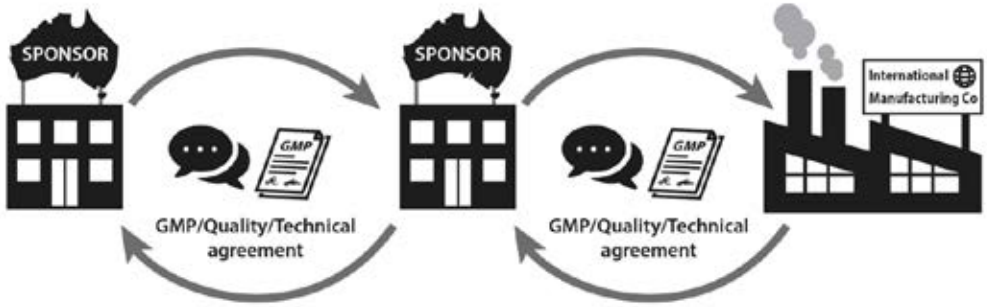
A condition will be placed on your GMP Clearance to reflect this and the expiry date may be reduced. Your GMP Clearance may be cancelled if it is determined that the condition has not been adhered to.

- For contract laboratories, 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 evaluated 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 evaluated 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).

We do not routinely require Release for further processing (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 Australian 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.

Annex 16 requirements

From 3 June 2024 the PIC/S Guide to GMP version 16 applies to the manufacture of medicines, APIs and sunscreens, unless exempt under provisions in the *Therapeutic Goods Act 1989* (the Act). Additional information may be requested as part of your application evaluation such as:

- supply chain overviews
- Authorised person job descriptions
- training procedures and records for authorised person
- supplier qualification procedures
- release for further processing procedures

This documentation is not required at application submission but may be requested where other documentation does not sufficiently cover the annex 16 clauses.

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. Where the Validation master plan does not contain sufficient information to verify that all critical validation and requalification of the facility, utilities, processes, equipment methods and cleaning etc. are up to date, additional evidence demonstrating this should be provided.

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 for that dosage form. 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. The GMP Clearance may be conditioned for you to provide the PQR as soon as it becomes available.

List of authorised tests (contract testing laboratories 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.

Take particular care

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

API declaration

When we require it

An API declaration is required when the substances in your application were not specifically covered as part of the most recent inspection provided as evidence.

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 authorised person/qualified person of that manufacturer
- confirms that the API(s) listed in the declaration and corresponding GMP Clearance application are manufactured:
  - in the same facility (for example, Building ABC/ workshop 123 / Clean room XYZ) as those covered by and referenced in the inspection report provided as evidence

AND

  - confirm if the buildings are multiproduct or dedicated and 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

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.

Other types of evidence

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 (for LoA to evidence only).

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. Do not provide multiple LoAs.
- the LoA clearly references **one** tracking number for either an existing approved GMP Clearance OR a submitted GMP clearance application.
- the application or clearance 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

Recognising the lifecycle of a GMP Clearance, it is crucial that sponsors correctly reference a single GMP Clearance number in any LoA provided as evidence.

- If the LoA refers to **a submitted GMP clearance application** that is in the queue for evaluation, your application will be tied to the outcome of that parent GMP Clearance
- If the LoA refers to an **existing approved GMP clearance**, your application will mirror the details of that GMP Clearance only. Sponsors should be aware that this may result in GMP Clearances being approved with short expiry dates and additional applications may be required.

The best use of a LoA to Clearance is to access **existing approved** GMP Clearances.

Common deficiencies with using LoA:

- The application to which access is granted has expired
- The LoA provided does not refer to a valid GMP Clearance tracking number
- The LoA does not clearly indicate the type (LoA to evidence or clearance)
- The LoA refers to a GMP clearance that has been issued based on another LoA ('daisy-chaining')

TGA certificates

TGA certificates issued as a result of a successful TGA 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 and associated ARTG numbers (specific to the application)
- the latest product quality review (specific to the products in the application)
- an API declaration.

û 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 TGA inspection.

Common deficiencies:

- Sponsor has declined to contribute to the TGA inspection
- Sponsor specific information is not provided, such as the GMP agreement
- Scope of TGA certificate does not support application
- Most recent TGA GMP certificate was not provided

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	Manufacturing Quality Branch	March 2019

Version	Description of change	Author	Effective date
	Added information on how to withdraw applications Minor editorial changes		
V18.3	Provided information on the processing target timelines for CV applications Provided additional information on prioritisation requests	Manufacturing Quality Branch	July 2019
V18.4	Removal of TBS application submission instructions into a separate guidance document Removal of target processing timeframes and inclusion of reference to the GMP Clearance Sponsor Information Dashboard (SID) Moving evidence requirements further down the guidance Updating hyperlinks following guidance re-structure Clarification on processes and information required from Sponsors	Manufacturing Quality Branch	Nov 2023
V18.5	Updated title to: 'How to obtain GMP clearance through inspection reliance'.	Manufacturing Quality Branch	Nov 2024
V18.6	Added information on CV requirements when using Health Canada Exit notice for certain application scopes Added information on release for supply in relation to Annex 16 Clarified processing times and LoA requirements Clarified the requirement for medical devices under 'Why GMP Clearance Is Required'. Minor editorial changes Update to Department name	Manufacturing Quality Branch	May 2025