



Australian Government

Department of Health

Therapeutic Goods Administration

# ***GMP Licence Applications***

## *Common pitfalls*

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Therapeutic Goods Administration

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**TGA** Health Safety  
Regulation

# Overview

- Common General Licence Application Pitfalls
- Variation Applications – Variation Application Type
- Licence Contact Details
- Domestic GMP Certificate Request Form Update
- Questions



# General Licence Application Pitfalls

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



# Variation Application – Type

- **Addition or removal of manufacturing site:** This variation type should be used when adding or removing a secondary manufacturing site to/from your GMP licence. The use of this variation type will incur an application fee.

Client Details	Primary Site	Secondary Site	Supporting Documents	Conditions	Fees and Payments	Type of Change
<div><p>* Select the activities intended to be undertaken at the licenced site(s):</p><ul style="list-style-type: none"><li><input checked="" type="checkbox"/> Medicine - API &amp; Sunscreens</li><li><input type="checkbox"/> Blood &amp; Blood Components (not HPC) Primary Site</li><li><input type="checkbox"/> Blood &amp; Blood Components (not HPC) Secondary Site</li><li><input type="checkbox"/> Haematopoietic Progenitor Cells (HPCs)</li><li><input type="checkbox"/> Biological</li></ul><p>* Licence variation type:</p><ul style="list-style-type: none"><li><input type="checkbox"/> Addition or removal of manufacturing site</li><li><input type="checkbox"/> Variation of manufacturing site authorisation</li><li><input type="checkbox"/> Other</li></ul></div>						



# Variation Application – Type

- **Variation of manufacturing site authorisation:** This variation type should be used when adding or removing manufacturing authorisations and/or conditions to/from your GMP licence. The use of this variation type will incur an application fee.

Client Details	Primary Site	Secondary Site	Supporting Documents	Conditions	Fees and Payments	Type of Change
<div>* Select the activities intended to be undertaken at the licenced site(s):<ul style="list-style-type: none"><li><input checked="" type="checkbox"/> Medicine - API &amp; Sunscreens</li><li><input type="checkbox"/> Blood &amp; Blood Components (not HPC) Primary Site</li><li><input type="checkbox"/> Blood &amp; Blood Components (not HPC) Secondary Site</li><li><input type="checkbox"/> Haematopoietic Progenitor Cells (HPCs)</li><li><input type="checkbox"/> Biological</li></ul></div> <div>* Licence variation type:<ul style="list-style-type: none"><li><input type="checkbox"/> Addition or removal of manufacturing site</li><li><input type="checkbox"/> Variation of manufacturing site authorisation</li><li><input type="checkbox"/> Other</li></ul></div>						



# Variation Application – Type

- **Other:** This variation type should only be used for administrative changes to your GMP licence. (e.g. licence nominee changes, manufacturer name change or administrative address change). There is no application fee associated with the use of this variation type.

Client Details	Primary Site	Secondary Site	Supporting Documents	Conditions	Fees and Payments	Type of Change
<div>★ Select the activities intended to be undertaken at the licenced site(s):</div> <div><input checked="" type="checkbox"/> Medicine - API &amp; Sunscreens <input type="checkbox"/> Blood &amp; Blood Components (not HPC) Primary Site <input type="checkbox"/> Blood &amp; Blood Components (not HPC) Secondary Site <input type="checkbox"/> Haematopoietic Progenitor Cells (HPCs) <input type="checkbox"/> Biological</div> <div>★ Licence variation type:</div> <div><input type="checkbox"/> Addition or removal of manufacturing site <input type="checkbox"/> Variation of manufacturing site authorisation <input type="checkbox"/> Other</div>						



# Licence Contact Details

- The contact details for a licence can only be updated to a person who is currently nominated as an organisational contact within the TGA's client database.
- The TBS account administrator for your company can create or update organisation contacts, however this organisation contact must have the system role of 'Submitter' to be nominated as the licence contact.
- Once an organisational contact has been created within TBS portal, send an email to the Licensing and Compliance Strategy Section at [GMP@health.gov.au](mailto:GMP@health.gov.au) to request the licence contact for your site to be updated.



# Domestic GMP Certificate Requests

## Current Form

**Request for certificate, or notarised copy of TGA licences and certificates, in relation to the manufacture of therapeutic goods**

Request for	Yes	Number of copies
1. Certificate of GMP Compliance <b>Note:</b> For Licensed Australian medicinal product manufacturers only. A certificate produced with a unique number. Electronically signed and issued by e-mail to the Client	<input type="checkbox"/>	N/A
2. Notarised copy of original Certificate of GMP Compliance	<input type="checkbox"/>	
3. Notarised copy of original GMP Licence	<input type="checkbox"/>	
4. Quality Systems Certificate <b>Note:</b> For medical device manufacturers holding a TGA Conformity Assessment Certificate only	<input type="checkbox"/>	
5. Notarised copy of original Quality Systems Certificate	<input type="checkbox"/>	
6. Certificate of GMP Compliance for Mutual Recognition Agreement (MRA) <b>Note:</b> For Licensed Australian medicinal product manufacturers only. For an EU or EFTA Regulatory Agency, HSA Singapore or Health Canada. A certificate produced with a unique number. Electronically signed and issued by e-mail to the Client	<input type="checkbox"/>	N/A

### Manufacturer details

Name:	
TGA Client ID:	
Manufacturing site address:	

Licence no:		
Contact person:		
	(if you are not the manufacturer, a Letter of Authorisation must accompany this request)	
Phone No:	Mobile phone No:	
Email address:	Fax No:	
Return postal address:		

### MRA certificate request only:

Product type and dosage form:	
Steps in manufacture:	

### Payment details

Our preferred method of payment is Electronic Funds Transfer (EFT). The TGA bank account details are as follows:

**Bank:** Commonwealth Bank of Australia  
**BSB:** 062-909  
**Account Number:** 10215498  
**IBAN:** 06290910215498  
**Swift Code:** CTBAU2S



- For advice on other payment methods, please refer to our [payment options](#) webpage.
- To ensure your payment is correctly allocated please include your Client ID and the word "Certificate".
- On completion please email this form with a copy of your EFT remittance advice to [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).
- For any finance related enquiries please contact 02 6221 6900 or email [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).
- For all other enquiries including assistance with this form, please phone 1800 020 653 or email [info@tga.gov.au](mailto:info@tga.gov.au).





# Domestic GMP Certificate Requests

## Updated Form

**Request for certificate, or notarised copy of TGA licences and certificates (Part A) or copy of Conformity Assessment Certificates (Part B)**

Part A - GMP Certificates & Licenses for Medicinal Products	Fee*	Number of Copies	Total
<b>Certificate of GMP Compliance</b> <small>Note: For Licensed Australian manufacturers only. A certificate will be produced with a unique number and will be electronically signed and issued by email. No hard copy will be issued.</small>	<input type="checkbox"/> \$ 180	1	\$
<b>Notarised copy of original Certificate of GMP Compliance.</b> <small>Note: This can only be requested if a Certificate of GMP Compliance has been issued. Certificates are not automatically issued after each inspection. You must request and pay for a certificate before it can be notarised.</small>	<input type="checkbox"/> \$ 70		\$
<b>Notarised copy of original GMP Licence</b>	<input type="checkbox"/> \$ 70		\$
<b>Certificate of GMP Compliance for Mutual Recognition Agreement (MRA) for:</b>			
• Canada	<input type="checkbox"/> \$ 350	1	\$
• European Union	<input type="checkbox"/> \$ 350	1	\$
• Iceland, Liechtenstein and Norway	<input type="checkbox"/> \$ 350	1	\$
• Singapore	<input type="checkbox"/> \$ 350	1	\$
• United Kingdom	<input type="checkbox"/> \$ 350	1	\$
<b>Part B - Certificates Medical Devices</b>			
<b>Quality Systems Certificate</b> <small>Note: For manufacturers holding a TGA Conformity Assessment Certificate for medical devices only.</small>	<input type="checkbox"/> \$180		\$
<b>Certified copy of original Quality Systems Certificate</b>	<input type="checkbox"/> \$ 70		\$

\*Note: These fees may increase on 1 July each year. For more information, please refer to the TGA [fees and charges](#) webpage for the fees for [medicinal products](#) and [medical devices](#).

Manufacturer's Details			
Manufacturer's Name:			
Manufacturing Site:			
Licence/Certificate Reference/ID :			
Client ID:	<small>Note: Client IDs usually starts with TGA00 and are ten digits long eg. TGA00XXXX.</small>		
Contact Person:	<small>Note: If you are not the manufacturer, a 'Letter of Authorisation' must accompany this request.</small>		
Phone No:		Mobile phone No:	
Email Address:			
Return Street Address:	<small>Note: This must be a street address as notarised copies are posted, and sent via registered mail.</small>		
Payment Details			
<small>Our preferred payment method is via credit card. For EFT payments, the TGA bank account details are:</small>			
Bank:	Commonwealth Bank of Australia		
BSB:	062-909	Account Number:	10215498
IBAN:	06290910215498	Swift Code:	CTBAU2S
Reference:	Please enter your 'Client ID' and the word 'Certificate' in this field.		



- For other payment methods eg credit card etc, please refer to our [payment options](#) webpage.
- For online/credit card payments choose 'Biller Code 17'.
- This form cannot be processed until a payment is made. No invoice will be issued until your payment has been received by the TGA.
- Please note fees are for one copy of a notarised or certified certificate.
- On completion of the form, please email this form and a copy of your payment remittance advice to [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).
- For finance related enquiries, please contact 1800 241 615 or email [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au).
- For all other enquiries including assistance with this form, please phone 1800 020 653 or email [gmp@health.gov.au](mailto:gmp@health.gov.au).



# Questions?





# Contact Us

- Email: [GMP@health.gov.au](mailto:GMP@health.gov.au)
- Phone: 1800 020 653
- **Useful Online Resources:**
  - Domestic and Overseas Application Step-by-Step Guidance:  
<https://www.tga.gov.au/publication/australian-manufacturing-licences-and-overseas-gmp-certification>
  - Domestic Variation Application Step-by-Step Guidance:  
<https://www.tga.gov.au/requesting-variations-your-manufacturing-licence>
  - TBS Administrator Questions and Answers – Updating and Creating Organisational Contacts:  
<https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators>
  - Domestic GMP Certificate Requests:  
<https://www.tga.gov.au/form/request-certificates-or-notarised-copies-tga-licences-and-certificates>



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