

## **GMP Licence Applications**

Common pitfalls

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### **Overview**

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



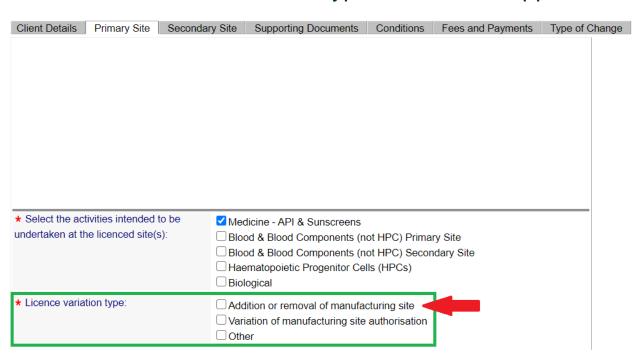
# **General Licence Application Pitfalls**

- 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

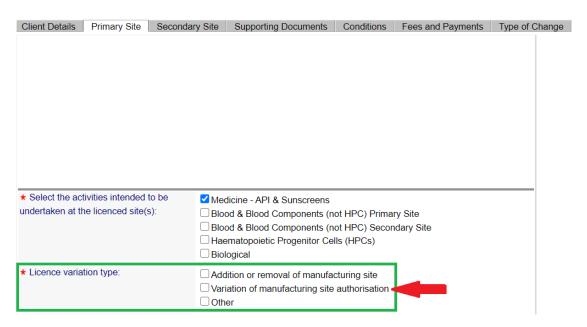
 Addition or removal of manufacturing site: This variation type should be used when adding or removing a secondary manufacturing site to/from your GMP licence. The use of this variation type will incur an application fee.





# Variation Application – Type

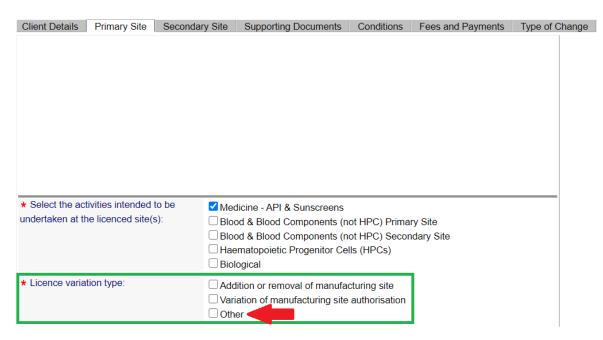
 Variation of manufacturing site authorisation: This variation type should be used when adding or removing manufacturing authorisations and/or conditions to/from your GMP licence. The use of this variation type will incur an application fee.





# 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.





## **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 <u>GMP@health.gov.au</u> 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.	Certific	ate of GMP Compliance		
	Note:	For Licensed Australian medicinal product manufacturers only.		N/A
		A certificate produced with a unique number. Electronically signed and issued by e-mail to the Client		IVA
2.	Notaris	ed copy of original Certificate of GMP Compliance		
3.	Notaris	sed copy of original GMP Licence		
ı.	Quality	Systems Certificate		
	Note:	For medical device manufacturers holding a TGA Conformity Assessment Certificate only		
i.	Notaris	ed copy of original Quality Systems Certificate		
j.	Certificate of GMP Compliance for Mutual Recognition Agreement (MRA)			
	Note:	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		N/A

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:

roduct type and dosage form:	
teps 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

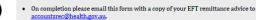
BSB: 062-909

Account Number: 10215498

IBAN: 06290910215498

Swift Code: CTBAAU2S

- . 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".



- For any finance related enquiries please contact 02 6221 6900 or email accountsrec@health.gov.au.
- For all other enquiries including assistance with this form, please phone 1800 020 653 or email info@tga.gov.au.



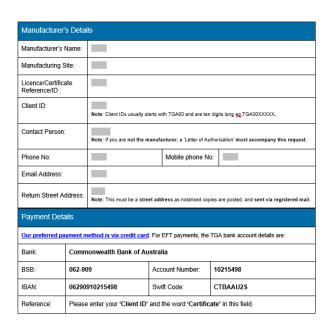
# **Domestic GMP Certificate Requests**

### **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	
Certificate of GMP Compliance		\$ 180	1	\$	
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.					
Notarised copy of original Certificate of GMP Compliance.  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.		\$ 70		\$	
Notarised copy of original GMP Licence		\$ 70		s	
Certificate of GMP Compliance for Mutual Recognition Agreement (MRA) for:					
Canada		\$ 350	1	\$	
European Union		\$ 350	1	s	
Iceland, Liechtenstein and Norway		\$ 350	1	s	
Singapore		\$ 350	1	\$	
United Kingdom		\$ 350	1	s	
Part B - Certificates Medical Devices					
Quality Systems Certificate  Note: For manufacturers holding a TGA Conformity Assessment Certificate for medical devices only.		\$180	_	\$	
Certified copy of original Quality Systems Certificate		\$ 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.



- 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 <u>one copy</u> 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.
- For finance related enquiries, please contact 1800 241 615 or email <u>accountsrec@health.gov.au</u>
- For all other enquiries including assistance with this form, please phone 1800 020 653 or email gmp@health.gov.au.





## **Questions?**





## **Contact Us**

Email: GMP@health.gov.au

Phone: 1800 020 653

### <u>Useful Online Resources:</u>

- Domestic and Overseas Application Step-by-Step Guidance:
- <a href="https://www.tga.gov.au/publication/australian-manufacturing-licences-and-overseas-gmp-certification">https://www.tga.gov.au/publication/australian-manufacturing-licences-and-overseas-gmp-certification</a>
- 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:
- <a href="https://www.tga.gov.au/form/request-certificates-or-notarised-copies-tga-licences-and-certificates">https://www.tga.gov.au/form/request-certificates-or-notarised-copies-tga-licences-and-certificates</a>



## **Australian Government**

## **Department of Health**

Therapeutic Goods Administration