

HEALTH SCIENCES AUTHORITY

REPUBLIC OF SINGAPORE

**APPLICATION FORM TO REQUEST FOR
GMP EVIDENCE EVALUATION
[OR GMP DOCUMENTARY EVIDENCE VERIFICATION APPLICATION (GMP DEVA)]**

This form may require 20 minutes to complete.

Please read *GMP Conformity Assessment of Overseas Manufacturers (GUIDE-MQA-020)* before filling up this application form

It is available via: <https://www.hsa.gov.sg/therapeutic-products/register/gmp-conformity-assessment>

The completed application form and supporting documents including GMP evidence should be scanned and attached in the associated product application(s) in PRISM

**Delete where applicable*

Tick where applicable

[A] APPLICANT INFORMATION

A1. Name of company:
(IN BLOCK LETTERS)

.....

Address:

.....

.....

Tel No.: Fax No.:

Company Registration No.:
(Attach photocopy of certificate)

A2. Person authorised to submit the application on behalf of the company

Name (*Mr/Ms/Mrs/Mdm/Dr):
(IN BLOCK LETTERS)

*NRIC (Pink/Blue)/Passport No./FIN No.:

Designation:

Tel No.: Fax No.:

Handphone No.:

Official Email Address:

[B] OVERSEAS MANUFACTURER INFORMATION

(Please ensure that the name of the manufacturer and the complete site address, including the postal code, is completely aligned with the information stated in the GMP evidence submitted)

Name of Manufacturer:
(IN BLOCK LETTERS)

.....

Manufacturer's Site Address:

.....

.....

Tel No.: Fax No.:

[C] PHARMACEUTICAL DOSAGE FORM OF PRODUCTS MANUFACTURED / ASSEMBLED BY THE OVERSEAS MANUFACTURER

	Manufacture	Primary Assembly	Secondary Assembly
<input type="checkbox"/> Injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Admixtures for intravenous infusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Reconstituted cytotoxic preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Total parenteral nutrition preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Implants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile powder for injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile non injectable liquid preparation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Liquid preparations for inhalation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile semi-solid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile powder for irrigations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Others (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Manufacture	Primary Assembly	Secondary Assembly
<input type="checkbox"/> Sterile powder for topical application	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Intraocular drug delivery systems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile strips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Oral liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Tablets for oral administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Soft Capsules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Hard Capsules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powders and granules for oral liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Oral powder and granules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pastille	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> External liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Ear drops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Nasal solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Foams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Heamodialysis solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Non-sterile semi-solid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Non sterile powders for topical applications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powder for haemodialysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powder Preparations for inhalation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Suppositories	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pessaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated soap bars	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Transdermal patches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated gums	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Tablet for external administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Beads	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated Tampons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Solution for contact lens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Dry powder inhalers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicinal gases	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Others (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[D] SUPPORTING DOCUMENTS

Please submit a valid GMP evidence that is issued by a PIC/S member authority and provide the details of the document/s submitted in the List of Attachments .

[E] DECLARATION

1. I have been duly authorised by my company to submit this application on its behalf.
2. I hereby confirm that the information submitted in this application is true and accurate.
3. I understand that if any information submitted in this application is found to be false or inaccurate, my company and I may be liable to prosecution.

Name of Applicant :

Signature :

Date :

LIST OF ATTACHMENTS

S/N.	Type of GMP evidence submitted	Document Reference Number	Issuing Country / Authority	Expiry Date

Remarks: To be routed to Overseas Audit Unit of ALD Division for Assessment