

HEALTH SCIENCES AUTHORITY

REPUBLIC OF SINGAPORE

APPLICATION FORM TO REQUEST FOR AN OVERSEAS GMP AUDIT

This form may require 20 minutes to complete.

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

The document (GUIDE-MQA-020) is available via:

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

**Delete where applicable*

Tick where applicable

[A] APPLICANT INFORMATION

A1. Name of company:
(IN BLOCK LETTERS)

.....

Address:

.....

.....

Tel No.: Fax No.:

Official email address:

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):

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

Designation:

Tel No.: Fax No.:

Official Email Address:

[B] OVERSEAS MANUFACTURER INFORMATION

B1. Name of Manufacturer:
(IN BLOCK LETTERS)

.....
Manufacturer's Site Address:

.....
.....

Tel No.: Fax No.:

Official email address:

B2. Person to contact

Name:
(IN BLOCK LETTERS)

Designation:

Mailing Address:

.....

Tel No.: Fax No.:

Official email address:

B3. Is the manufacturer approved by the relevant competent authority/regulatory agency?
(Delete as appropriate) Yes / No
(Attach copy of approval)

B4. Manufacturer Licence No. (If applicable):
(Attach copy of manufacturer licence)

B5. Warehouse Address (if different from above):
.....
.....
.....

B6. Storage Condition of the warehouse (please tick the appropriate boxes):

Temperature:

15°C to 30°C (Room temperature)

8°C to 15°C (Cold)

2°C to 8°C (Refrigerate, Do not freeze)

-10°C to -20°C (Freeze)

Below -18°C (Deep Freeze)

Others (please specify) °C to °C

Relative Humidity:% to%

B7. State if any of the following categories of products are manufactured:

	Categories	Manufacture	Assembly	Dedicated Facilities available
<input type="checkbox"/>	Penicillins or Cephalosporins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Cytotoxics or Anti-cancer preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Hormones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Steroids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Biologicals (e.g. vaccines, blood products, biotechnology products, preparations containing micro-organisms)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Non-medicinal products that contain toxic or hazardous substances such as insecticides, pesticides, formaldehydes etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Others (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**[C] PHARMACEUTICAL DOSAGE FORM OF PRODUCTS
MANUFACTURED / ASSEMBLED**

	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 injectables 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"/> 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"/>

	Manufacture	Primary Assembly	Secondary Assembly
<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] KEY PERSONNEL INFORMATION

D1. Person in charge of production and /or assembly.

Production:

Name:
(IN BLOCK LETTERS)

National Identification Number/Passport No.:

Designation: Directly reporting to:
(Position)

No. of years of relevant experience:

Assembly:

Name:
(IN BLOCK LETTERS)

National Identification Number/Passport No.:

Designation: Directly reporting to:
(Position)

No. of years of relevant experience:

D2. Person in charge of quality control and/or quality assurance.

Quality Control:

Name:
(IN BLOCK LETTERS)

National Identification Number/Passport No.:

Designation: Directly reporting to:
(Position)

No. of years of relevant experience:

Quality assurance:

Name:
(IN BLOCK LETTERS)

National Identification Number/Passport No.:

Designation: Directly reporting to:
(Position)

No. of years of relevant experience:

D3. Person who authorises the release of products

Name:
(IN BLOCK LETTERS)

National Identification Number/Passport No:

Designation: Directly reporting to:
(Position)

No. of years of relevant experience:

[E] CONTRACT MANUFACTURER/ASSEMBLER INFORMATION

Contract manufacturer Contract Assembler

The contractors refer to those engaged by the overseas manufacturer. If there is more than one contractor, please specify all the contractors and provide all the relevant details as required below

E1. Name of Company:
(IN BLOCK LETTERS)

Company address:.....

.....

.....

Tel No.: Fax No.:

Official email address:

E2. Manufacturing/ Assembling Site

Address:

.....

.....

Tel No.: Fax No.:

Official email address:

E3. Scope of Manufacturing / Assembling Activities (please specify):

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[F] CONTRACT TESTING LABORATORY INFORMATION

Please state NIL if your company does not engage the services of any contract testing laboratories.

If there is more than one contract testing laboratory, please specify all the contract testing laboratories and provide all the relevant details as required below.

F1. Name of testing laboratory:
(IN BLOCK LETTERS)

.....

Address:

.....

.....

Tel No.: Fax No.:

Official email address:.....

F2. Types of analytical tests performed:

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F3. Is the contract testing laboratories accredited to ISO/IEC 17025 or other quality system standards? If so, please specify the standard and the scope of accreditation. Please attach the certificate of accreditation.

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All applicants under the Medicines Act (MA) / Health Products Act (HPA) must comply with the MA/HPA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

[G] 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 :

