HEALTH SCIENCES AUTHORITY

NOTES ON APPLICATION FORM TO REQUEST FOR AN OVERSEAS GMP AUDIT

This form may take you 20 minutes to fill in.
You will need the following information to fill in the form:

a) Quality System Dossier or Site Master File, in English
b) Details of overseas manufacturing site

1. This application form is for requesting an overseas GMP audit. If this is the first time application, the completed application form and the Quality System Dossiers (QSD), otherwise, just the completed application form should be submitted to the Therapeutic Products Branch (TPB) at the address listed at paragraph 6.

2. The application should be made by a Singapore registered firm/company who should authorise a responsible person (e.g. Managing Director, Pharmacist, Regulatory Personnel) to request for an overseas GMP audit. This person must have an Account and Corporate Regulatory Authority of Singapore (ACRA) account.

3. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable. Incomplete information may cause unnecessary delay in processing the application.

4. If the space provided in the application form is insufficient, a separate sheet (A4 size) may be used. However, proper enclosure numbers should be made at the top right hand corner of such extension sheets.

5. All enclosures should be listed in the “List of Enclosures” provided, with the enclosure numbers corresponding to those in the columns of the application form.

6. The complete application form and QSD must be sent to:

Therapeutic Products Branch (TPB)
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667

7. Mode of Payment:

   Please note that there will be no refund of any payment made in relation to applications submitted.

   The mode of payment available is as follows:

   - Non-GIRO: eNETS (Credit/Debit Card)
   - GIRO

   Payment by GIRO requires pre-registration. The GIRO application form is required to be submitted by post to the HSA Finance Department. The correspondence address can be found in the application form. The registration process will take around 3 to 4 weeks after the submission of the application form.

8. Useful links:

   For more details on Services Charges, please refer to:
   https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_of_Manufacturers/GMP_Conformity_Assessment/Service_Charges.html

   For more details on GMP Conformity Assessment of an Overseas Manufacturer, please refer to:
   https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_of_Manufacturers/GMP_Conformity_Assessment/Guidance_Documents.htm

   For information on Guidance Documents for Industry and Applicants, please refer to:
   http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Guidance_Documents_for_Industry_and_Applicants.html

9. Manufacturers that have been previously audited by HSA are only required to submit the application form together with the updated site master file for assessment by HSA.
   Submission of QSD is not required under normal circumstances unless there is a major difference in the manufacturing operations that was audited previously by HSA.
   Service charge for the overseas re-audit should be made at the point of application submission.
   The submission of the application form and site master file should be made at the following address:

Audit & Licensing Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01, Helios,
Singapore 138667

HEALTH SCIENCES AUTHORITY

REPUBLIC OF SINGAPORE

APPLICATION FORM TO REQUEST FOR AN OVERSEAS GMP AUDIT

Please read the Notes on Application Form for Requesting an Overseas GMP Audit before filling up this form.

**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.: ……
(Enclose 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
(Enclose copy of approval)

B4. Manufacturer Licence No. (*If applicable*): ……..
(Enclose 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
☐	Penicillins or Cephalosporins	☐	☐	☐
☐	Cytotoxics or Anti-cancer preparations	☐	☐	☐
☐	Hormones	☐	☐	☐
☐	Steroids	☐	☐	☐
☐	Biologicals (e.g. vaccines, blood products, biotechnology products, preparations containing micro-organisms)	☐	☐	☐
☐	Non-medicinal products that contain toxic or hazardous substances such as insecticides, pesticides, formaldehydes etc.)	☐	☐	☐
☐	Others (please specify):	☐	☐	☐

[C] PHARMACEUTICAL DOSAGE FORM OF PRODUCTS MANUFACTURED / ASSEMBLED

		Manufacture	Primary Assembly	Secondary Assembly
☐	Injection	☐	☐	☐
☐	Admixtures for intravenous infusion	☐	☐	☐
☐	Reconstituted cytotoxic preparations	☐	☐	☐
☐	Total parenteral nutrition preparations	☐	☐	☐
☐	Implants	☐	☐	☐
☐	Sterile powder for injection	☐	☐	☐
☐	Sterile non injectables liquid preparation	☐	☐	☐
☐	Liquid preparations for inhalation	☐	☐	☐
☐	Sterile semi-solid preparations	☐	☐	☐
☐	Sterile powder for irrigations	☐	☐	☐
☐	Sterile powder for topical application	☐	☐	☐
☐	Intraocular drug delivery systems	☐	☐	☐
☐	Sterile strips	☐	☐	☐
☐	Oral liquid preparations	☐	☐	☐
☐	Tablets for oral administration	☐	☐	☐
☐	Soft Capsules	☐	☐	☐
☐	Hard Capsules	☐	☐	☐
☐	Pills	☐	☐	☐
☐	Powders and granules for oral liquid preparations	☐	☐	☐
☐	Oral powder and granules	☐	☐	☐
☐	Pastille	☐	☐	☐
☐	External liquid preparations	☐	☐	☐
☐	Ear drops	☐	☐	☐
☐	Nasal solution	☐	☐	☐
☐	Foams	☐	☐	☐
☐	Heamodialysis solution	☐	☐	☐
☐	Non-sterile semi-solid preparations	☐	☐	☐
☐	Non sterile powders for topical applications	☐	☐	☐
☐	Powder for haemodialysis	☐	☐	☐
☐	Powder Prepartions for inhalation	☐	☐	☐
☐	Suppositories	☐	☐	☐
☐	Pessaries	☐	☐	☐
☐	Medicated soap bars	☐	☐	☐
☐	Transdermal patches	☐	☐	☐
☐	Medicated gums	☐	☐	☐
☐	Tablet for external administration	☐	☐	☐
☐	Beads	☐	☐	☐
☐	Medicated Tampons	☐	☐	☐
☐	Solution for contact lens	☐	☐	☐
		Manufacture	**Primary Assembly**	**Secondary Assembly**

☐	Dry powder inhalers	☐	☐	☐
☐	Medicinal gases	☐	☐	☐
☐	Others (please specify):	☐	☐	☐

[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):

……

……

……

[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: …………………………………….

……………………………………………………………….……………

………………………………………………………………………..……...

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.

………..……………………………………………………………………

……………………………………………………………………………

..…………………………………………………………..…………………

…………………………………………………………………………….

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, I and my company may be liable to prosecution.

Name of Applicant : ……

Signature : ……

Date : ……

LIST OF ENCLOSURES

S/N.	Nature of Enclosure	Document Reference Number

Remarks: To be routed to Overseas Audit Unit of Audit and Licensing Division for assessment.