HEALTH SCIENCES AUTHORITY

NOTES ON APPLICATION FORM FOR LETTER ON STATUS OF GMP COMPLIANCE FOR HUMAN CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

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

a) ACRA document for locally registered company
b) Details of manufacturing premise
c) Site Master File

1. This application form is to request for a GMP conformity assessment for the manufacture of Human Cell, Tissue and Gene Therapy Products in Singapore.

2. The application should be made by a Singapore registered firm/company who should authorise a responsible person (e.g. Managing Director, Regulatory Personnel) to submit the application.

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. A site master file for the manufacturing premise should be prepared and submitted together with the completed application form. Please refer to PIC/S PE 008-4 Explanatory Notes for Pharmaceutical Manufacturers On The Preparation Of A Site Master File, which is available at:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Guidance_Documents_for_Industry_and_Applicants.html.

6. 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.

7. The complete application form must be sent to:

AUDIT & LICENSING DIVISION
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01 Helios
Singapore 138667

Note: The first page is to be detached when submitting the application form.

FOR OFFICIAL USE ONLY
Application No.

Company Code

HEALTH SCIENCES AUTHORITY

APPLICATION FORM FOR LETTER ON STATUS OF GMP COMPLIANCE FOR HUMAN CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

Please read the Notes on Application Form For Letter on Status of GMP Compliance For Human Cell, Tissue And Gene Therapy Products (CTGTP) before filling up this form.

**Delete where applicable*
☑*Tick where applicable*

[A] COMPANY PARTICULARS

A1. Name of company: ……
(*IN BLOCK LETTERS*)
……

Address: ……

……

…… Level: …… Unit: ……

Postal Code: ……

Tel No.: …… Fax No.: ……

Official email address: ……

Company Registration No.: ……
(Enclose photocopy of certificate)

Billing Address (*if different from above*):

Address: ……

……

…… Level: …… Unit ……

Postal Code: ……

[B] APPLICANT PARTICULARS

B1. 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: ……

Residential address: ……..……..

……..……..……..……..…… Level: ……. Unit: ……

Postal Code: ……..……..……

Tel No.: ……..……..…… Fax No.: ……..……..….

Official Email Address: ……..……..……..…

Preferred contact mode: ☐ Email / ☐ Fax *
(Please ensure that the relevant details above is entered for your preferred contact mode)

[C] MANUFACTURER DETAILS
(If there is more than one manufacturing facility, please specify all the facilities, and provide all the relevant details as required below in a separate sheet.):

C1. Address: ……..……..……..……

……..……..……

……..……..……Level: ……. Unit: ……

Postal Code: ……..……..……...

C2 Product Description: ……..……..……..……..

……..……..……...

……..……..……...

C3. State if any of the following categories of products are manufactured in the same site:

	Categories	Manufacture	Dedicated facilities
☐	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):	☐	☐

[D] WAREHOUSE INFORMATION

(If there is more than one warehouse, please specify all the warehouses, and provide all the relevant details as required below in a separate sheet.):

D1. Warehouse Address (*if different from manufacturing/assembly site*):

……..……

……..……Level: …… Unit: ……

Postal Code: ……...

D2. Storage Condition of the warehouse

Temperature:

☐ 15°C to 30°C

☐ 8°C to 15°C

☐ 2°C to 8°C

☐ -10°C to -20°C

☐ Below -20°C

☐ Others (please specify) ……°C to ……°C

Relative Humidity: ……% to ……%

[E] CONTRACT TESTING LABORATORY

(If there is more than one contract testing laboratory, please specify all the laboratories, and provide all the relevant details as required below in a separate sheet.):

E1. Name of company: ……..……..…. (*IN BLOCK LETTERS*)

……..……..……..

Address: ……..……..……..……

……..……

……..……..……..…… Level: ……..…… Unit: ……

Postal Code: ……..……..……

Tel No.: ……..……..…… Fax No.: ……..……..….

E2. Type of analytical tests performed:

……

……

……

E3. 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.

……

……

[F] KEYPERSONNELINFORMATION

F1. Person in charge of production.

Name (*Mr/Ms/Mrs/Mdm/Dr): ……..…...

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

Designation: ……..……..

Directly reporting to: ……..……..……
(Position)

No. of years of relevant experience: ……..……

F2. Person in charge of quality control/quality assurance.

Name (*Mr/Ms/Mrs/Mdm/Dr): ……..…...

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

Designation: ……..……..

Directly reporting to: ……..……..……
(Position)

No. of years of relevant experience: ……..……

[G] APPLICANT DECLARATION

1. I, ……..……..., in my capacity as ……..……..
(name of person making the declaration) *(designation in company)*

of ……...……., have been duly authorised by my
(company name)
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.

Signature : ……

Name : ……

Date : ……

LIST OF ENCLOSURES

Enclosure No.	Nature of Enclosure	For Official Use Only

AUDIT & LICENSING DIVISION
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667

TERMS AND CONDITIONS

Thank you for your interest in seeking GMP conformity assessment for the manufacture of Human Cell, Tissue and Gene Therapy Products (CTGTP) from HSA. In addition to the application form, please go through the following terms and conditions, sign it and submit it together with the completed application form to the Audit & Licensing Division, Health Products Regulation Group, Health Sciences Authority.

1. The request for GMP conformity assessment is accepted based on the information provided by you in the application form entitled "Application Form For Letter On Status Of GMP Compliance For the manufacture of Human Cell, Tissue and Gene Therapy Products". The Audit & Licensing Division reserves the right not to carry out or continue the GMP audit, or to withhold the issuance of the letter attesting to the GMP compliance status of the manufacturing site, or to withdraw the attestation letter so issued, if and where applicable, in the event that any error or inaccuracy, even if unintentionally made, is found in the information provided by you in the application form.
2. Audit & Licensing Division reserves the right with three (3) working days prior written notice to discontinue the GMP audit or withhold the issuance of the letter attesting to the GMP compliance status of the manufacturing site if any information furnished or to be furnished is false or lacking or for any reason whatsoever.
3. Payment in advance for the application fees for the GMP conformity assessment is required. Except where the GMP audit is discontinued or the letter attesting to the GMP compliance status of the manufacturing site is not issued due to your default such that no refund is applicable, Audit & Licensing Division will refund your fees in full in the event of discontinuance of the GMP audit or non-issuance of the letter attesting to the GMP compliance status of the manufacturing site for any other reason.
4. Audit & Licensing Division reserves the right to include external specialist, including auditor(s)/inspector(s) from Ministry of Health and/or overseas regulatory agencies in the audit team for the GMP audit.
5. The attestation letter is a statement of the manufacturing quality system standard of the manufacturer but is not an endorsement of the quality of the product(s) nor the approval of the product(s) manufactured. For any human cell and tissue-based therapeutic products manufactured for commercial supply in Singapore, separate product licence approval will be required from the Health Products Regulation Group of the Health Sciences Authority.
6. The holder of the attestation letter shall not use the letter for any advertising purposes.
7. The Audit & Licensing Division shall under no circumstances be liable to you or your agents, servants or representatives, in contract, tort (including negligence or breach of statutory duty) or otherwise for any direct or indirect loss or damage suffered by you, your agents, servants or representatives howsoever arising, irrespective of its connection with the service provided by the Audit & Licensing Division herein and regardless of whether the Audit & Licensing Division has advised the possibility of such loss or damage.
8. It is the onus on your company to ensure the operation in the premise is in compliance with other applicable legislative and regulatory requirements.

We agree to abide by the Terms and Conditions above.

Signature : ……

Name : ……

Date : ……

PAYMENT ADVICE

The total payment for your application is SGD$6,180.00 (inclusive of GST).

Please indicate the payment mode (tick where appropriate):

☐ Existing **GIRO** Client *(Your bank account will be deducted accordingly)*

☐ For clients not on GIRO payment *(please tick one of the below options)*

CREDIT CARD *(please tick Visa or Mastercard)*

☐ Visa ☐ Mastercard

Name of Cardholder: _____

Card Expiry Date: _____

Card No: _____

Charge Amount: SGD _____

(Amount Payable: SGD$6,180.00)