APPLICATION FOR GMP CONFORMITY ASSESSMENT VIA GMP INSPECTION OF AN OVERSEAS MANUFACTURER OF CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

NOTES:

1. Your company must have a CRIS account with HSA and obtain a client code in order to submit this application.

2. This application form is intended for a local sponsor to apply for a Good Manufacturing Practice (GMP) inspection of an overseas manufacturer in support of CTGTP registration in Singapore.

3. Each application form is intended for one applicable overseas manufacturing site. Separate forms are to be submitted if there are multiple overseas manufacturing sites even if it is the same manufacturer.

4. The form should be completed by the applicant who is authorised by the company. The applicant will be the point of contact for all matters related to this application.

5. This form may take you 30 minutes to fill in. You will need the following information to fill in the form:
    a. Local Sponsor Information
    b. Information on overseas manufacturing premise, operations, outsourced activities, key personnel
    c. Supporting documents (refer to Section 8)

6. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable.

7. If the space provided in any section of this form is insufficient, the information pertaining to the affected section(s) may be submitted as an attachment together with this completed form as a PDF document. Please indicate the section numbers clearly in the attachment for ease of reference.

8. This completed form with its relevant supporting documents should be submitted to the Advanced Therapeutic Product Branch (ATPB) as part of the submission for CTGTP product registration.

APPLICATION FOR GMP CONFORMITY ASSESSMENT VIA GMP INSPECTION OF AN OVERSEAS MANUFACTURER OF CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

Name of CTGTP Product:	

Information of Overseas Manufacturer Site	
Name of Manufacturer Site:	
Address of Manufacturer Site:	_____ _____ _____ _____

Type of Manufacturer

(Select, wherever applicable)

- ☐ CTGTP Finished Product Manufacturer
- ☐ Active Substance Manufacturer used in manufacture of CTGTP
- ☐ CTGTP Starting Materials Manufacturer such as Viral Vector Manufacture used in the manufacture of CTGTP
- ☐ Others (*Please specify)*: _____

Responsible Activities / Manufacturing Processes

(Select, wherever applicable)

- ☐ Manufacture of Fully Packaged Finished Product
- ☐ Bulk Production (Prior to Secondary Packaging)
- ☐ Bulk Production (Prior to Sterile Filling)
- ☐ Partial Bulk Production (e.g. one or more specific manufacturing stage(s)) (*Please provide details of the manufacturing stage(s)*): _____
- ☐ Sterilisation and/or Sterile Filling only
- ☐ Manufacture of Critical Starting Materials such as Viral Vector
- ☐ Manufacture of API only
- ☐ Secondary Packager Only
- ☐ Others (*Please specify)*: _____

Section 1 - Company Information (Local Sponsor)	
1.1 Name of Company:	
1.2 UEN and Client Code:	
1.3 Company Address	
1.3.1 Postal Code:	
1.3.2 Block/House No.:	
1.3.3 Level – Unit:	
1.3.4 Street Name:	
1.4.5 Building Name:	
1.4 Billing Address *(if different from Company Address)*	
1.4.1 Postal Code:	
1.4.2 Block/House No.:	
1.4.3 Level – Unit:	
1.4.4 Street Name:	
1.4.5 Building Name:	
Section 2 - Applicant Information (Local Sponsor)	
2.1 Name (Mr/Ms/Mrs/Mdm/Dr):	
2.2 Designation:	
2.3 Contact Number:	
2.4 Contact Email Address:	
Section 3 - Overseas Manufacturer Information	
3.1 Name of Overseas Manufacturer:	
3.2 Overseas Manufacturing Site Address	
3.2.1 Postal Code:	
3.2.2 Block/House No:	
3.2.3 Level – Unit:	

3.2.4 Street Name:	
3.2.5 Building Name:	
3.2.6 Country:	
3.2.7 Contact Email Address:	
3.2.8 Contact number:	

3.3 Additional Manufacturing Site Address (*if different from above*)

(Please include additional field for each address if there are more than one)

☐ QC Only

☐ Warehouse Storage and Handling Only

☐ Not applicable

3.3.1 Postal Code:	
3.3.2 Block/House No:	
3.3.3 Level – Unit:	
3.3.4 Street Name:	
3.3.5 Building Name:	
3.3.6 Country:	

3.4 Storage Condition (For Storage and Handling site only)

3.4.1 Temperature:

☐ Non-cold chain (> 8°C)

☐ Cold chain (≤ 8°C)

☐ Cryogenic storage temperature _____°C

3.4.2 Relative Humidity: Min% - Max%: _____

3.4.3 Other Storage Conditions: _____

Section 4 - Check on Submission Requirements

4.1 Is there a latest valid documentary GMP evidence such as GMP certificate issued by PIC/S member authority)?

(List of PIC/S member authorities is accessible at https://www.picscheme.org/)

☐ Yes (Please submit the Application Form for GMP DEVA for CTGTP instead of this form)

☐ No (Please proceed with Section 4.2)

4.2 Is this the first request for GMP on site inspection by HSA for this overseas manufacturer?

☐ Yes, please submit Quality System Dossier (QSD) with this completed form. Refer to Section 8 for details

Section 5 - Manufacturing Operations

5.1 Manufacturing process:

Type of dosage form	Aseptically prepared
Large volume liquids (>100 ml/unit)	☐
Semi-solids	☐
Small volume liquids (≤100 ml/unit)	☐
Solids and implants	☐
Others (please specify): _____	☐

5.2 Type of CTGTP manufactured:

☐ Cell or tissue therapy product

☐ Gene therapy product

☐ CTGTP combined with a therapeutic product or a medical device

☐ Active Substance (please specify: _____)

☐ Critical Starting Material (please specify: _____)

☐ Others e.g., please specify:

_____

5.3 Packaging:

☐ Secondary packaging

5.4 Quality Control Testing:

☐ Chemical / Physical

☐ Microbiological

☐ Biological

☐ Not applicable

5.5 Other manufacturing activities

- ☐ Manufacture of starting materials
- ☐ Manufacture of active substances
- ☐ Manufacture of products other than CTGTP
- ☐ Manufacture involving viral vectors or viruses
- ☐ Manufacture of pathogenic organisms (biosafety level 3 and 4)
- ☐ Sterilisation of active substances/starting materials/finished product
- ☐ Others: _____
- ☐ Not applicable

5.6 Batch Release

Is the manufacturer responsible for performing the final batch release (including release testing of products or approving or certifying the batch for release)?

☐ Yes ☐ No, Clarifying remarks (if any): _____

5.7 Sterilisation of starting materials, active substances and finished products:

☐ Filtration	☐ Gamma irradiation
☐ Dry heat	☐ Others (please specify):
☐ Moist heat	……
☐ Chemical	☐ Not applicable
☐ Electron beam	

6. Outsourced activities

- ☐ Manufacturing *(fill in section 6.1)*
- ☐ Warehouse *(fill in section 6.2)*
- ☐ QC testing *(fill in section 6.3)*
- ☐ None

Are written contracts or quality agreements with all outsourced sites in place?

☐ Yes (Attach in Section 7) ☐ No

If No, please explain why:

_____

_____

_____

6.1 Contract Manufacturer Particulars *(attach additional sheets if necessary)*	
6.1.2 Name of contract manufacturer:	
6.1.2 Name of contract manufacturer:	
6.1.3 Name of contract manufacturer:	
6.1.4 Name of contract manufacturer:	
6.2 Contract Warehouse Particulars *(attach additional sheets if necessary)*	
6.2.1 Name of contract warehouse:	
6.2.2 Address of contract warehouse	
6.2.2.1 Postal Code:	
6.2.2.2 Block/House No:	
6.2.2.3 Level – Unit:	
6.2.2.4 Street Name:	
6.2.2.5 Building Name:	
6.2.2.6 Country:	
6.2.2.7 Contact Email Address:	
6.2.2.8 Contact Number:	

6.2.3 Storage Condition:

6.2.3.1 Temperature:

- ☐ Non-cold chain (> 8°C)
- ☐ Cold chain (≤ 8°C)
- ☐ Cryogenic storage temperature _____ °C

6.2.3.2 Relative Humidity: Min% - Max% _____

6.2.3.3 Other Storage Conditions: _____

6.3 Contract Testing Laboratory Particulars *(attach additional sheets if necessary)*	
6.3.1 Name of contract testing laboratory:	
6.3.2 Address of contract testing laboratory	
6.3.2.1 Postal Code:	
6.3.2.2 Block/House No:	
6.3.2.3 Level – Unit:	
6.3.2.4 Street Name:	
6.3.2.5 Building Name:	
6.3.2.6 Country:	
6.3.2.7 Contact Email Address:	
6.3.2.8 Contact Number:	

6.3.3 Testing activities outsourced to contract testing laboratory

Testing activity	**Type of Test performed**
☐ Finished product testing including in-process testing for batch release	☐ Chemical / Physical ☐ Microbiological ☐ Biological
☐ Starting materials testing	☐ Chemical / Physical ☐ Microbiological ☐ Biological
☐ Stability testing on finished products or active substance or starting materials	☐ Chemical / Physical ☐ Microbiological ☐ Biological
☐ Others, e.g. environmental monitoring for sterile manufacturing, identification of microorganisms (please state below): _____ _____ _____	☐ Chemical / Physical ☐ Microbiological ☐ Biological

Section 7 - Particulars of Key Personnel	
7.1 Person in-charge of Production	
7.1.1 Name:	
7.1.2 Designation:	
7.1.3 Directly reporting to:	
7.1.4 Contact Email or Number:	
7.1.5 Number of Years of Relevant Experience:	
7.1.6 Qualifications (relevant to this application):	
7.2 Person in-charge of Quality Control and/or Quality Assurance	
7.2.1 Name:	
7.2.2 Designation:	
7.2.3 Directly reporting to:	
7.2.4 Contact Email or Number:	
7.2.5 Number of Years of Relevant Experience:	
7.2.6 Qualifications (relevant to this application):	
7.3 Person in-charge of the Authorisation for the Release of Products	
7.3.1 Name:	
7.3.2 Designation:	
7.3.3 Directly reporting to:	
7.3.4 Contact Email or Number:	
7.3.5 Number of Years of Relevant Experience:	
7.3.6 Qualifications (relevant to this application):	

Section 8 - Supporting Documents	
The following documents (whenever applicable) should be submitted with this completed form. Please tick the checkboxes below to confirm the information and supporting documents have been included with this form.	
☐ Submitted	Quality System Dossier (QSD) *(QSD submission is applicable for the first application for GMP on-site audit by HSA for the overseas manufacturer.)* Note: On-site GMP audit will only be initiated if the outcome of the evaluation of the QSD is deemed satisfactory
☐ Submitted ☐ N/A	Other supporting documents. Please specify _____

Section 9 - Declaration	
☐ I, on behalf of my company, confirm that the information submitted in this application is true and accurate. ☐ I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.	
Name of Applicant:	Signature and Date:

Application Fee

GMP On-Site Inspection of an Overseas CTGTP Manufacturer	$31,500

An invoice for the applicable fee will be sent to the company. For companies on the GIRO scheme, the fee will be deducted from the GIRO-linked bank account. For companies not on the GIRO scheme, the fee can be made by bank transfer. More information will be provided on the invoice.