APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) MANUFACTURER'S LICENCE OR GMP CERTIFICATE

NOTES:

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

2. This 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.

3. This form may take you 30 minutes to fill in. You will need the following information to fill in the form:
   a. Company and applicant details
   b. Particulars on licence type, manufacturing operations, premises, activities outsourced, responsible persons
   c. Supporting documents (see section 8)

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

5. 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.

6. A site master file is one of the supporting documents required for this application. Please refer to the PIC/S PE 008-4 Explanatory Notes for Pharmaceutical Manufacturers On The Preparation Of A Site Master File.

7. This completed form with its relevant supporting documents should be submitted as an attachment in the online FormSG - CTGTP Dealer's Submission. Corppass is required to access this FormSG. For more information, please visit the Corppass website. If the company intends to apply for both Manufacturer Licence and GMP Certificate for the same site, please submit this completed application form in separate FormSG submissions, respectively.

APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) MANUFACTURER'S LICENCE OR GMP CERTIFICATE

Please select the applicable one ○ MANUFACTURER'S LICENCE ○ GMP CERTIFICATE	
Section 1 - Company Particulars	
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 Particulars	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact No.:	
2.4 Official Email address:	

Section 3 - Scope

3.1 Application for Manufacturer's Licence (☐ Not Applicable)

- ☐ Finished product
- ☐ Bulk product
- ☐ Secondary packaging only

3.2 Application for GMP Certification: (☐ Not Applicable)

- ☐ Investigational CTGTP Finished product
- ☐ Investigational CTGTP Bulk product
- ☐ Active substances used in the manufacture of CTGTP
- ☐ Starting materials used in the manufacture of CTGTP
- ☐ Secondary packaging only

Section 4 - Manufacturing Operations

(Manufacturers conducting secondary packaging only do not need to fill in this Section)

4.1 Type of Product(s):

- ☐ Cell or tissue therapy product
- ☐ Gene therapy product
- ☐ CTGTP combined with a therapeutic product or a medical device
- ☐ Active substances, please specify: _____
- ☐ Starting materials, please specify: _____
- ☐ Others, please specify: _____

4.2 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	☐

Other remarks:

_____

_____

_____

4.3 Packaging:

☐ Secondary packaging

4.4 Quality Control Testing:

☐ Chemical / Physical

☐ Microbiological

☐ Biological

☐ Not applicable

4.5 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

Section 5 - Particulars on Premises *(attach separate sheet if necessary)*

5.1 Manufacturing Site Address

5.1.1 Postal Code:	
5.1.2 Block/House No:	
5.1.3 Level – Unit:	
5.1.4 Street Name:	
5.1.5 Building Name:	

5.2 Other Manufacturing Site Address

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

☐ QC Only

☐ Storage and Handling Only

☐ Not applicable

5.2.1 Postal Code:	
5.2.2 Block/House No:	
5.2.3 Level – Unit:	
5.2.4 Street Name:	
5.2.5 Building Name:	

5.3 Storage Condition	
5.3.1 Temperature: ☐ Non cold chain (> 8°C) ☐ Cold chain (≤ 8°C) ☐ Cryogenic storage temperature _____°C	
5.3.2 Relative Humidity:	Min%_____ to Max%_____
5.3.3 Other Storage Conditions:	
Section 6 - Outsourced Activities	
☐ Manufacturing *(fill in section 6.1)* ☐ Warehousing *(fill in section 6.2)* ☐ QC testing *(fill in section 6.3)* ☐ None of the above	
Are written contracts or quality agreements with all outsourced sites in place? ☐ Yes *(Attach in Section 8)* ☐ No If No, please explain why: _____ _____	
6.1 Contract Manufacturer Particulars *(attach additional sheets if necessary)*	
6.1.1 Name of Contract Manufacturer:	
6.1.2 Address of Contract Manufacturer	
6.1.2.1 Postal Code:	
6.1.2.2 Block/House No:	
6.1.2.3 Level – Unit:	
6.1.2.4 Street Name:	
6.1.2.5 Building Name:	
6.1.2.6 Country:	
6.1.2.7 Contact Email Address:	
6.1.2.8 Contact Number:	

6.1.3 Manufacturing Activities Outsourced to Contract Manufacturer

(a) Manufacturing Processes:

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): _____	☐

(b) Sterilisation of Starting Materials, Active Substances and Finished Products:

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

(c) Packaging:

☐ Secondary packaging

(d) Quality Control Testing:

☐ Chemical / Physical

☐ Microbiological

☐ Biological

☐ Not applicable

(e) 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)

_____

_____

_____

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%_____ to 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(s) 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 substances 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 Responsible Persons	
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:	
7.2 Person in-charge of Quality Operations	
7.2.1 Name:	
7.2.2 Designation:	
7.2.3 Directly reporting to:	
7.2.4 Contact Email or Number:	

Section 8 - Supporting Documents

- ☐ Site Master File (in accordance with the PIC/S Guidance for Site Master File)
- ☐ Written contract / Quality Agreement with contract acceptor for laboratory, manufacturer and/or warehouse
- ☐ A latest copy (valid within 3 years assessment) of the certificate or report that indicates the contract acceptor complies with relevant quality system standard (i.e. GMP, GDP, ISO 17025) for the specific outsourced activities
- ☐ *Curriculum Vitae* (CV) of all responsible persons
- ☐ Others e.g. CMC (chemistry, manufacturing and control) of active substance and/or product

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

Manufacturer's Licence – Scope of Activities	**Fee**
Manufacture of Bulk and/or Finished Product	$22,000
Secondary Packaging Only	$10,600
GMP Certificate with Technical Assessment (including site inspection)	$22,000

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.