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

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 the amendment of licence type, manufacturing operations, premises, activities outsourced, responsible persons
   c. Supporting documents (see section 8)

4. You may amend your company's information in order to change particulars such as company name and address, provided there is no change to the company's Unique Entity Number (UEN). For change in UEN, you will need to apply for a new CRIS account and thereafter submit a new application. If the new Manufacturer Licence application is meant to replace the existing licence issued under old UEN, please also submit a cancellation application for the existing licence.

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

6. 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.

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.

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

Section 1 - Company Particulars	
☐ No change (skip whole of Section 1) ☐ Amendment (complete the details below)	
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:	
1.3.5 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	
☐ No change (skip whole of Section 2) ☐ Amendment (complete the details below)	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact No.:	
2.4 Official Email address:	

Section 3 - Scope of Licence

☐ No change (skip whole of Section 3)

☐ Amendment (complete the details below)

☐	Finished product	☐ Addition	☐ Removal
☐	Bulk product	☐ Addition	☐ Removal
☐	Secondary packaging only	☐ Addition	☐ Removal

Section 4 - Manufacturing Operations

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

☐ No change (skip whole of Section 4)

☐ Amendment (complete the details below)

4.1 Manufacturing Process:

☐ No change (skip Section 4.1)

☐ Amendment (complete the details below)

Type of dosage form	Aseptically prepared	Amendment
Large volume liquids (>100 ml/unit)	☐	☐ Addition ☐ Removal
Semi-solids	☐	☐ Addition ☐ Removal
Small volume liquids (≤100 ml/unit)	☐	☐ Addition ☐ Removal
Solids and implants	☐	☐ Addition ☐ Removal

Other remarks:

4.2 Type of CTGTP:

☐ No change (skip Section 4.2)

☐ Amendment (complete the details below)

☐ Cell or tissue therapy product	☐ Addition	☐ Removal
☐ Gene therapy product	☐ Addition	☐ Removal
☐ CTGTP combined with a therapeutic product or a medical device	☐ Addition	☐ Removal
☐ Others e.g., please specify: _____	☐ Addition	☐ Removal

4.3 Packaging:

☐ No change (skip Section 4.3) ☐ Addition ☐ Removal

☐ Secondary packaging

4.4 Quality Control Testing:

☐ No change (skip Section 4.4)

☐ Amendment (complete the details below)

☐ Chemical / Physical	☐ Addition	☐ Removal
☐ Microbiological	☐ Addition	☐ Removal
☐ Biological	☐ Addition	☐ Removal
☐ Not applicable	☐ Addition	☐ Removal

4.5 Other Manufacturing Activities:

☐ No change (skip Section 4.5)

☐ Amendment (complete the details below)

☐ Manufacture of starting materials	☐ Addition	☐ Removal
☐ Manufacture of active substances	☐ Addition	☐ Removal
☐ Manufacture of products other than CTGTP	☐ Addition	☐ Removal
☐ Manufacture involving viral vectors or viruses	☐ Addition	☐ Removal
☐ Manufacture of pathogenic organisms (biosafety level 3 and 4)	☐ Addition	☐ Removal
☐ Sterilisation of active substances/starting materials/finished product	☐ Addition	☐ Removal
☐ Others: _____	☐ Addition	☐ Removal

☐ Not applicable

Section 5 - Particulars on Premises *(attach separate sheet if necessary)*	
☐ No change (skip whole of section 5) ☐ Amendment (complete the details below)	
5.1 Manufacturing Site Address ☐ No change (skip Section 5.1) ☐ Amendment (complete the details below)	
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 ☐ No change (skip Section 5.2) ☐ Amendment (complete the details below) *(Please include additional field for each address if there are more than one)* ☐ QC Only ☐ Addition ☐ Removal ☐ Storage and Handling Only ☐ Addition ☐ Removal ☐ 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: ☐ No change (skip Section 5.3) ☐ Amendment (complete the details below)	
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

☐ No change (skip Whole of Section 6)
☐ Amendment (complete the details below)
☐ Manufacturing *(fill in section 6.1)* ☐ Addition ☐ Removal
☐ Warehousing *(fill in section 6.2)* ☐ Addition ☐ Removal
☐ QC testing *(fill in section 6.3)* ☐ Addition ☐ Removal
☐ 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)*

☐ No change (skip Section 6.1)
☐ Amendment (complete the details below)

6.1.1 Name of Contract Manufacturer:	☐ Addition ☐ Removal ☐ Change of activities _____
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:

☐ No change (skip Section 6.1.2)

☐ Amendment (complete the details below)

(a) Manufacturing processes:

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

(b) Sterilisation of starting materials, active substances and finished products:

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

(c) Packaging:

☐ No change ☐ Amendment (complete the details below)

☐ Secondary packaging ☐ Addition ☐ Removal

(d) Quality Control Testing:

☐ No change ☐ Amendment (complete the details below)

☐ Chemical / Physical ☐ Addition ☐ Removal

☐ Microbiological ☐ Addition ☐ Removal

☐ Biological ☐ Addition ☐ Removal

☐ Not applicable ☐ Addition ☐ Removal

(e) Batch Release

☐ No change ☐ Addition ☐ Removal

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) ☐ No change (skip Section 6.2) ☐ Amendment (complete the details below)	
6.2.1 Name of Contract Warehouse:	☐ Addition ☐ Removal ☐ Change of activities _____
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: ☐ No change (skip Section 6.2.3) ☐ Amendment (complete the details below) 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)*

☐ No change (skip Section 6.3)

☐ Amendment (complete the details below)

6.3.1 Name of Contract Testing Laboratory:	☐ Addition ☐ Removal ☐ Change of activities _____
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

☐ No change (skip Section 6.3.3)

☐ Amendment (complete the details below)

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

Section 7 - Particulars of Responsible Persons	
☐ No change (skip Whole of Section 7) ☐ Amendment (complete the details below)	
7.1 Person in-charge of Production ☐ No change (skip Section 7.1) ☐ Amendment (complete the details below)	
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 ☐ No change (skip Section 7.2) ☐ Amendment (complete the details below)	
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 (for applicable changes)
☐ Site Master File (in accordance with the PIC/S Guidance for Site Master File)
☐ Written contract / Quality Agreement with contract acceptor
☐ 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
☐ Other supporting documents 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

Scope of Manufacturing Activities	Type of Amendment	Fee
Manufacture of Bulk and/or Finished Product	Without technical assessment	$ 180
	With technical assessment	$ 5,100
Secondary Packaging Only	Without technical assessment	$ 180
	With technical assessment	$ 2,700

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.