



## APPLICATION FOR A CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) GOOD DISTRIBUTION PRACTICE 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 of warehouse
  - c. Supporting documents (see section 5)
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 for the premises should be prepared and submitted together with the completed application form. Please refer to the [GUIDE-22 Guidance Notes on Preparation of a Site Master File for Good Distribution Practice Certification](#).
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](#).



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<b>Section 1 - Company Particulars</b>	
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 <i>(if different from Company Address)</i>	
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:	
<b>Section 2 - Applicant Particulars</b>	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact Number:	
2.4 Official Email Address:	
<b>Section 3 - Information on Products Distributed <i>(multiple selection allowed)</i></b>	
<input type="checkbox"/> CTGTP <input type="checkbox"/> CTGTP as Clinical Research Materials <i>(Investigational products)</i> <input type="checkbox"/> Active substances used in CTGTP <input type="checkbox"/> Starting materials used in CTGTP	

**Section 4 - Particulars on premises** *(attach additional sheets if necessary)*

**4.1 Address of Warehouse 1**

4.1.1 Postal Code:	
4.1.2 Block/House No:	
4.1.3 Level – Unit:	
4.1.4 Street Name:	
4.1.5 Building Name:	
4.1.6 Other Address:	

**4.2 Storage Condition of Warehouse 1**

4.2.1 Temperature *(multiple selection allowed)*:

Non-cold chain (Above 8°C)

Cold chain (Not more than 8°C)

4.2.1.1 Actual Temperature Range:

15 to 30°C (Room Temperature)

8 to 15°C (Cool)

2 to 8°C (Refrigerate, Do not freeze)

- 10 to - 20°C (Freeze)

Cryogenic storage temperature \_\_\_\_\_ °C

Others: \_\_\_\_\_

4.2.2 Relative Humidity (Non-Cold Chain): Min% - Max%: \_\_\_\_\_

4.2.3 Relative Humidity (Cold Chain): Min% - Max%: \_\_\_\_\_

4.2.4 Other Storage Conditions: \_\_\_\_\_

**4.3 Address of Warehouse 2**

4.3.1 Postal Code:	
4.3.2 Block/House No:	
4.3.3 Level – Unit:	
4.3.4 Street Name:	
4.3.5 Building Name:	
4.3.6 Other Address:	

**4.4 Storage Condition of Warehouse 2**

4.4.1 Temperature (*multiple selection allowed*):

- Non-cold chain (Above 8°C)
- Cold chain (Not more than 8°C)

4.4.1.1 Actual Temperature Range:

- 15 to 30°C (Room Temperature)
- 8 to 15°C (Cool)
- 2 to 8°C (Refrigerate, Do not freeze)
- 10 to - 20°C (Freeze)
- Cryogenic storage temperature \_\_\_\_\_ °C
- Others: \_\_\_\_\_

4.4.2 Relative Humidity (Non-Cold Chain): Min% - Max%: \_\_\_\_\_

4.4.3 Relative Humidity (Cold Chain): Min% - Max%: \_\_\_\_\_

4.4.4 Other Storage Conditions: \_\_\_\_\_

**Section 5 - Supporting Documents**

- Store Layout Plan
- Site Master File
- Other supporting documents

**Section 6 - 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:
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**Application Fee**

<b>CTGTP GDP Certificate with Technical Assessment (including site inspection)</b>	<b>\$3,700</b>
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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.