**For HSA use only**

Application no.:

**APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) GMP CERTIFICATE**

**NOTES:**

1. Your company must have a [CRIS](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html) 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. All entries shall be typed in English. All the information required in the form should be supplied as far as they are applicable.
4. If the company has multiple manufacturing sites, please click on the  icon at the bottom right-hand corner of section 3.2, 3.3 to duplicate the required fields.
5. The fields with (\*) indicate details which would be reflected in the Certificate issued. Please ensure that the information filled in these fields are accurate.
6. This completed form with its relevant supporting documents should be submitted as an attachment in the online FormSG - [CTGTP Dealer’s Submission](https://go.gov.sg/ctgtp-dealers-submission). CorpPass is required to access this FormSG. For more information, please visit the [CorpPass website](http://www.corppass.gov.sg/).
7. **This form cannot be processed until a payment is made**. 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 payment information will be provided on the invoice.
8. For enquiries regarding application matters, please email [HSA\_ALD\_Appl@hsa.gov.sg](mailto:HSA_ALD_Appl@hsa.gov.sg)

**APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) GMP CERTIFICATE**

|  |  |
| --- | --- |
| **Section 1 - Company Particulars** | |
| 1.1 Name of Company: | Click or tap here to enter text. |
| 1.2 Company Business Unity Entity Number (UEN): | Click or tap here to enter text. |
| 1.3 Client Code: | Click or tap here to enter text. |
| 1.4 Company Address | |
| 1.4.1 Postal Code: | Click or tap here to enter text. |
| 1.4.2 Address, including level, unit no. and building name (if applicable): | Click or tap here to enter text. |
| 1.5 Billing Address *(if different from Company Address)* | |
| 1.5.1 Postal Code: | Click or tap here to enter text. |
| 1.5.2 Address, including level, unit no. and building name (if applicable): | Click or tap here to enter text. |
| **Section 2 - Applicant Particulars** | |
| 2.1 Name (as in NRIC/FIN): | Click or tap here to enter text. |
| 2.2 Designation: | Click or tap here to enter text. |
| 2.3 Contact No.: | Click or tap here to enter text. |
| 2.4 Official Email address: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Section 3 - Manufacturing Site Information** | |
| **3.1 Manufacturer Name\***  Click or tap here to enter text. | |
| **3.2 Manufacturing Site Address**  *Please list all addresses where manufacturing operations will take place under this site. If there are multiple manufacturing addresses, please click on the*  *icon at the bottom right-hand corner of section 3.2.2 to duplicate the fields. Please indicate main contact address with “(main)” if there are multiple addresses.* | |
| 3.2.1 Postal Code:\* | Click or tap here to enter text. |
| 3.2.2 Address:\* | Click or tap here to enter text. |

|  |
| --- |
| 3.3 Other Manufacturing Site Address  *If the manufacturing activities (i.e., Quality Control testing, storage and handling) are carried out at addresses which are not adjacent or in close proximity (i.e., at a different postal code), then fill in this section.*  *The manufacturing activities carried out at these other addresses must be under the same pharmaceutical quality system and under the responsibility of the same key personnel for these separate addresses to be considered under a single Manufacturer’s Licence application.*  *Please include additional field for each address if there are more than one by please clicking on the*  *icon at the bottom right-hand corner of section 3.3.2 to duplicate the fields.* |

|  |  |
| --- | --- |
| Quality Control Testing Only  Storage and Handling Only  Not applicable | |
| 3.3.1 Postal Code:\* | Click or tap here to enter text. |
| 3.3.2 Address:\*  *Please list the level,unit no. and building name (if applicable) which is the main contact address first.* | Click or tap here to enter text. |

|  |
| --- |
| **Section 4 – Scope of Application** |
| **4.2 Application for GMP Certification:\***  Investigational Finished Product  Finished Product  Others, please specify (e.g. intermediate product): Click or tap here to enter text. |
| **Section 5 - Manufacturing Operations**  *Please provide a* *list of products as described in section 8.* |
| **5.1 Product Type:\***  Cell therapy products  Gene therapy products  Tissue therapy products  CTGT products combined with a therapeutic product or a medical device  Others, please specify: Click or tap here to enter text. |
| **5.2 Manufacturing Process:\*** ( Not Applicable)   |  |  |  |  | | --- | --- | --- | --- | | **Aseptically processed dosage form** | **Finished Product** | **Intermediates** | **Others** | | Injections |  |  |  | | Injections, cryopreserved |  |  |  | | Others (please specify):  Click or tap here to enter text. |  |  |  |   ***Other remarks:***  Click or tap here to enter text. |
| **5.3 Packaging:\*** ( Not Applicable)  Secondary packaging  ***Remarks (if any):*** Click or tap here to enter text. |
| **5.4 Quality Control Testing:\***  Chemical / Physical  Microbiological  Biological  Not applicable |
| **5.5 Other Manufacturing Activities Conducted at the Same Site:**  Manufacture involving starting materials, viral vectors or viruses  Manufacture of pathogenic organisms (biosafety level 3 and 4)  Manufacture of products other than CTGT products  Others: Click or tap here to enter text.  Not applicable |

|  |  |
| --- | --- |
| **Section 6 - Responsible Persons** | |
| **6.1 Person in-charge of Production Operations** | |
| 6.1.1 Name: | Click or tap here to enter text. |
| 6.1.2 Designation: | Click or tap here to enter text. |
| 6.1.3 Directly reporting to: | Click or tap here to enter text. |
| 6.1.4 Contact number: | Click or tap here to enter text. |
| 6.1.5 Email: | Click or tap here to enter text. |
| **6.2 Person in-charge of Quality Operations** | |
| 6.2.1 Name: | Click or tap here to enter text. |
| 6.2.2 Designation: | Click or tap here to enter text. |
| 6.2.3 Directly reporting to: | Click or tap here to enter text. |
| 6.2.4 Contact number: | Click or tap here to enter text. |
| 6.2.5 Email: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Section 7 – Application fee** | |
| Please select the application fee below:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **GMP Certificate** | | **Fee** | **Number of copies** | **Total** | | **GMP Certificate (with technical assessment)**  **Note:** For new application requiring site inspection. |  | $22,000 | Not Applicable | $ 22,000 | | **Additional copy of GMP Certificate (without technical assessment)**  **Note:** This is only for company who wishes to obtain additional copy of GMP Certificate for same new application above |  | $210 | Click or tap here to enter text. | $ Click or tap here to enter text. | | **Additional copy of a GMP Certificate (without technical assessment)**  **Note**: This is applicable if a GMP Certificate has been issued. Please fill up Sections 1 and 2 of the form and provide the Certificate number below,  **GMP Certificate Number**:  Click or tap here to enter text. |  | $210 | Click or tap here to enter text. | $ Click or tap here to enter text. | | **GMP Certificate (without technical assessment)**  **Note**: For a manufacturer who is already holding a manufacturer’s licence, please complete all the sections in this form and indicate the latest inspection date below  **Manufacturer’s Licence Number**:  Click or tap here to enter text.  **Inspection Dates**:  Click or tap here to enter text. |  | $210 | Click or tap here to enter text. | $ Click or tap here to enter text. | | |
| **Section 8 - Supporting Documents** | |
| Site Master File (in accordance with the PIC/S Guidance for Site Master File PE 008-4).#  If this is not included in the SMF, please provide a list of products manufactured as indicated in sections 4 and 5. Please include the description (or name if available) of the active substance(s), finished product(s), product indication(s), brief description of the manufacturing process, clinical trial authorisation approval/application number(s).#  If the site is manufacturing intermediates or bulk products, please provide inform on where (name and address of manufacturers) the intermediate products would be distributed to for further manufacturing.  Others (please state): Click or tap here to enter text.  # *Submission of these information is required for acceptance of application.* | |
| **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:  Click or tap here to enter text. | Signature and Date: |