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

**For HSA use only**

Application no.:

**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. 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.
4. All entries shall be typed in English. All the information required in the form should be supplied as far as they are applicable.
5. If the company has multiple manufacturing sites, contract storage, contract testing laboratories, or other contract manufacturing activities, please click on the  icon at the bottom right-hand corner of section 3.3, 3.4, 7.1, 7.2 or 7.3 to duplicate the required fields.
6. The fields with (\*) indicate details which would be reflected in the licence issued. Please ensure that the information filled in these fields are accurate.
7. 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/).
8. **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.
9. For enquiries including assistance with this form, please email HSA\_ALD\_Appl@hsa.gov.sg

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

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| **Section 1 - Company Particulars** |
| [ ]  No change (skip whole of Section 1)[ ]  Amendment (complete the details below) |
| 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 or unit no.: | 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 or unit no.: | Click or tap here to enter text. |
| **Section 2 - Applicant Particulars** |
| [ ]  No change (skip whole of Section 2)[ ]  Amendment (complete the details below) |
| 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. |

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| **Section 3 - Manufacturing Site Information** |
| [ ]  No change (skip whole of Section 3)[ ]  Amendment (complete the details below) |
| **3.1 Manufacturer Name:\*** Click or tap here to enter text. |
| **3.2 Manufacturer’s Licence No:\***Click or tap here to enter text. |
| **3.3 Manufacturing Site Address***Please list all addresses where manufacturing operations will take place under this proposed Manufacturer’s Licence. If there are multiple manufacturing addresses, please click on the*  *icon at the bottom right-hand corner of section 3.3.2 to duplicate the fields.* *Any site which holds a Manufacturer’s Licence and carries out processing operations or packaging of products is also understood to be authorised for storage and distribution those batches of products unless indicated in the clarifying remarks.* |
| 3.3.1 Postal Code:\* | Click or tap here to enter text. |
| 3.3.2 Address:\* *Please list the level or unit no. which is the main contact address first.* | Click or tap here to enter text. |

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| **3.4 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 clicking on the*  *icon at the bottom right-hand corner of section 3.4.2 to duplicate the fields.* |
| [ ]  QC Testing Only[ ]  Storage and Handling Only[ ]  Not applicable |
| 3.4.1 Postal Code:\* | Click or tap here to enter text. |
| 3.4.2 Address:\**Please list the level or unit no. which is the main contact address first.* | Click or tap here to enter text. |

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| **Section 4 – Scope of Application** |
| [ ]  No change (skip whole of Section 4)[ ]  Amendment (complete the details below) |
| *If you are manufacturing CTGTP which are registered or have marketing authorisations for commercial distribution, please select ‘Finished product’**If you are healthcare institutions or contract manufacturers engaged by healthcare institutions for manufacturing unregistered Class 2 CTGTP for supply to patients, please select ‘Finished product for specially authorised clinical use’.**If you are manufacturing CTGTP intermediates which would undergo further manufacturing steps or secondary packaging or labelling at another site, please select ‘Intermediate or bulk product’*[ ]  Finished product [ ]  Addition [ ]  Removal[ ]  Finished product for specially authorised clinical use  [ ]  Addition [ ]  Removal[ ]  Intermediate product [ ]  Addition [ ]  Removal |
| **Section 5 – Manufacturing Operations***Please provide a* *list of products as described in section 8.* |
| [ ]  No change (skip whole of Section 5)[ ]  Amendment (complete the details below) |
| **5.1 Product Type:\***[ ]  Cell therapy products [ ]  Addition [ ]  Removal[ ]  Gene therapy products [ ]  Addition [ ]  Removal[ ]  Tissue therapy products [ ]  Addition [ ]  Removal[ ]  CTGTP combined with a therapeutic product or a medical device [ ]  Addition [ ]  Removal |
| **5.2 Manufacturing Process for Finished Product:\***[ ]  No change (skip Section 5.2)

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| **Aseptically processed dosage form** | **Finished product** | **Finished product for specially authorized clinical use** | **Intermediate product** |
| Injections | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal |
| Injections, cryopreserved | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal |
| Others (please specify): Click or tap here to enter text. | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal | [ ]  Addition [ ]  Removal |

 ***Other remarks:*** Click or tap here to enter text. |
| **5.3 Packaging:\*** [ ]  No change (skip Section 5.3) Secondary packaging [ ]  Addition [ ]  Removal**Remarks (if any)**: Click or tap here to enter text. |
| **5.4 Quality Control Testing:\***[ ]  No change (skip Section 5.4) [ ]  Chemical / Physical [ ]  Addition [ ]  Removal [ ]  Microbiological [ ]  Addition [ ]  Removal[ ]  Biological [ ]  Addition [ ]  Removal[ ]  Not applicable  ***Remarks (if any):*** Click or tap here to enter text. |
| **5.5 Other Manufacturing Activities Conducted at the Same Site:***Please provide information on the products (if any) in the supporting documents*[ ]  No change (skip Section 5.5)[ ]  Manufacture of investigational CTGTP [ ]  Addition [ ]  Removal[ ]  Manufacture involving starting materials, viral vectors or viruses [ ]  Addition [ ]  Removal[ ]  Manufacture of pathogenic organisms (biosafety level 3 and 4) [ ]  Addition [ ]  Removal[ ]  Others: Click or tap here to enter text. [ ]  Addition [ ]  Removal[ ]  Not applicable |

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| **Section 6 - Responsible Persons** |
| [ ]  No change (skip whole of Section 6)[ ]  Amendment (complete the details below) |
| **6.1 Person in-charge of Production**[ ]  No change (skip Section 6.1) [ ]  Amendment (complete the details below) |
| 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**[ ]  No change (skip Section 6.2) [ ]  Amendment (complete the details below) |
| 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 - Outsourced Activities** |
| [ ]  No change (skip whole of Section 7)[ ]  Amendment (complete the details below)[ ]  Storage *(fill in section 7.1)* [ ]  Addition [ ]  Removal[ ]  QC testing *(fill in section 7.2)* [ ]  Addition [ ]  Removal[ ]  Manufacturing *(fill in section 7.3)* [ ]  Addition [ ]  Removal |

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| **7.1 Contract Storage Site Information** [ ]  No change (skip Section 7.1)[ ]  Amendment (complete the details below)*If there are multiple contract warehouses, please click on the*  *icon at the bottom right-hand corner of section 7.1.3 to duplicate the fields.* |
| **7.1.1 Name of Contract Warehouse:** | [ ]  Addition [ ]  Removal[ ]  Change of activitiesClick or tap here to enter text. |
| If the contract warehouse is an existing licence holder, please specify the licence number: Click or tap here to enter text. |
| **7.1.2 Address of Contract Warehouse:** |
| 7.1.2.1 Country:\* | Click or tap here to enter text. |
| 7.1.2.2 Postal Code:\* | Click or tap here to enter text. |
| 7.1.2.3 Address, including level, unit no. and building name (if applicable):\* | Click or tap here to enter text. |
| 7.1.2.4 Point of Contact:  | Click or tap here to enter text. |
| 7.1.2.5 Contact Email Address: | Click or tap here to enter text. |
| 7.1.2.6 Contact Number: | Click or tap here to enter text. |
| **7.1.3 Contract Agreement**1. **Have the contract warehouse been assessed to be fit for purpose?**

[ ]  Yes [ ]  No, clarifying remarks (if any)1. **Is written contract or quality agreement with contract warehouse in place?**

[ ]  Yes [ ]  No, clarifying remarks (if any)1. **Is the contract warehouse aware that they have been named and may be subject to inspection by HSA, where necessary?**

[ ]  Yes [ ]  No, clarifying remarks (if any)***Remarks:*** Click or tap here to enter text. |

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| **7.2 Contract Testing Laboratory Site Information** [ ]  No change (skip Section 7.2)[ ]  Amendment (complete the details below)*If there are multiple contract testing laboratories, please click on the*  *icon at the bottom right-hand corner of section 7.2.4 to duplicate the fields.* |
| **7.2.1 Name of Contract Testing Laboratory:** | [ ]  Addition [ ]  Removal [ ]  Change of activitiesClick or tap here to enter text. |
| **7.2.2 Address of Contract Testing Laboratory** |
| 7.2.2.1 Country:\* | Click or tap here to enter text. |
| 7.2.2.2 Postal Code:\* | Click or tap here to enter text. |
| 7.2.2.3 Address, including level, unit no. and building name (if applicable):\* | Click or tap here to enter text. |
| 7.2.2.4 Point of Contact: | Click or tap here to enter text. |
| 7.2.2.5 Contact Email Address: | Click or tap here to enter text. |
| 7.2.2.6 Contact Number: | Click or tap here to enter text. |
| **7.2.3 Testing Activities Outsourced to Contract Testing Laboratory**[ ]  No change (skip Section 7.2.3)[ ]  Amendment (complete the details below)Type of testing outsourced:\* [ ]  Chemical / Physical [ ]  Addition [ ]  Removal [ ]  Microbiological [ ]  Addition [ ]  Removal [ ]  Biological [ ]  Addition [ ]  Removal |
| **7.2.4 Contract Agreement**1. **Have the contract testing laboratory been assessed to be fit for purpose?**

[ ]  Yes [ ]  No, clarifying remarks (if any)1. **Is written contract or quality agreement with contract laboratory in place?**

[ ]  Yes [ ]  No, clarifying remarks (if any)1. **Is the contract laboratory aware that they have been named and may be subject to inspection by HSA, where necessary?**

[ ]  Yes [ ]  No, clarifying remarks (if any)**Remarks:**Click or tap here to enter text. |

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| **7.3 Contract Manufacturing Activities**[ ]  No change (skip Section 7.3) [ ]  Amendment (complete the details below)*The contract manufacturing sites should be named when a Manufacturer’s Licence holder outsources manufacturing activities for which it is responsible through technical agreements, all sites where these outsourced activities occur are required to be listed.* *If there are multiple contract manufacturers, please click on the*  *icon at the bottom right-hand corner of section 7.3.4 to duplicate the fields.* |
| **7.3.1 Name of Contract Manufacturer\*** | [ ]  Addition [ ]  Removal [ ]  Change of activitiesClick or tap here to enter text.  |
| If the contract manufacturer is an existing licence holder, please specify the licence number: Click or tap here to enter text. |
| **7.3.2 Address of Contract Manufacturer\*** |
| 7.3.2.1 Country:\* | Click or tap here to enter text. |
| 7.3.2.2 Postal Code:\* | Click or tap here to enter text. |
| 7.3.2.3 Address, including level, unit no. and building name (if applicable):\* | Click or tap here to enter text. |
| 7.3.2.4 Point of Contact:  | Click or tap here to enter text. |
| 7.3.2.5 Contact Email Address: | Click or tap here to enter text. |
| 7.3.2.6 Contact Number: | Click or tap here to enter text. |
| **7.3.3 Manufacturing Activities Outsourced to Contract Manufacturer:**[ ]  No change (skip Section 7.3.3)[ ]  Amendment (complete the details below)*The operations described at the contract manufacturing site should reflect what will actually be conducted at the contract site on behalf of the Manufacturer’s Licence holder. For example, if a contract manufacturing site is authorised to perform multiple manufacturing operations, but will only conduct sterilization on behalf of the Manufacturer’s Licence holder, only sterilization operations would be specified for the site.* 1. **Sterilisation of Starting Materials, Intermediates, Finished Products or others\***

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| [ ]  Filtration [ ]  Addition [ ]  Removal[ ]  Dry heat [ ]  Addition [ ]  Removal[ ]  Moist heat [ ]  Addition [ ]  Removal[ ]  Chemical [ ]  Addition [ ]  Removal[ ]  Electron beam [ ]  Addition [ ]  Removal | [ ]  Gamma irradiation [ ]  Addition [ ]  Removal[ ]  Others (please specify):  [ ]  Addition [ ]  Removal[ ]  Not applicable |

**Remarks**: Click or tap here to enter text.1. **Manufacturing Process:\* (**[ ]  **Not Applicable)**

[ ]  No change [ ]  Amendment (complete the details below)

|  |  |
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| **Aseptically processed dosage form** | **Finished product** |
| Injections | [ ] [ ]  Addition [ ]  Removal |
| Injections, cryopreserved | [ ] [ ]  Addition [ ]  Removal |
| Others (please specify):Click or tap here to enter text. | [ ] [ ]  Addition [ ]  Removal |

 ***Other remarks:*** Click or tap here to enter text.1. **Quality Control Testing:\***

[ ]  No change [ ]  Amendment (complete the details below)[ ]  Chemical / Physical [ ]  Addition [ ]  Removal[ ]  Microbiological [ ]  Addition [ ]  Removal[ ]  Biological [ ]  Addition [ ]  Removal[ ]  Not applicable  **Remarks**: Click or tap here to enter text.1. **Other Manufacturing Activities:\*** Click or tap here to enter text.

[ ]  No change [ ]  Amendment |
| **7.3.4 Contract Agreement**1. **Has the contract manufacturer been assessed to befit for purpose?**

[ ]  Yes [ ]  No, clarifying remarks (if any)1. **Is written contract or quality agreement with contract manufacturer in place?**

[ ]  Yes [ ]  No, clarifying remarks (if any)***Remarks:*** Click or tap here to enter text. |

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| **Section 8 - Application Fee** |
| Please select the application fee below:

|  |  |
| --- | --- |
| **Type of Amendments to Manufacturing Activities**  | **Fee** |
| **Manufacture of Finished Product****(Without Technical Assessment)** | [ ]  | $180 |
| **Secondary Packaging Only****(Without Technical Assessment)** | [ ]  | $180 |
| **Manufacture of Finished Product** **(With Technical Assessment)** | [ ]  | $5,100 |
| **Secondary Packaging Only****(With Technical Assessment)** | [ ]  | $2,700 |

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| **Section 9 - Supporting Documents** |
| [ ]  Site Master File (in accordance with the PIC/S Guidance for Site Master File PE 008-4).[ ]  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 products, treatment indications, brief description of the manufacturing process, list of product registration or marketing authorisation approval/application.[ ]  *Curriculum Vitae* (CV) of all responsible persons.[ ]  If the site is also manufacturing investigational CTGTP as indicated in section 5.5, please provide a copy of the GMP Certificate or HSA GMP Certificate number if any. If the GMP Certificate is not available, please provide a list of investigational CTGTP including the description (or name if available) of the active substance(s), finished products, product indication(s), brief description of the manufacturing process, clinical trial authorisation approval/application number(s).[ ]  If the site is also manufacturing other materials or products as indicated in section 5.5, provide a list of the materials or products, and indicate if they are handled in the same facility as the authorised CTGTP.[ ]  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.[ ]  A list of contract warehouses and the type of materials or products stored or handled as well as the storage conditions (temperature and relative humidity), where applicable.[ ]  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.[ ]  Others (please state): Click or tap here to enter text. |
| **Section 10 - 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:  |