**APPLICATION FORM TO REQUEST FOR GMP DOCUMENTARY EVIDENCE VERIFICATION APPLICATION (GMP DEVA)**

**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. The application should be made by a Responsible Person (e.g. Managing Director, Head of Quality) from a Singapore registered firm/company with a valid Account and Corporate Regulatory Authority of Singapore (ACRA) account.
3. The Applicant/Authorised Person (e.g. Regulatory Affairs personnel) should hold either the ‘Submitter’ role for ‘Assessment of GMP Evidence from Overseas Manufacturer’ or a ‘CRIS Admin’ role in PRISM.
4. The Applicant/Authorised Person will be the point of contact for all matters related to this application.
5. Please refer to [GMP Conformity Assessment of Overseas Manufacturers (GUIDE-MQA-020)](https://www.hsa.gov.sg/therapeutic-products/register/gmp-conformity-assessment) before filling up this application form.
6. All entries shall be typed in English. All the information required in the form should be provided.
7. The completed application form and relevant supporting documents should be scanned and attached in the associated product registration application(s) in PRISM. The documents should be submitted to Therapeutic Products Branch (TPB) as part of the submission for Therapeutic Product registration.

|  |  |
| --- | --- |
| **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 Company Address | |
| 1.3.1 Postal Code: | Click or tap here to enter text. |
| 1.3.2 Address: | Click or tap here to enter text. |
| 1.4 Particulars of Company’s Responsible Person | |
| 1.4.1 Name: | Click or tap here to enter text. |
| 1.4.2 Designation: | Click or tap here to enter text. |
| 1.4.3 Contact No.: | Click or tap here to enter text. |
| 1.4.4 Official Email Address | Click or tap here to enter text. |
| **Section 2 – Particulars of Applicant/Authorised Person** | |
| 2.1 Name: | Click or tap here to enter text. |
| 2.2 NRIC/Passport/FIN: | Click or tap here to enter text. |
| 2.3 Designation: | Click or tap here to enter text. |
| 2.4 Contact No.: | Click or tap here to enter text. |
| 2.5 Official Email address: | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| **Section 3 – Overseas Manufacturer Site Information** | | |
| **3.1 Manufacturer Name**  Click or tap here to enter text. | | |
| **3.2 Manufacturing Site Address**  *Please ensure that the name of manufacturer and the complete site address, including the postal code, is completely aligned with the information stated in the GMP documentary evidence submitted.* | | |
| 3.2.1 Postal Code: | Click or tap here to enter text. | |
| 3.2.2 Address: | Click or tap here to enter text. | |
| **Section 4 - Supporting Documents**  *Please submit valid GMP documentary evidence that is issued by a PIC/S member authority and is representative of the latest GMP compliance status of the overseas manufacturing site. The GMP documentary evidence should contain information relevant to the manufacturing activities and dosage form of the product to be registered.* | | |
| 4.1 GMP Documentary Evidence Information  *If there are multiple pieces of GMP evidence submitted, please click on the*  *icon at the bottom right-hand corner of section 4.1.3 to duplicate the fields.* | | |
| 4.1.1 Type of GMP evidence: | | Click or tap here to enter text. |
| 4.1.2 Document Reference No.: | | Click or tap here to enter text. |
| 4.1.3 Inspection start & end date(s): | | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Section 5 - Declaration** | |
| I have been duly authorised by my company to submit this application of its behalf.  I hereby confirm that the information submitted in this application is true and accurate.  I understand that if any information submitted in this application is found to be false or inaccurate, my company and I may be liable to prosecution.  I agree to submit any further information requested by the authorities which are relevant for the evaluation of the GMP Documentary Evidence Verification Application (GMP DEVA).  I agree to the fee associated with this GMP Documentary Evidence Verification Application (GMP DEVA). | |
| Name of applicant/authorised person:  Click or tap here to enter text. | Signature and Date: |