**APPLICATION FORM TO REQUEST FOR AN**

**OVERSEAS GMP INSPECTION**

**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 ‘Overseas Audit Programme’ 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 supplied.
7. The completed application form and supporting documents should be scanned and attached in the associated product registration application(s) in PRISM. For Quality System Dossier (QSD), due to the large file size, it may be sent to Therapeutic Product Branch (TPB) directly.

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| **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. |
| **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 list all addresses where manufacturing operations will take place for the product(s) to be registered. If there are multiple manufacturing addresses, please click on the*  *icon at the bottom right-hand corner of section 3.2.4 to duplicate the fields.* | |
| 3.2.1 Postal Code: | Click or tap here to enter text. |
| 3.2.2 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. |
| 3.2.3 Additional site information:  *Please list the workshop no., room no. and/or line no. where the manufacturing activities of the product(s) to be registered take place, if applicable.* | Click or tap here to enter text. |
| 3.2.4 Type of manufacturing activities:  *E.g. Manufacturing, Quality Control Testing, storage and handling etc.* | Click or tap here to enter text. |

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| **Section 4 - Manufacturing Operations** | |
| **4.1 Dosage form(s) of product(s) to be registered**  Click or tap here to enter text. | |
| **4.2 Manufacturing activities of the product(s) to be registered:**  Manufacture of Finished Product  Primary Packaging  Secondary Packaging  Others *(e.g. Aseptic Filling Only)*: Click or tap here to enter text. | |
| **4.3 Categories of products manufactured at the same site:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Product Categories** | **Manufacture** | **Primary Packaging** | **Secondary Packaging** | **Dedicated Facilities Available** | | Penicillin or cephalosporins |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Cytotoxic or Anti-cancer preparations |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Hormones |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Steroids |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Biologicals  *(e.g. vaccines, blood products, biotechnology products, preparations containing micro-organisms)* |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Non-medicinal products that contain toxic or hazardous substances such as insecticides, pesticides, formaldehyde etc. |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | Others (please specify):  Click or tap here to enter text. |  |  |  | Specify the dedicated building/workshop/room. Otherwise, indicate NA | | |
| **4.4 Quality Control Testing:**  Chemical / Physical  Microbiological  Biological  Not applicable  ***Remarks (if any):*** Click or tap here to enter text. | |
| **Section 5 – Responsible Persons** | |
| **5.1 Person in-charge of Production Operations** | |
| 5.1.1 Name: | Click or tap here to enter text. |
| 5.1.2 Designation: | Click or tap here to enter text. |
| 5.1.3 Directly reporting to: | Click or tap here to enter text. |
| 5.1.4 Contact number: | Click or tap here to enter text. |
| 5.1.5 Email: | Click or tap here to enter text. |
| **5.2 Person in-charge of Quality Operations** | |
| 5.2.1 Name: | Click or tap here to enter text. |
| 5.2.2 Designation: | Click or tap here to enter text. |
| 5.2.3 Directly reporting to: | Click or tap here to enter text. |
| 5.2.3 Contact number: | Click or tap here to enter text. |
| 5.2.4 Email: | Click or tap here to enter text. |
| **Section 6 - Outsourced Activities** | |
| Storage *(fill in section 6.1)*  QC testing *(fill in section 6.2)*  Manufacturing activities *(fill in section 6.3)*  None of the above *(proceed to section 7)* | |

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| **6.1 Contract Warehouse Information**  *If there are multiple contract warehouses, please click on the*  *icon at the bottom right-hand corner of section 6.1.2.3 to duplicate the fields.* | |
| **6.1.1 Name of Contract Warehouse:** | Click or tap here to enter text. |
| **6.1.2 Address of Contract Warehouse** | |
| 6.1.2.1 Country: | Click or tap here to enter text. |
| 6.1.2.2 Address, including level, unit no. and building name (if applicable): | Click or tap here to enter text. |
| 6.1.2.3 Postal Code: | Click or tap here to enter text. |

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| **6.2 Contract Testing Laboratory Site Information**  *If there are multiple contract testing laboratories, please click on the*  *icon at the bottom right-hand corner of section 6.2.4 to duplicate the fields.* | |
| **6.2.1 Name of Contract Testing Laboratory** | Click or tap here to enter text. |
| **6.2.2 Address of Contract Testing Laboratory** | |
| 6.2.2.1 Country: | Click or tap here to enter text. |
| 6.2.2.2 Postal Code: | Click or tap here to enter text. |
| 6.2.2.3 Address, including level, unit no. and building name (if applicable): | Click or tap here to enter text. |
| **6.2.3 Testing Activities Outsourced to Contract Testing Laboratory** | |
| 6.2.3.1 Type of testing outsourced:  Chemical / Physical  Microbiological  Biological | |
| **6.2.4 Accreditation of Contract Testing Laboratory** | |
| 1. **Is the contract testing laboratory accredited to ISO/IEC 17025?**   Yes  No  If no, please specify the standard and scope of accreditation:  Click or tap here to enter text. | |

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| **6.3 Contract Manufacturer Information**  *The contract manufacturer(s) refer to those engaged by the overseas manufacturer for the manufacture of the product(s) to be registered. The contract manufacturing site(s) should be named when the overseas manufacturer outsources manufacturing activities related to the product(s) to be registered.*  *If there are multiple contract manufacturers, please click on the*  *icon at the bottom right-hand corner of section 6.3.3 to duplicate the fields.* | |
| **6.3.1 Name of Contract Manufacturer** | Click or tap here to enter text. |
| **6.3.2 Address of Contract Manufacturer** | |
| 6.3.2.1 Country: | Click or tap here to enter text. |
| 6.3.2.2 Postal Code: | Click or tap here to enter text. |
| 6.3.2.3 Address, including level, unit no. and building name (if applicable): | Click or tap here to enter text. |
| 6.3.2.4 Point of Contact: | Click or tap here to enter text. |
| 6.3.2.5 Contact Email Address: | Click or tap here to enter text. |
| 6.3.2.6 Contact Number: | Click or tap here to enter text. |
| **6.3.3 Manufacturing Activities Outsourced to Contract Manufacturer**    Manufacture of bulk intermediates  Sterilisation of starting materials, intermediates, finished products or others:  Indicate mode of sterilization: Click or tap here to enter text.  Aseptic filling  Primary packaging  Secondary packaging  Others: Click or tap here to enter text. | |

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| **Section 7 – Regulatory Inspection Information of Overseas Manufacturer** | |
| **7.1 Regulatory Inspection History**  *Please list the GMP inspections conducted at the overseas manufacturer in the past 5 years and submit the associated GMP certificate/ manufacturer’s licence issued in association with the GMP inspection conducted.*  *If there are multiple GMP inspections, please click on the*  *icon at the bottom right-hand corner of section 7.1.5 to duplicate the fields.* | |
| 7.1.1 GMP inspection dates  *(i.e. Start and end inspection dates)* | Click or tap here to enter text. |
| 7.1.2 Inspecting Authority/Country | Click or tap here to enter text. |
| 7.1.3 Type of GMP inspection  *(e.g. Pre-approval, routine or unannounced)* | Click or tap here to enter text. |
| 7.1.4 Mode of inspection  *(e.g. desktop review, remote assessment or on-site inspection)* | Click or tap here to enter text. |
| 7.1.5 Dosage form(s) covered during inspection | Click or tap here to enter text. |

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| **7.2 Regulatory Submissions**   1. **Has the company (stated in Section 1) submitted product registration applications for the same product(s) in other countries?**   Yes  No  If yes, please submit the information as requested in Section 8.   1. **Does the company (stated in Section 1) intend to submit product registration applications for the same product(s) in other countries in the next 1-2 years?**   Yes  No  If yes, please submit the information as requested in Section 8. | |
| **Section 8 - Supporting Documents** | | |
| Quality System Dossier (in accordance with the Guidance Notes on Preparation of a Quality System Dossier).#  Site Master File (SMF)# (in accordance with the PIC/S Guidance for Site Master File  *Curriculum Vitae* (CV) of all responsible personsindicated in Section 5.  Certificate of accreditation for contract testing laboratories indicated in Section 6.2.  List of countries where company has submitted product registration applications for the same product(s) to be registered in Singapore. The list should include the countries, status of application in the respective countries and whether GMP inspections have been requested/conducted by the respective regulatory authorities. **[Section 7.2(a)]**  List of countries which company intends to submit product registration applications for the same product(s) to be registered in Singapore. The list should include the countries & anticipated submission timeline. **[Section 7.2(b)]**  Others (*please state*): Click or tap here to enter text.  # *For first time application, QSD is to be submitted. For subsequent applications, where the overseas manufacturer has been previously inspected by HSA, only the updated SMF is required to be submitted.* | | |
| **Section 9 - Declaration** | | |
| I have been duly authorised by my company to submit this application on 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 this Overseas GMP Inspection application.  I agree to the fees associated with this Overseas GMP Inspection application. | | |
| Name of applicant/authorised person:  Click or tap here to enter text. | Signature and Date: | |