

APPLICATION FOR GOOD DISTRIBUTION PRACTICE (GDP) CERTIFICATE

1. The online application form may take you 30 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, internet performance etc. The recommended computer and network configurations are at

http://www.hsa.gov.sg/publish/hsaportal/en/services/prism/sys_requirements.html. Please note that the time stated above excludes time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. You need the following information/item(s) to fill in the form:

- ARCA document for locally registered company*
- Store layout Plan*
- Good Distribution Practices Standard Operating Procedures
- Good Distribution Practices Records
- Site Master File
- CD Submission (if any)
- Other supporting Documents (if any)

* Important notes:

- 1) All documents submitted need to be translated into English if they are in other foreign language.
- 2) All documents marked * are to be submitted as scanned copy during your application. The other documents may be submitted at a later stage, in hardcopy to

Manufacturing and Quality Audit Division.
Centre for Drug Administration
11 Biopolis Way
#11-03 Helios
Singapore 138667

3. For company who is applying a licence/certificate with HSA for the first time, you are required to register with CRIS.

4. User requires a Singpass or HSA Pin to login the system for authentication and authorization.

For more information on Singpass, please visit
<http://www.ecitizen.gov.sg/singpass/index.htm>.

For more information on HSA Pin, please visit
http://www.hsa.gov.sg/publish/hsaportal/en/services/hsa_pin.html.

5. Mode of payment

You would not need to make any payment during the on-line submission. The exact amount payable would be made known to you at a later stage. Payment would then be made via GIRO (preferred) or cheque, made payable to "Health Sciences Authority".

For GIRO registration, applicant will need to submit the [GIRO application form](#) to HSA Finance department. The address can be found in the application form.

Application Form

Part One – GDP Certificate Particulars

The section requires applicant to choose the following options:

- A) New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval
- B) New GDP Certificate for companies not audited for GDP/GMP compliance.

For Option A), this section requires applicant to furnish these information

- 1) Licence type – the licence that your company is holding/applying that would require a GDP audit
- 2) Licence No. or application No. of the above licence type
- 3) Categories of products which the scope of GDP certificate will apply

For Option B), this section requires applicant to furnish these information

- 1) Business Activity
- 2) Categories of products that your company is dealing with
- 3) Categories of products which the scope of GDP certificate will apply

Part Two – Company Particulars

These details should be automatically displayed for your confirmation.

- 1) Company Name
- 2) Location code
- 3) Company business Address, Postal Code, Level and Unit number
- 4) Contact Details such as Telephone/Fax no.
- 5) Company/Business Registration number (ACRA Number)

Important note:

- 1) Applicant could fill the billing address, only if it is different from the company address.

Part Three – Applicant Particulars

The section requires applicant to furnish this information

- 1) Applicant name, NRIC/FIN no, designation
- 2) Applicant's residential address
- 3) Applicant's contact details – Tel, Fax, Handphone, pager or Email
- 4) Preferred contact mode

Part Four – Store Particulars

The section requires applicant to furnish this information

- 1) Store address
- 2) Storage condition of store – temperature, relative humidity
- 3) Approval of store (if any) by any other authorities

Add the warehouse address by clicking on the “Add Warehouse” button. You will see the page refreshes, and the refreshed page will display the details of the warehouse particulars you have added.

Part Five – Other Products Stored in Same Premises

The section requires the applicant to furnish this information (as necessary)

- 1) Other Categories of Products stored in the same premises

Important note:

If “Others” is chosen, please state if the products contain hazardous or toxic substances.

Other useful information

Computer based online tutorial (CBT) is available to provide a means for applicant to familiarize with various HSA’s online e-services. The CBT is located at

<http://www.hsa.gov.sg/publish/hsaportal/en/services/cybertutor.html>.

NOTE:

The CBT provided might not be identical to the actual e-services forms; it only provides a means for applicant to have an insight of how our e-services work. You may refer to the module on “Apply for Licence to Import Medicinal Products”, available under “Manufacturing and Quality Audit” as a guide to familiarise yourself with the module.

You can contact the HSA PRISM and CRIS Helpdesk should you assistance with your application. The Helpdesk is made available via phone, fax or email, and they can be reached at

Hotline : 6776-0168 (from 7:00 am to midnight daily)

Fax No. : 6872-3054

Email ID. : helpdesk@hsahelp.gov.sg

If your queries relate to regulations and licence policies, please contact
Manufacturing & Quality Audit Division

Tel: 68663516

Fax: 64789068

Email: hsa_gdp@hsa.gov.sg