



Natural and Non-prescription Health Products Directorate

- Site Licensing - FAQs

1. Do I need a site licence?

A site licence (SL) is issued to natural health product (NHP) sites in Canada engaged in one, or more, of the following activities: manufacturer, package, label and import. Distribution, storing and testing do not require a licence.

An SL is evidence that the site is in compliance with applicable Good Manufacturing Practices requirements outlined in Part 3 of the *Natural Health Products Regulations* (NHPR) – NHP GMPs.

2. What are GMPs?

GMPs are ongoing measures to provide an effective overall approach to product quality and risk management by setting appropriate standards and practices for the manufacturing, packaging, labeling and importing of NHPs for sale in Canada. GMPs are broken down into four (4) main categories: People, Premises, Processes and Product. The [Good Manufacturing Practices Guidance Document](#) provides interpretation of Part 3 of the NHPR.

3. How do I apply for a new site licence?

In order to obtain an SL, applicants must submit an SL application to the Natural and Non-prescription Health Product Directorate (NNHPD). The application package must include:

- A duly completed SL application form; and
- acceptable evidence to demonstrate compliance with Part 3 of the NHPR, for each site.

Further details are found in the [Site Licensing Guidance Document](#)

4. What about foreign sites?

NHPs that are imported in Canada must be compliant with the NHP GMPs. A foreign site reference number (FSRN) is not a regulatory requirement but is a tool developed to streamline SL applications for imported NHPs. The foreign manufacturer, packager, and/or labeller, can apply to be pre-screened under this process and, if deemed compliant with the NHP GMPs, will be issued a FSRN. This reference number can be given to the importer for their application, instead of a full evidence package from the foreign site.

The importer is ultimately the responsible party to ensure compliance with Part 3 and will be contacted if issues are identified.

5. Who is the importer?

In order to import a NHP into Canada, there must be an importer in Canada who will be responsible for the product, regardless of whether the importer maintains a storage facility or products are sent directly to consumers. The importer must have a Quality Assurance Person who is responsible for performing or confirming finished product testing, maintenance of specifications, product release, record maintenance, accessibility of records (for those off-site), and stability (establishing expiry date).

6. What change of information requires an amendment to a site licence?

An application to amend an SL is required when adding a new building, activity or sterile dosage form. The site licence amendment package needs to include an SL application form and supporting GMP evidence.

7. What is a renewal?

Site licences need to be renewed as described in section 36 of the NHPR. The renewal cycle is from the date of issuance, and follows the timeline below:

- Every year for years 1 to 3
- Every two years for years 4-9
- Every three years when over 9 years

The expiry date of the Site Licence is clearly indicated in the upper right corner of the licence. Renewals packages must be submitted no later than 30 days before the day on which the licence expires. Renewals submitted beyond this timeframe will be refused.

The Summary of Net Changes form allows the SL holder to renew their site licence through an attestation that their GMP activities are unchanged or to describe any changes at the site, as well as provide records demonstrating that the procedures described in the initial application continue to be in place. [Instructions for Completing the Summary of Net Changes Form](#) is available for additional information.

8. What are the service standards?

The NNHPD has implemented service standards for the review of site licence applications. The three-stream approach of 35, 65, or 95 days for issuing a licensing decision is based on the type of evidence provided and the associated effort involved in assessing an application. Refer to the [Site Licence Guidance Document](#) for additional information.

9. Where could I get more information?

The NNHPD has developed guidance material, including:

[Site Licence Guidance Document](#)
[Good Manufacturing Practices Guidance Document](#)
[Quality of Natural Health Products Guide](#)

Specific enquiries can be directed to the NNHPD's email box at: hc.nnhpd-dpsnso.sc@canada.ca