Health Canada Santé Canada

Natural Health Products

DIRECTORATE

Site Licensing – A Step by Step Guide

Canada

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Our mission is to help the people of Canada maintain and improve their health.
Health Canada

Également offert en français sous le titre :
Licence d'exploitation – Un guide étape par étape

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This publication can also be made available in alternate format(s) upon request.

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1. Introduction

All natural health products for sale in Canada are subject to the *Food and Drugs Act and the Natural Health Product Regulations.*

The *Natural Health Product Regulations,* which came into force on January 1, 2004, define the specific regulatory requirements for the manufacture, packaging, labelling, storing, importing, distributing, and sale of natural health products in Canada to ensure that all Canadians have access to natural health products that are safe, effective, and of good quality.

This workbook is intended to provide information to the natural health product manufacturers, packagers, labellers, importers, about site licence applications, the requirements for licensing, and the Good Manufacturing Practices (GMPs) as they apply to the Quality Assurance Report (QAR).

Site Licensing: A Step-by-Step Guide provides guidance and advice on the process of site licensing for natural health products in accordance with the *Natural Health Products Regulations.*

2. General Overview of Site Licensing

Site Licence

A site licence is an authorization given to an applicant by the Natural Health Products Directorate to perform activities related to the manufacturing, packaging, labelling, or importing of natural health products.

[*Natural Health Products Regulations*]

Who Needs a Site Licence?

A site licence gives the licensee authorization to manufacture, package, label, or import natural health products. These activities must be carried out according to the good manufacturing practices outlined in Part 3 of the *Natural Health Products Regulations.*

All businesses in Canada who wish to manufacture, package, label, or import a natural health product for sale must hold a current site licence.

A business involved in manufacturing, packaging, labelling, or importing a natural health product may choose to apply for one site licence for all business operations, i.e., at multiple buildings or locations, or for individual site licences for the respective buildings or locations.

Licensee Obligations

- As the applicant, you are required to provide a valid and complete application.
- The following are examples where NHPD has deemed the information submitted to be insufficient—requiring Level 1, Submissions Management Division to send out processing deficiency letters:
  - Sections/fields on the Site Licence Application (SLA) form have not been completed.
  - The name of the Quality Assurance Person(s) for Parts 3 and 4 (when applicable) is not complete.
  - If the activity type indicates Homeopathic Medicines, a completed Quality Assurance Report (QAR) and Supplementary Quality SQAR have not been submitted.
  - The sites that hold an Establishment Licence (EL) have not submitted a valid copy of their current EL with a completed SLA form.
  - The activity type(s) listed on the SLA form do not match the activity type(s) listed on the EL, and a QAR was not submitted for this new activity.
  - The building address(es) listed on the SLA form does not match the building address(es) on the EL, and a QAR was not submitted for the new site(s) not listed on the current EL.

- Licensees must meet renewal obligations to maintain their site licence. A site licence expires on the first anniversary of the day on which it was issued unless it is renewed.
- Licensees must also notify NHPD of:
  - changes to the information in their Site Licence Application;
  - changes to buildings or processes.

Establishment Licence Holders

Establishment licence holders may also hold a Site Licence and would need to renew their licence according to Section 36 of the *Natural Health Products Regulations.*

In place of the Quality Assurance Report Form, establishment licence holders may submit a copy of their current **Establishment Licence** (EL) with the application for renewal. The Establishment Licence lists the last date of inspection and all buildings where activities such as manufacturing, packaging, labelling, importing, and distributing are authorized for drug products under the *Food and Drug Regulations*. When the activities and buildings match up exactly with those mentioned in the Site Licence Application Form for which a licence is requested, no further evidence of compliance relating to the good manufacturing practices is required.

Establishment licence holders must submit a separate Quality Assurance Report Form for those additional activities and buildings that are not listed in the establishment licence dealing exclusively with natural health products.

Amendments to Site Licence

- A **licence amendment** is required for one or more of the following changes to a site licence:
  - adding a new activity;
  - adding a new building;
  - changing from manufacturing, packaging, labelling, or importing a non-sterile dosage form to sterile dosage form.
- The licensee, when amending a site licence, has to provide an amendment submission including the site licence application form containing the following information:
  - the licence number;
  - the amendment being requested, i.e., each new building or new activity that the licensee is proposing to conduct; and
  - a detailed Quality Assurance Report Form indicating that the buildings, equipment, practices, and procedures used in each new activity comply with the requirements set out in Part 3 of the *Natural Health Products Regulations.*

- NHPD only issues or amends a site licence according to Section 29 when the applicant has submitted a complete application with all the required supporting data (as per Sections 28 and 32(2)) and has also provided NHPD with all additional information under Section 37, when requested, to assess whether the applicant is fully compliant with the *Natural Health Products Regulations*. The applicant must also ensure that there is no false or misleading information in the application form.
- NHPD may refuse to issue or amend a site licence when it finds the application to be deficient, when the applicant does not provide additional information on request, or when the information submitted is false or misleading. Sections 30 and 31 of the Regulations specify the process by which NHPD may refuse to issue or amend a site licence.
- When a site licence application is refused, NHPD sends the applicant a notice stating the reasons for refusal.
- When the applicant would like NHPD to reconsider this refusal, the applicant may make such a request within 30 days after the day on which the notice is sent. In this case, NHPD will give the applicant an opportunity to be heard regarding the refusal, after which NHPD will reconsider the initial refusal and decide whether to issue or amend a site licence.
- When the decision is made to uphold the refusal to issue or amend a site licence, NHPD sends the applicant a final notice stating the reasons for refusal. Applicants have the right to appeal decisions relating to the issuance of a licence.

Request for Licence Renewal

- Licensees must submit a request for renewal **no later than 30 days before the day on which their licence expires**. For example, if a site licence is issued on January 1, 2005 which is valid until January 1, 2006, the licensee must submit a request for renewal to NHPD *before December 1, 2005*.
- The renewed site licence expires on the day on which the renewal period ends, unless the licence is renewed again.
- The site licence must be renewed as follows:
  - every year, when the licensee has held the licence less than three years from the date of issuance;
  - every two years, when the licensee has held the licence for a period of at least three years from the date of issuance but less than nine years;
  - every three years, when the licensee has held the licence for nine years from the date of issuance or more.

Example

A company applies for a site licence for the first time and Natural Health Products Directorate issues the licence on January 1, 2004.

The issued licence bears this information:

Site Licence No.: 000001 A		
Issued to: QRS Living		
To perform the following activities at authorized buildings:		
■ **Manufacturing** ■ **Packaging** ■ **Labelling** ■ **Importing**	☐ **Sterile dosage**	
Issued on: January 1, 2004	**Amended on:**	**Expires on:** January 1, 2005

This company must renew its licence as follows.

Date of issuance	Date of renewal for the first three years	Date of renewal for years four to nine	Date of renewal after nine years
January 1, 2004	January 1, 2005 January 1, 2006 January 1, 2007 (i.e., every year)	January 1, 2009 January 1, 2011 January 1, 2013 (i.e., every second year)	January 1, 2016 January 1, 2019, etc. (i.e., every three years)

Note:

- When a company has been renewing a licence for three years or more and then adds a building or activity, it may continue renewing according to the renewal process, i.e., without starting again from the beginning of the renewal cycle.
- Licensees may renew their licence by the method described here or may submit a complete application form with all required supporting data. In either case, licensees must submit a new Quality Assurance Report Form with the renewal summary report.
- NHPD sends the licensee an expiry notice 60 days prior to the expiry. This notice includes the Renewal Summary Report and Record of Change Form. The Renewal Summary Report includes all the information in the most recent application for which a licence was issued. The licensee must sign the renewal summary report indicating that there have been no changes to the information since then.

Notification

- Section 33 specifies the situations under which licensees must notify NHPD **within 60 days** of a change in the information contained in their original application.

  These changes include:

  - a change in the name, address, telephone number, fax number or email address;
  - any substantial change that alters any building, equipment, practice, or procedure that was previously referred to in the Quality Assurance Report Form submitted to NHPD.

  Examples of such changes include:

  - adding another wing or an extension to an authorized building;
  - changing the production flow in a significant way;
  - changing from conventional methods to advanced processes; and
  - changing from general cleaning to other practices such as fumigation and dry heat cleaning.
- The licensee, when notifying NHPD of changes related to a site licence, has to provide the following:
  - Site Licence application form
  - Licence number
  - Notification Description form, if applicable. This form can be found in the *Site Licence Guidance Document*.

    Note: a notification form is not required if changing only the contact information.
- Changes related to operational information, i.e., a substantial change that alters any building, equipment, practice, or procedure, must be accompanied by an Attestation from the Quality Assurance Person stating that the activities and buildings authorized by the site licence will remain in compliance with the good manufacturing practices set out in Part 3 of the *Natural Health Products Regulations.*
- NHPD manages submissions for notification as described in the *Site Licence Guidance Document, Section* 3. Licensees are issued a written acknowledgment letter indicating that NHPD received the notification and is reviewing it. When necessary, NHPD will ask for information relating to the floor plan or flow diagram, or for an updated Quality Assurance Report Form. A site assessment may also be conducted when NHPD deems it necessary.

Suspension of Site Licence

- NHPD may **suspend** a site licence under the following circumstances:
  - the licensee is found to have contravened the *Natural Health Product Regulations* or any provision of the *Food and Drugs Act;*
  - the licensee is found to have made a false or misleading statement in the site licence application or application to amend the site licence; or
  - NHPD has enough evidence to believe that it is necessary to suspend the licence to prevent injury to the health of purchasers or consumers.
- In the last case, suspension may be immediate. Otherwise, NHPD sends the licensee a notice of the intention to suspend indicating the reason for the suspension. The licensee has 90 days to respond from the date of issuance of the notice and to do the following:
  - submit evidence to NHPD that the situation that led to the intended suspension has been rectified; or
  - provide NHPD with evidence demonstrating that the situation giving rise to the intended suspension does not exist.
- When the licensee does not submit the above information to NHPD within 90 days the licence is **suspended.** The NHPD will **reinstate** the licence if within 90 days of the effective date of suspension, the licensee provides NHPD with evidence demonstrating that the situation giving rise to suspension does not exist or has been corrected.

Cancellation of Site Licence

- The licence is cancelled when, within 90 days of the effective date of suspension, the licensee does not provide NHPD with any information relating to the situation that led to the site licence suspension. If NHPD cancels the site licence, a **notice of cancellation,** setting out the reasons and effective date of cancellation, is sent to the licensee.
- No manufacturer, packager, labeller, or importer may conduct any activity authorized by the site licence while the licence is suspended (under Section 39 or 40) and after it is cancelled (under Section 41(b)).
- Licensees have the right to appeal decisions relating to the suspension or cancellation of a licence. For detailed information on the appeal process, refer to the Dispute Avoidance and Resolution Framework on the NHPD website.

Products Manufactured At Foreign Sites

- Importers must submit the following:
  - Complete Site Licence Application
  - Quality Assurance Report or Establishment Licence
  - Quality Assurance Report or Evidence of GMP Compliance for each Foreign Site listed on their SLA.
- Canadian importers must be licensed and the onus is on them to provide evidence that imported products come from sites that meet Canadian Good Manufacturing Practices (GMPs) under Part 3 of the *Natural Health Products Regulations,* or equivalent standards.
- One of the following types of evidence is required from importers with respect to the foreign sites:
  - A Quality Assurance Report signed and dated by a quality assurance person who has the training, experience, and technical knowledge relating to the activity conducted in order to assess compliance with the GMPs outlined in Part 3 of the *Natural Health Products Regulations*;
  - A Certificate of Compliance (CoC) issued by a Regulatory Authority from any of the countries listed in the *Site Licence Guidance Document* for a Site/Recognized Building located in its jurisdiction for which the date of inspection indicated is no more than 3 years old;
  - The most recent inspection report (including the corrective actions taken) that is no more than 3 years old issued by a Regulatory Authority* from any of the countries listed in the *Site Licence Guidance Document* for a site located outside its jurisdiction as long as the inspection has been conducted based on its GMP standard or the Canadian GMP guidelines;
  - The most recent inspection report (including the corrective actions taken) from a Qualified Authority* for a site located within or outside its jurisdiction.

For up-to-date information, please refer to the Mutual Recognition Agreements (MRA) available at: http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/international_e.html

* see reference to *Health Products and Food Branch Inspectorate Guidance Document* in Section 5 of this workbook.

3. Site Licensing

A) Site Licence Submission

A Site Licence is an authorization given to an applicant by the Natural Health Products Directorate to perform activities related to the manufacturing, packaging, labelling, or importing of natural health products. [*Natural Health Products Regulations*]

The site licence information submitted is evaluated to ensure that the natural health products being marketed in Canada are safe, of good quality, and are manufactured, packaged, and labelled at sites that comply with the good manufacturing practices outlined in the *Natural Health Products Regulations.*

There are several different submission requirements depending on the role of the applicant, the type of activity, and the type of product being marketed.

Applicants provide a site licence submission when they:

- want to manufacture, package, label, or import a natural health product for the Canadian market;
- wish to notify NHPD about a change in information relating to the buildings or process;
- wish NHPD to amend the site licence;
- wish to renew the site licence.

Natural Health Product Directorate assigns a submission number and a company file number to each application. Issuance of a site licence occurs when:

- the applicant meets all the regulatory requirements outlined in the *Natural Health Products Regulations*;
- any and all of the additional information requested has been submitted;
- the application contains no false or misleading information.

Highlights

A completed site license application submission includes:

- A **Site License Application Form**
- A **Quality Assurance Report Form**
- A **Supplementary Quality Assurance Report Form for Homeopathic Medicines** (where applicable)
- A **Quality Assurance Person Qualifications Form**
- A **Designated Party Authorization Form** (where applicable)

3.A. Annotated Site Licence Application Form

PART 1: APPLICANT OR LICENSEE INFORMATION

This information pertains to the applicant or licensee information

Applicant/Company Name: Legal name of applicant or company. This applicant/company will be the site licence holder.

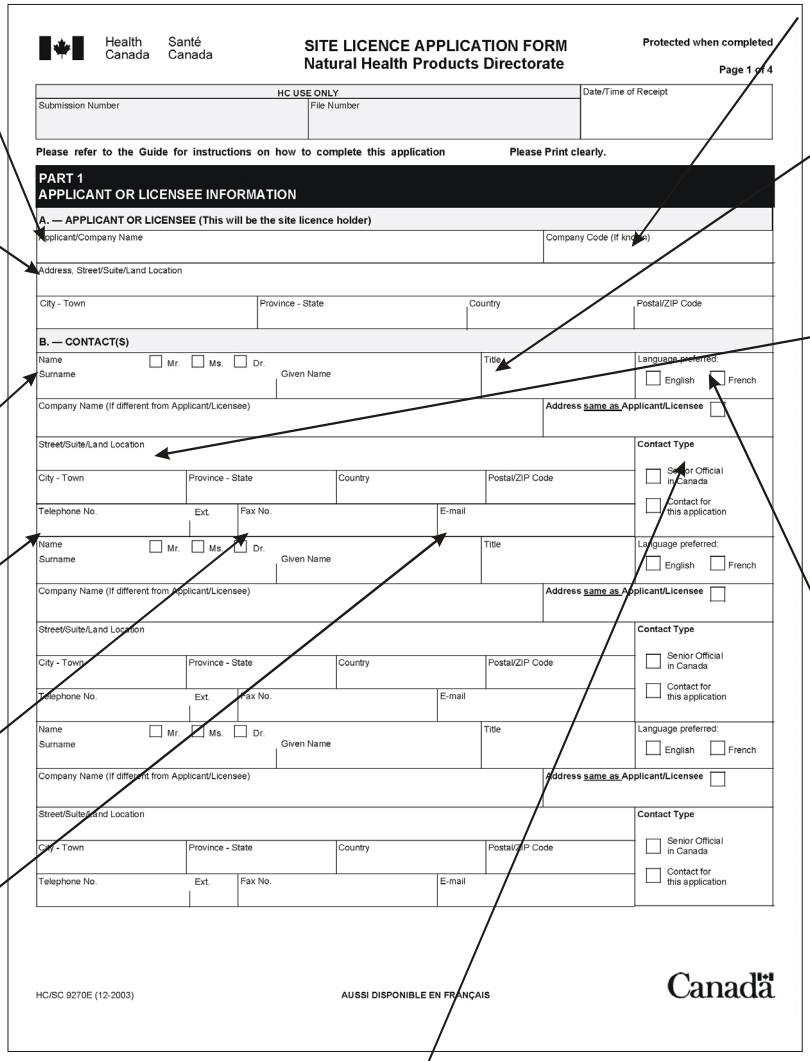
Address: Street address, city/town, province, country, and postal code of the applicant or company. **Note:** In case of international company, this address should be of the Canadian office.

Name: Name of the senior official/contact person for the company/licensee/ applicant.

Telephone Number: Number at which the senior official/contact person can be reached.

Fax Number: Number for the senior official/ contact person.

Email: Electronic mailing address for senior official/contact person.



Health Canada / Santé Canada

SITE LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

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HC USE ONLY | Submission Number | File Number | Date/Time of Receipt

Please refer to the Guide for instructions on how to complete this application — Please Print clearly.

PART 1
APPLICANT OR LICENSEE INFORMATION

A. — APPLICANT OR LICENSEE (This will be the site licence holder)

Applicant/Company Name | Company Code (If known)

Address, Street/Suite/Land Location

City - Town | Province - State | Country | Postal/ZIP Code

B. — CONTACT(S)

Name: Mr. Ms. Dr. | Surname | Given Name | Title | Language preferred: English French

Company Name (If different from Applicant/Licensee) | Address same as Applicant/Licensee

Street/Suite/Land Location | Contact Type: Senior Official in Canada; Contact for this application

City - Town | Province - State | Country | Postal/ZIP Code

Telephone No. | Ext. | Fax No. | E-mail

(Repeated for a second contact)

(Repeated for a third contact)

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Company Code: Code assigned by Health Canada, if known.

Title: Senior official/contact person title or position.

Address: Street address, city/town, province, country and postal code of the senior official/contact person.

Language Preferred: Language in which NHPD will correspond.

Contact Type: Indicate if you are:

- **Senior official** (CEO or a Director - person to contact for regulatory notices).
- **Contact person** (person to contact regarding the submission).

Annotated Site Licence Application Form

PART 2: SUBMISSION APPLICATION

This information pertains to the type of submission and identifies what the licensee has indicated. (SLA) Site Licence Application Form.

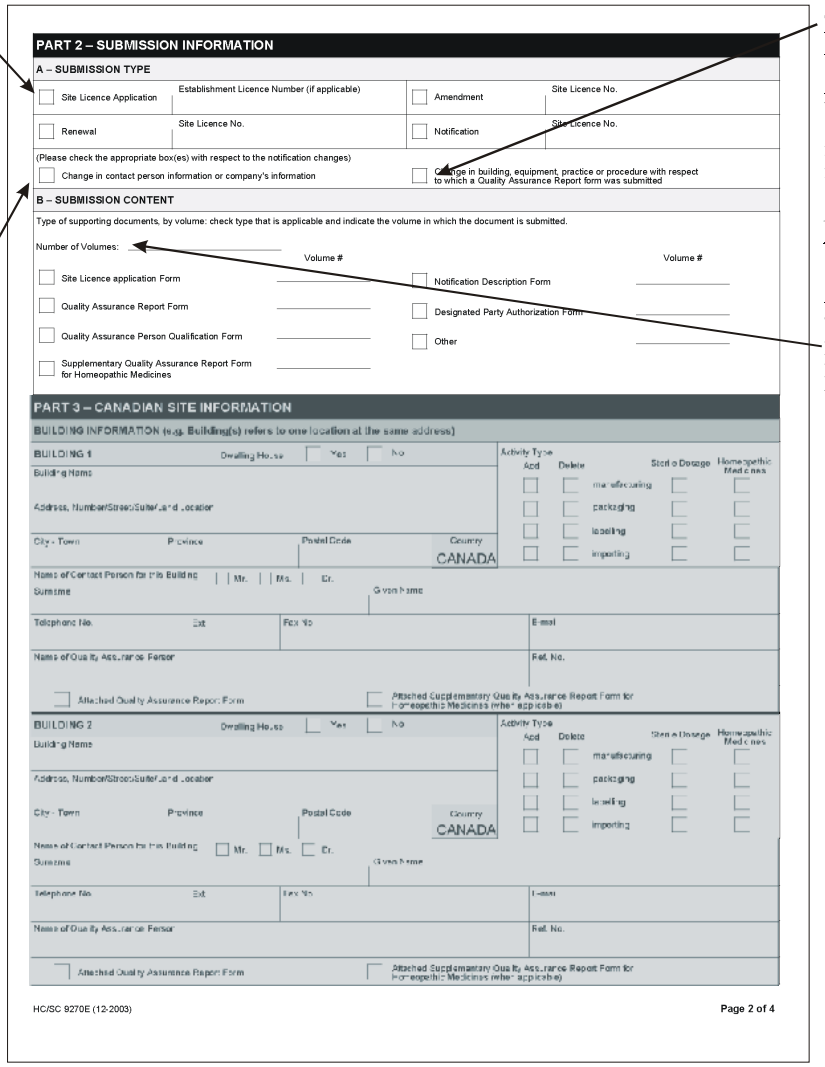
A. Submission Type

Site licence application: First-time applications

Indicate your establishment licence number (when applicable)

When seeking an **amendment, notification,** or **renewal,** enter the site licence number in the space provided.

Check when the changes to be made to the site licence are only to the company name, address, telephone number, or e-mail address or to contact information.



PART 2 – SUBMISSION INFORMATION

A – SUBMISSION TYPE

Site Licence Application | Establishment Licence Number (if applicable) | Amendment | Site Licence No.

Renewal | Site Licence No. | Notification | Site Licence No.

(Please check the appropriate box(es) with respect to the notification changes)

Change in contact person information or company's information | Change in building, equipment, practice or procedure with respect to which a Quality Assurance Report form was submitted

B – SUBMISSION CONTENT

Type of supporting documents, by volume: check type that is applicable and indicate the volume in which the document is submitted.

Number of Volumes:

Site Licence application Form | Volume # | Notification Description Form | Volume #

Quality Assurance Report Form | Designated Party Authorization Form

Quality Assurance Person Qualification Form | Other

Supplementary Quality Assurance Report Form for Homeopathic Medicines

PART 3 – CANADIAN SITE INFORMATION

BUILDING INFORMATION (e.g. Building(s) refers to one location at the same address)

BUILDING 1 | Dwelling House | Yes | No

Activity Type: Add | Delete | Sterile Dosage | Homeopathic Medicines

manufacturing | packaging | labelling | importing

Building Name

Address, Number/Street/Suite/Rural Location

City - Town | Province | Postal Code | Country: CANADA

Name of Contact Person for this Building | Mr. | Ms. | Dr.

Surname | Given Name

Telephone No. | Ext | Fax No. | E-mail

Name of Quality Assurance Person | Ref. No.

Attached Quality Assurance Report Form | Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

BUILDING 2 | Dwelling House | Yes | No

Activity Type: Add | Delete | Sterile Dosage | Homeopathic Medicines

manufacturing | packaging | labelling | importing

Building Name

Address, Number/Street/Suite/Rural Location

City - Town | Province | Postal Code | Country: CANADA

Name of Contact Person for this Building | Mr. | Ms. | Dr.

Surname | Given Name

Telephone No. | Ext | Fax No. | E-mail

Name of Quality Assurance Person | Ref. No.

Attached Quality Assurance Report Form | Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

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Check when there have been changes in building, equipment, practice, or procedure with respect to which a quality assurance report form was submitted and fill out the notification description form (*Site Licence Guidance Document, Appendix 5*)

B. Submission Content

Number of volumes: Indicate the number of volumes (binders) included in the submission.

Annotated Site Licence Application Form

PART 3: CANADIAN SITE INFORMATION

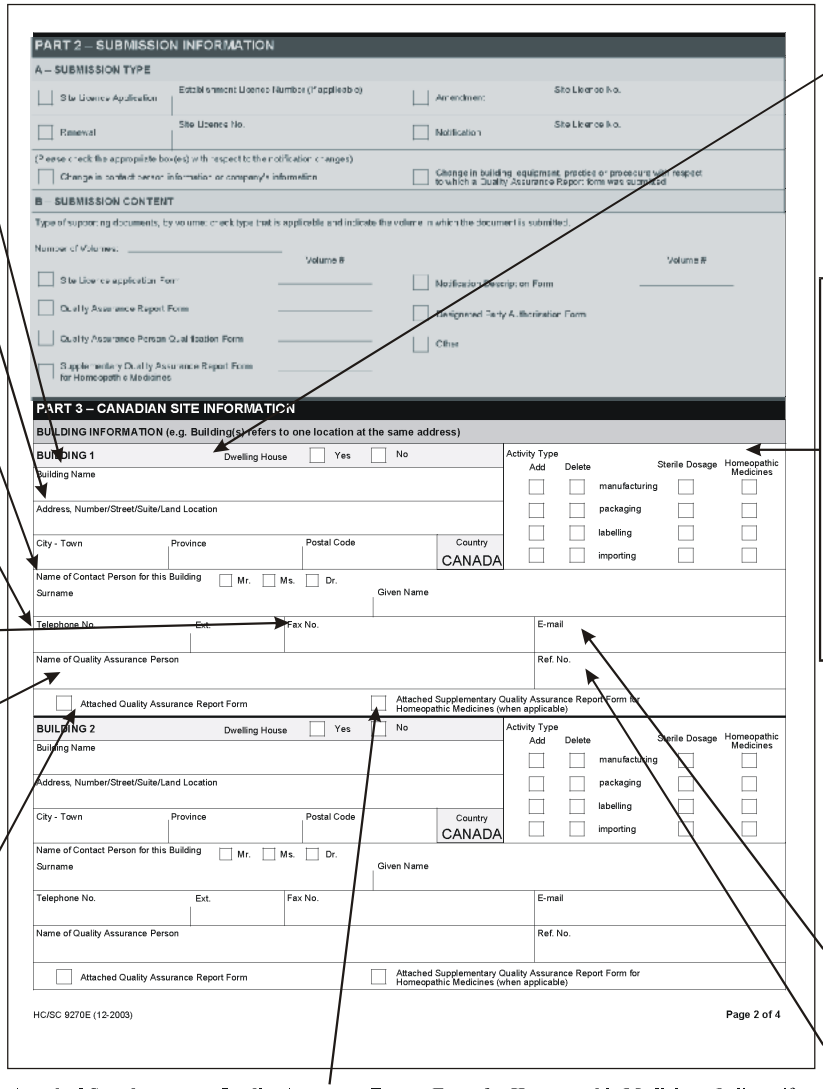
Building Information

When an applicant carries out activities in more than one building, this part must be completed for each building. Building refers to one location at one address.

Designate each building in numerical order (i.e., 1, 2, 3, 4) and complete the respective sections of the form. When there are more than four buildings, add the required information for the additional building as an attachment.

Importers must complete this part for all buildings where imported natural health products are stored within Canada.

Building 1, 2, 3 or 4



Building Name: Legal name or the name of the building

Address: Street address, city/town, province, postal code, country where the building is located.

Name of Contact Person for this building: Contact person responsible for this building.

Telephone Number: Number for the contact person.

Fax Number: Fax number for the contact person.

Name of Quality Assurance Person: Person who completed the Quality Assurance Report Form for this building.

Attached Quality Assurance Report Form: Indicate if a Quality Assurance Report Form is being attached.

Dwelling House: Indicate whether the building is a place of residence

Activity Type: The activity the applicant performs in this building.

Sterile Dosage: Indicate whether the activity is performed in sterile dosage.

Homeopathic Medicines: Indicate whether the activity performed is for homeopathic medicines.

E-mail: Electronic mailing address for the contact person.

Reference Number: Assigned by Natural Health Products Directorate, if known.

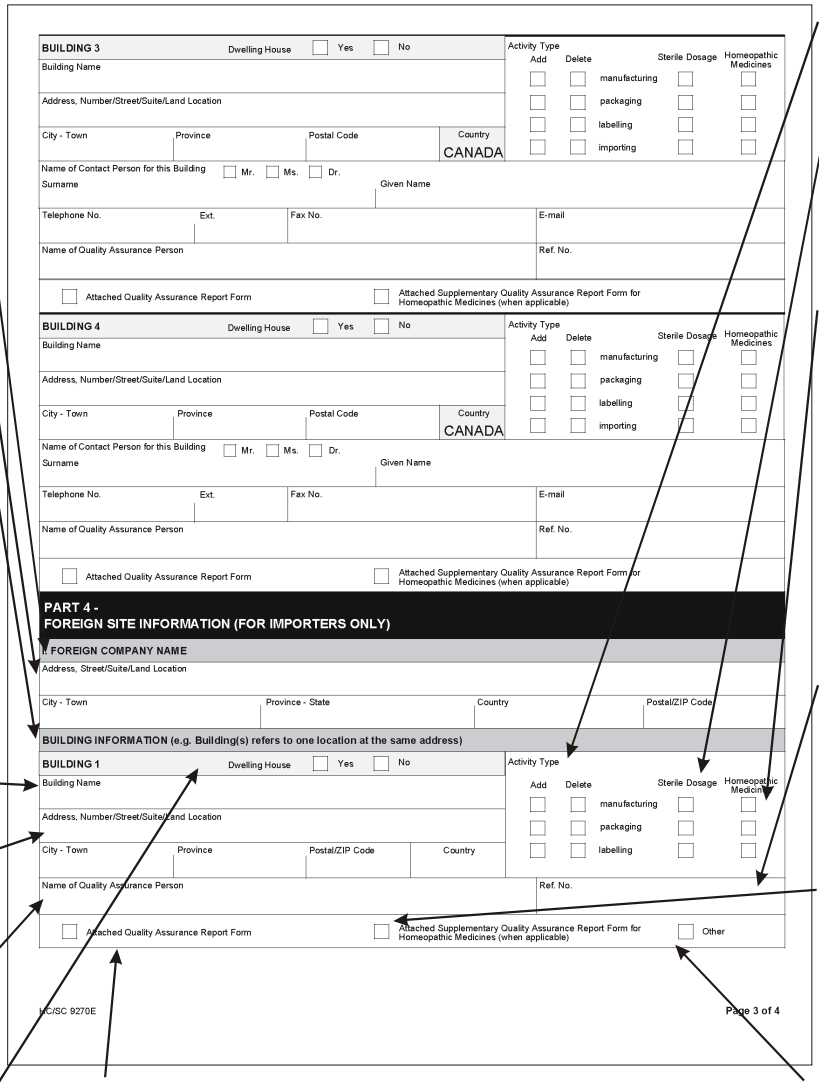
Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines: Indicate if a Supplementary Quality Assurance Report Form for Homeopathic Medicines is being attached.

Note: A Supplementary Quality Assurance Report Form for Homeopathic Medicines should be attached by applicant/company dealing with homeopathic medicines.

* **Note:** Manufacturers, packagers, labellers, importers and distributors must treat all sterile natural health products in the same manner as any other sterile health product. Follow the guidance provided in the guidelines published by Health Canada's Health Products and Food Branch Inspectorate and Therapeutics Products Directorate. The latest version of this document is available at: http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gmp_guidelines_2002_entire_e.html

Annotated Site Licence Application Form

PART 4: FOREIGN SITE INFORMATION (FOR IMPORTERS ONLY)
The importers are asked to fill out information regarding the foreign site from which they are importing. When there are more than two companies, add the required information for the additional company as an attachment



BUILDING 3 — Dwelling House ☐ Yes ☐ No
Building Name
Address, Number/Street/Suite/Land Location
City - Town | Province | Postal Code | Country: CANADA
Name of Contact Person for this Building ☐ Mr. ☐ Ms. ☐ Dr.
Surname | Given Name
Telephone No. | Ext. | Fax No. | E-mail
Name of Quality Assurance Person | Ref. No.
☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

Activity Type — Add | Delete | Sterile Dosage | Homeopathic Medicines
manufacturing
packaging
labelling
importing

BUILDING 4 — Dwelling House ☐ Yes ☐ No
Building Name
Address, Number/Street/Suite/Land Location
City - Town | Province | Postal Code | Country: CANADA
Name of Contact Person for this Building ☐ Mr. ☐ Ms. ☐ Dr.
Surname | Given Name
Telephone No. | Ext. | Fax No. | E-mail
Name of Quality Assurance Person | Ref. No.
☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

Activity Type — Add | Delete | Sterile Dosage | Homeopathic Medicines
manufacturing
packaging
labelling
importing

PART 4 -
FOREIGN SITE INFORMATION (FOR IMPORTERS ONLY)

If FOREIGN COMPANY NAME
Address, Street/Suite/Land Location
City - Town | Province - State | Country | Postal/ZIP Code

BUILDING INFORMATION (e.g. Building(s) refers to one location at the same address)

BUILDING 1 — Dwelling House ☐ Yes ☐ No
Building Name
Address, Number/Street/Suite/Land Location
City - Town | Province | Postal/ZIP Code | Country
Name of Quality Assurance Person | Ref. No.
☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable) ☐ Other

Activity Type — Add | Delete | Sterile Dosage | Homeopathic Medicines
manufacturing
packaging
labelling

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Foreign Company Name: The legal name of the company.

Address: The street address, city/town, province/state, country and postal/zip code of the company. This should be the company headquarters.

Building Information: Building refers to one location at one address. When an applicant carries out activities in more than one building, complete this part for each building.

Designate each building in numerical order, i.e. 1, 2, and complete the respective sections of the form. When there are more than two buildings, add the required information for the additional building as an attachment.

Building Name: Legal name of the building

Address: Street address, city/town, province/state, postal/zip code, country where the building is located

.

Name of Quality Assurance Person: The name of the quality assurance person who completed the Quality Assurance Report Form for this building

Dwelling House: Indicate whether the building in question is a place of residence.

Activity Type: The activity the applicant proposes to perform in this building.

Sterile Dosage:* Indicate whether the activity is performed in sterile dosage.

Indicate whether the activity performed is for **homeopathic medicines.**

Reference Number : Assigned by Natural Health Products Directorate, if known.

Indicate if a **Supplementary Quality Assurance Report Form** for Homeopathic Medicines is being attached.

Other: Indicate if any other document is attached.

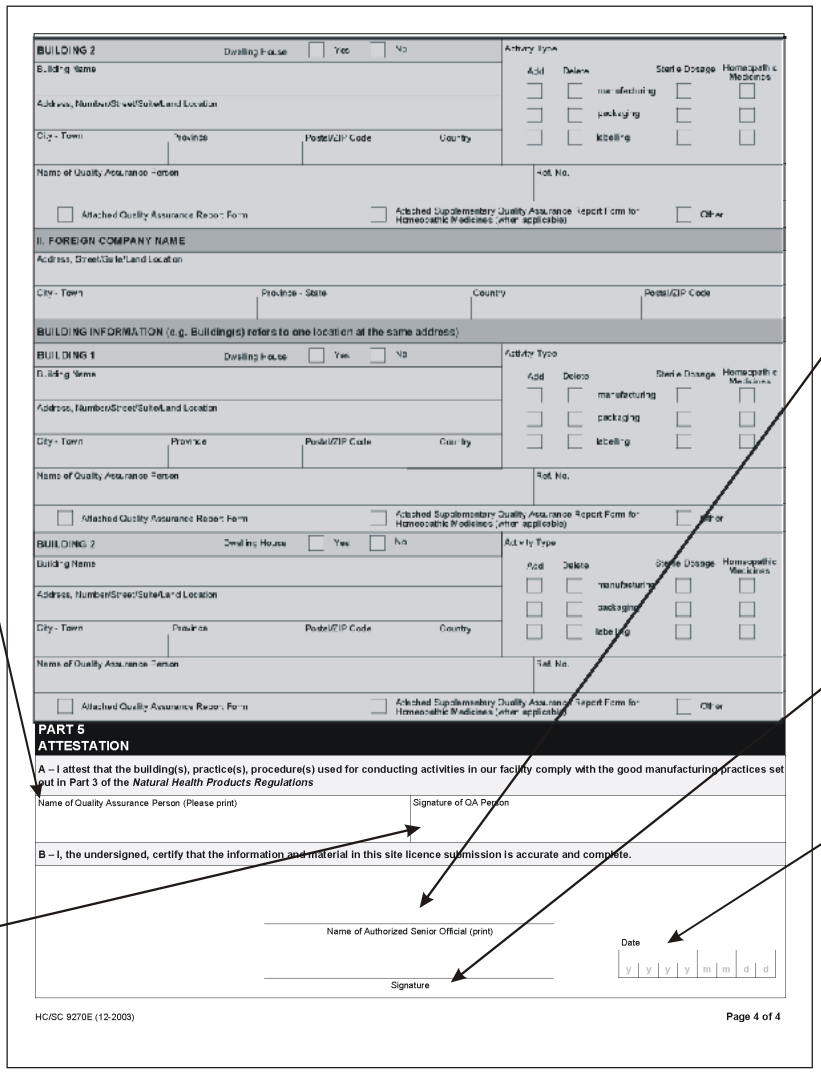
Indicate if a **Quality Assurance Report Form** is being attached.

* **Note:** Manufacturers, packagers, labellers, importers and distributors must treat all sterile natural health products in the same manner as any other sterile health product. Follow the guidance provided in the guidelines published by Health Canada's Health Products and Food Branch Inspectorate and Therapeutics Products Directorate. The latest version of this document is available at :
http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gmp_guidelines_2002_entire_e.html

Annotated Site Licence Application Form

The QA Person, as per section 51 of the *Natural Health Product Regulations*, is attesting that the building(s), procedure(s) used for conducting activities in the referenced facility complies with the GMP set out in Part 3 of the Regulations.

PART 5: ATTESTATION
The Quality Assurance Person (QAP) and the Authorized Senior Official are asked to complete this part.



A. Name of Quality Assurance Person: This person may be the one who completed the Quality Assurance Report Form as described in Part 2, Section 28(f) or the quality assurance person mentioned in Part 3, Section 51 of the Natural Health Products Regulations.

Signature: The signature of the quality assurance person.

B. Name of Authorized Senior Official: Name of the senior official of the company. If this person is different from the senior official indicated in Part 1B, complete the Designated Party Authorization Form and attach it to the application.

Signature: Signature of the person listed as the authorized senior official.

Date: Date the application was completed and signed.

The QA Person, as per section 51 of the *Natural Health Product Regulations*, is attesting that the building(s), procedure(s) used for conducting activities in the referenced facility complies with the GMP set out in Part 3 of the Regulations.

3. Site Licence Submission Process Flow

NHPD accepts submissions for site licence application, renewal of site licence, and changes to site licence. This section outlines how NHPD manages the information that the site licence applicants/licensees submit.

Level 1: Verification

- NHPD screens the submission for the company information and gives each submission a file number (for new applications) and submission number. **Note:** Applicant/Licensee should use the file number assigned on all subsequent correspondence about the submission including renewal, amendment, and notification submissions. If for some reason, an applicant/licensee does not know the file number, he or she should mention his or her name or the company's name, the address, and the activity being performed.
- NHPD sends out an acknowledgment notice to the applicant confirming receipt of the submission. The letter lists the file number and submission number, and notes the date of receipt. If NHPD notices deficiencies in the submission information, these will be outlined in the acknowledgement notice. (See sample acknowledgement letter in Appendix I.) Applicants must respond to this notice within 15 calendar days of the date of issue.
- If no response is received, NHPD considers the application to be withdrawn and sends a notice of withdrawal to the applicant. Applicants may re-submit withdrawn applications at a later date.

Level 2: Processing

- NHPD checks the Site Licence Application Form and the appropriate supporting data for completeness.
- This supporting data includes:
  - the **Quality Assurance Report Form**
  - the **Supplementary Quality Assurance Report Form** for Homeopathic Medicines when applicable
  - the **Quality Assurance Person Qualification Form**
  - the **Designated Party Authorization Form** when applicable
- When deficiencies are identified, NHPD issues a processing deficiency notice (PDN), requesting the missing information or clarification related to the completeness of the application form and supporting data. NHPD only sends this notice once for a particular piece of information. (See Appendix I for a sample PDN letter.)
- When there is no response within 30 days from the date the notice is issued, or inadequate response, NHPD withdraws the application and sends a notice of withdrawal to the applicant.

Level 3: Assessment

When the submission reaches this level, the application form and supporting data are then assessed for compliance with the *Natural Health Products Regulations*.

When NHPD needs additional information to assess the application, it may send an additional information request to the applicant in accordance with Section 37 of the *Natural Health Product Regulations*.

Level 4: Decision

When NHPD deems a site licence submission fully compliant with the *Natural Health Products Regulations*, it issues a site licence. When NHPD refuses a site licence application, the applicant receives a notice stating the reason for refusal.

Where to Submit an Application

Completed submissions including site licence applications, amendments, notifications, and renewals with their respective attachments should be submitted to the Natural Health Products Directorate at:

Mail:

Submission Management Division
Bureau of Product Review and Assessment
Natural Health Products Directorate
Health Products and Food Branch
Qualicum, Tower A
2936 Baseline Rd.
AL 3300B
Ottawa, ON K1A 0K9 **Couriers:** K2H 1B3

How to Submit a General Submission Inquiry

Any inquiries relating to submission process and/or requirements, can be submitted either by mail above, email, or fax:

Email: submission_info@hc-sc.gc.ca

Fax: 613-954-2877

Highlights: A Complete Submission

Applicants are required to provide a valid and complete application.

In order to be seen as a complete submission, applicants must ensure that:

- all fields on the Site Licence Application (SLA) form are complete;
- name of the Quality Assurance Person(s) for Parts 3 and 4, if applicable, are complete;
- if activity type for Homeopathic Medicines has been checked off, a completed Quality Assurance Report (QAR) and Supplementary Quality SQAR is included;
- sites holding an Establishment Licence (EL) submit a valid copy of their current EL with a completed SLA form;
- the activity type(s) listed on the SLA form matches the activity type(s) listed on the EL; however, for any new activity for which they do not hold an EL, a QAR must be submitted;
- the building address(es) listed on the SLA form should match the building address (es) on the EL, however, for any new site for which they do not hold an EL, a QAR must be submitted;
- all activity types listed on the SLA are accounted for in the Quality Assurance Report (QAR) form;
- all completed answers, not including N/A, have a list of relevant SOPs;
- at least one sample record is attached per SOP listed in the QAR;
- information provided in Part A of the QAR and Part A of the SLA form do not conflict;
- any references to attachments (such as SOPs, records, resumes, certificates, floor plans, etc.) are in fact included with the submission.

See also Appendix V: Site Licence Submission Checklist

3B) The Quality Assurance Report (QAR)

Part 3 of the *Natural Health Products Regulations*, Sections 43 to 62, divides the good manufacturing practices into the following four categories: **Places**, **People**, **Processes**, and **Products**.

Manufacturers, packagers, labellers and importers must demonstrate that they are adhering to Good Manufacturing Practices by self-assessing their operation against the requirements and completing a Quality Assurance Report (QAR). Applicants must complete the Quality Assurance Report Form (QARF) to self-assess their operations against the requirements.

The **Quality Assurance Report** is divided into the following three sections:

- General Information
- Detailed Quality Assurance Report
- Attestation

Applicants are encouraged to use the *Good Manufacturing Practices Guidance Document* (see References) while they complete the QAR, since the GMPs set the appropriate standards and practices for product testing, manufacturing, storage, handling, and distribution.

Applicants must complete one report per building or location at the same address, and the report must be completed by a person who has the necessary qualifications to assess the operations of the facility.

Instructions

Detailed Quality Assurance Report

Part 3 (Sections 43 to 62) of the *Natural Health Products Regulations* sets out the good manufacturing practices (GMPs) that manufacturers, packagers, labellers and importers must meet before a site licence for each location will be issued in order to allow the sale of natural health products in Canada.

The Risk Classification system of GMP Observations (Chapter 4 of the *Good Manufacturing Guidance Document),* assists the Quality Assurance Person to identify potential risks and take the necessary action.

- Risk 1: Immediate corrective action required
- Risk 2 and Risk 3: Corrective action required

Statements/Questions: Yes/No

The statements/questions in this report are divided into four sections in accordance with the *Good Manufacturing Practices Guidance Document*:

- **Places** (premises and equipment),
- **People** (personnel and quality assurance),
- **Processes** (sanitation program and operations),
- **Products** (specifications, stability, samples, records, recall reporting, and sterile products).

Check off the response to the statement/question as either YES that the statement/question is correct or NO that the statement/question is not correct. If the statement/question is unclear, refer to the appropriate section(s) in the *GMP Guidance Document* for assistance.

If yes is answered to the statement/question, in the space provided clearly describe how the site complies with the referenced section of *Natural Health Products Regulations.*

If no is answered, in the space provided provide a clear rationale as to why the statement/question is not applicable to the activities conducted at the site.

> **Note:** Additional pages may be attached if the space provided is not sufficient. Identify in the "list of attachments" under the Supporting Documentation the additional pages that have been attached.

Standard Operating Procedures (SOPs)

An SOP is an authorized written procedure giving instructions for performing operations, and are not necessarily specific to a given product or material but of a more general nature. SOPs can be defined as established methods to be followed routinely for the performance of designated operations or in designated situations. These are concise and specific step-by-step instructions that allow an individual with limited knowledge or experience on the procedure to successfully reproduce the activities. Certain SOPs may be used to supplement product-specific master production documents.

For each statement/question, the applicant is required to list the title(s) and the number(s) of the relevant standard operating procedure(s) that are in place at the site.

Example: *FACIL-001 - Pest Control*

> **Note:** The actual SOP(s) does not need to be attached, unless the applicant feels that the SOP(s) will help in the assessment of the site licence application.

For each SOP listed, a copy of any record/log/checklist should be attached as supporting documentation to show that the SOPs that are listed are being followed on a daily/monthly/annual basis.

Records should be completed (not blank templates) and the records must have been or are currently in use within a six-month time period from the inspection date.

Examples:

The SOP listed is FACIL–001 Pest Control; supporting documentation is required to show that the Pest Control program is in place and is used at the site. If the SOP states that a pest inspection should be conducted every month, the records are required to show that the inspection(s) has been done.

The SOP listed is PERS–011 Employee Training; complete job descriptions and ongoing training records for employees at the site. Photocopies of selected job descriptions and training records can be used as supporting documentation.

Note: Any personal employee information may be blacked out.

Deviations and Corrective Actions

For each statement/question, the applicant is required to list any deviations to the Natural Health Products GMPs that were observed during the site inspection.

If the applicant indicates a deviation(s), they must describe in the space provided a description of the deviation(s) and rationale for the deviation(s) where applicable, and the details of the corrective action(s) that were taken or to be taken.

For action to be taken, a corrective action plan with time line should be attached. The deviation(s) listed could be for minor correction(s) within the site (such as screening and trapping floor drains, or the removal of temporary repairs on equipment) or could be the plans for more major correction(s) (such as the installation of an air filtration system, or the development of SOPs for this section of the Regulations).

Supporting Documentation

List all supporting documentation as described above (SOP record(s), and corrective action plan(s)), and attach the document(s) directly behind the statement/question page.

ATTESTATION

The Quality Assurance Person that completed the Quality Assurance Report (QAR) needs to print and sign his/her name and date this part of the QARF.

> **Note:** This Quality Assurance Person is identified in box # 16a of the QARF - General Information.

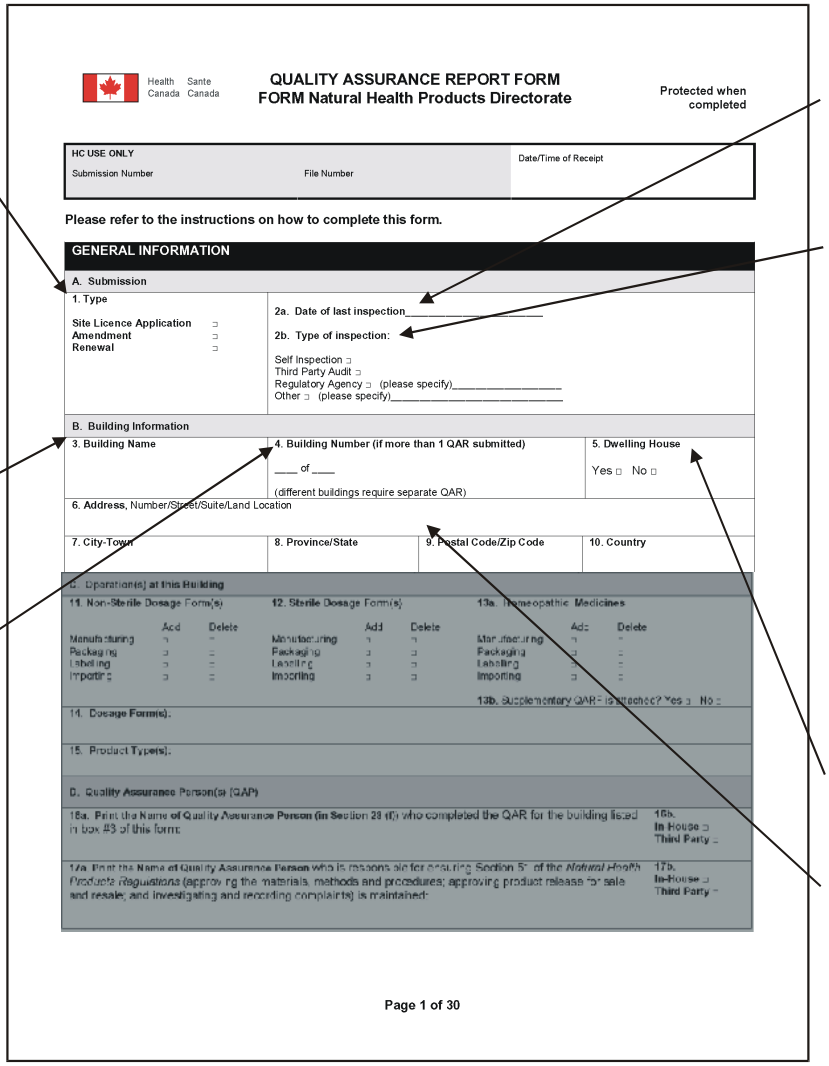
ATTESTATION		
I attest that the building(s), practice(s), procedure(s) used for conducting activities in our facility comply with the good manufacturing practices set out in Part 3 of the Natural Health Products Regulations		
Name of Quality Assurance Person (Please print)	Signature of QA Person	Date yyyy-mm-dd

3.B. Annotated Quality Assurance Report Form (QAR)

Type of Submission:
- **Site Licence Application -** First-time applications
- **Amendment -** Submission for amendment
- **Renewal -** Submission for renewal

Building Name: Registered name of the building

Building Number: Building refers to one location at one address. When an applicant carries out activities in more than one building at different addresses, a QAR must be completed for each address. Designate each building in numerical order (e.g., 1, 2) and complete the respective sections of the form. When one site has more than two buildings, add the required information for the additional building as an attachment.



Health Canada / Santé Canada

QUALITY ASSURANCE REPORT FORM
FORM Natural Health Products Directorate

Protected when completed

HC USE ONLY
Submission Number | File Number | Date/Time of Receipt

Please refer to the instructions on how to complete this form.

GENERAL INFORMATION

A. Submission

1. Type
Site Licence Application ☐
Amendment ☐
Renewal ☐

2a. Date of last inspection_____
2b. Type of inspection:
Self Inspection ☐
Third Party Audit ☐
Regulatory Agency ☐ (please specify)_____
Other ☐ (please specify)_____

B. Building Information

3. Building Name
4. Building Number (if more than 1 QAR submitted)
___ of ___
(different buildings require separate QAR)
5. Dwelling House
Yes ☐ No ☐
6. Address, Number/Street/Suite/Land Location
7. City-Town
8. Province/State
9. Postal Code/Zip Code
10. Country

C. Operation(s) at this Building

11. Non-Sterile Dosage Form(s)

	Add	Delete
Manufacturing	☐	☐
Packaging	☐	☐
Labelling	☐	☐
Importing	☐	☐

12. Sterile Dosage Form(s)

	Add	Delete
Manufacturing	☐	☐
Packaging	☐	☐
Labelling	☐	☐
Importing	☐	☐

13a. Homeopathic Medicines

	Add	Delete
Manufacturing	☐	☐
Packaging	☐	☐
Labelling	☐	☐
Importing	☐	☐

13b. Supplementary QAR is attached? Yes ☐ No ☐

14. Dosage Form(s).

15. Product Type(s).

D. Quality Assurance Person(s) (QAP)

16a. Print the Name of Quality Assurance Person (in Section 2B (f)) who completed the QAR for the building listed in box #3 of this form:
16b. In House ☐ Third Party ☐

17a. Print the Name of Quality Assurance Person who is responsible for ensuring Section 57 of the *Natural Health Products Regulations* (approving the materials, methods and procedures; approving product release for sale and resale; and investigating and recording complaints) is maintained:
17b. In-House ☐ Third Party ☐

Page 1 of 30

Date of last inspection: Date of last inspection at the building identified in box #3.

Type of Inspection:
- **Self inspection -** Inspection conducted internally
- **Third party audit -** Inspection conducted by independant person(s) or organization
- **Regulatory Agency -** Inspection report from a governmental body, such as Health Canada, or from another country
- **Other -** Any other type of audit

Dwelling House: Indicate if the building is a place of residence.

Address: Street address, city/town, province/state, postal/zip code, country, where the building is located.

Annotated Quality Assurance Report Form (QAR)

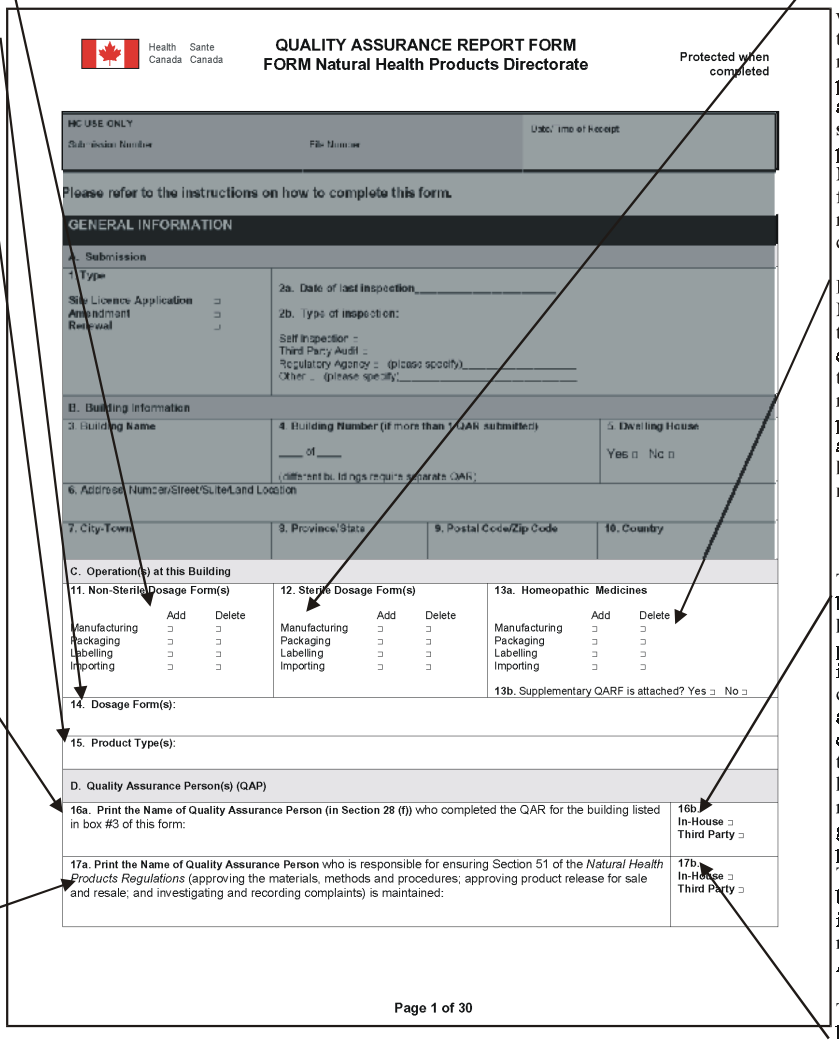
Non-Sterile Dosage Form(s): Activity being performed or will be performed in this building.

Dosage Form(s): Final physical form of the natural health product that may be used by the consumer without any further processing.

Product Types:
- Plant, alga, or fungus
- Non-human animal material
- Bacterium (non-living, e.g. tyndallized, spirulina)
- Extracts
- Isolates
- Enzymes
- Vitamins
- Minerals
- Amino acids
- Essential fatty acids
- Synthetic duplicates
- Probiotics
- Homeopathic medicines

Refers to Section 28 (f) of the *Natural Health Products Regulations*. **The name of the Quality Assurance Person** (QAP) who completed the QAR for the building listed in box #3 of this form.

The name of **Quality Assurance Person**(QAP) responsible for ensuring Section 51 of the *NHP Regulations* (approving the materials, methods, and procedures; approving product release for sale and resale; and investigating and recording complaints) is maintained.
Note: the person identified box # 17a could be the same person as identified box # 16a.



Health Canada / Santé Canada

QUALITY ASSURANCE REPORT FORM
FORM Natural Health Products Directorate

Protected when completed

HC USE ONLY
Submission Number | File Number | Date/Time of Receipt

Please refer to the instructions on how to complete this form.

GENERAL INFORMATION

A. Submission

1. Type
Site Licence Application ☐
Amendment ☐
Renewal ☐

2a. Date of last inspection_____
2b. Type of inspection:
Self Inspection ☐
Third Party Audit ☐
Regulatory Agency ☐ (please specify)_____
Other ☐ (please specify)_____

B. Building Information

3. Building Name | 4. Building Number (if more than 1 QAR submitted) ___ of ___ (different buildings require separate QAR) | 5. Dwelling House Yes ☐ No ☐

6. Address: Number/Street/Suite/Land Location

7. City-Town | 8. Province/State | 9. Postal Code/Zip Code | 10. Country

C. Operation(s) at this Building

11. Non-Sterile Dosage Form(s)	Add	Delete	12. Sterile Dosage Form(s)	Add	Delete	13a. Homeopathic Medicines	Add	Delete
Manufacturing	☐	☐	Manufacturing	☐	☐	Manufacturing	☐	☐
Packaging	☐	☐	Packaging	☐	☐	Packaging	☐	☐
Labelling	☐	☐	Labelling	☐	☐	Labelling	☐	☐
Importing	☐	☐	Importing	☐	☐	Importing	☐	☐

13b. Supplementary QARF is attached? Yes ☐ No ☐

14. Dosage Form(s):

15. Product Type(s):

D. Quality Assurance Person(s) (QAP)

16a. **Print the Name of Quality Assurance Person (in Section 28 (f))** who completed the QAR for the building listed in box #3 of this form:

16b. In-House ☐ Third Party ☐

17a. **Print the Name of Quality Assurance Person** who is responsible for ensuring Section 51 of the *Natural Health Products Regulations* (approving the materials, methods and procedures; approving product release for sale and resale; and investigating and recording complaints) is maintained:

17b. In-House ☐ Third Party ☐

Page 1 of 30

Sterile Dosage Form(s): Activity that is being performed or will be performed in this particular building: manufacturing, packaging, labelling and/or importing **sterile** natural health products.
Note: A sterile dosage form is free from microbial contamination.

Homeopathic Medicines: Activity that is being performed or will be performed in this particular building: manufacturing, packaging, labelling and/or importing **homeopathic medicines**.

The QAP identified in box #16a is an **in-house** QAP or **third party** (auditor) who is independent of the company he/she is auditing and who is qualified by education, training, and technical knowledge to conduct a natural health product good manufacturing practices site audit. The person identified in box #16a is the individual who is required to sign the Attestation of the QAR.

The QAP identified in box #17a is an **in-house** QAP or is a **third-party** quality assurance person who is independent of the company he/she is conducting the QA activities for and who is qualified by education, training, and technical knowledge.

3.B. Case Study: QAR Submission (see also Appendix IV)

Company Name: ABC Ltd.

Activities: Manufacturing; Packaging, Labelling, and Importing

Dosage Form: Powders, Capsules, Tablets (importing only)

Product Types: Vitamins, Minerals

Staff #: 25 (1 President/Production Manager, 1 Quality Assurance Manager, 3 office staff, 2 warehouse operators, 5 manufacturing operators, 3 packaging operators, 3 Quality Assurance staff, 2 lab staff, 2 Facilities staff, 3 Sanitation Operators)

Site: Two-story concrete structure, 3000 sq. m., divided into the following: production areas (Blending Room, Encapsulation Room, Packaging Room, Sampling Room); Testing Lab, Warehouse; and non-production areas (change room / restroom, office area & kitchen).

Mr. Smith is the President and Production Manager at ABC Ltd. with a B.Sc. in Chemistry from University of XYZ in Canada with three years' experience in production, two years as a supervisor and one year as a manager. Mr. Smith is attending ongoing courses of GMPs in Herbal Manufacturing from a local institution and has taken other courses such as Good Documentation Practices and Sanitation programs from trade organizations.

The Quality Assurance Person at the site, Ms. Best, works inhouse and has a three-year-degree in science, B.Sc. from the University of TUV in Canada with three years' experience in quality assurance and control, including approval of raw materials, finished product testing and development of standard operating procedures. Ms. Best has taken courses in ISO audits, product safety assessment and pharmaceutical GMPs, and is enrolled in a Good Manufacturing Practices audit course.

The company operates in accordance with their Standard Operating Procedures, written by the QA department and approved by Ms. Best. These outline the details of the following programs at their site: Sanitation; Maintenance & Calibration; Pest Control; Stability; Sample Retention; Training; Quality Assurance; Audit and Document Control. Each SOP details the appropriate steps to follow regarding each activity and the appropriate documentation (records) to be completed. All ABC employees undergo GMP training specific to their job functions and are required to read and keep up to date with their SOPs. Mr. Smith and Ms. Best are responsible for ensuring that all employees document their training.

Case Study: QAR Submission (see also Appendix IV)

PLACES

Premises [Section 45]

(1) Building is designed to prevent cross-contamination and mix-up of the natural health product(s) by way of:		
(a) appropriate space to carry out the operations of the facility;	Yes X	No □
(b) separated production and non-production areas; and	Yes X	No □
(c) sealed building surfaces (e.g. windows, floors, ceilings and production surfaces) made of materials that facilitate maintenance and sanitation.	Yes X	No □

If yes, describe for (a), (b) and (c) how the premises design complies with NHP GMPs.
If no, provide a rationale (e.g. Not applicable because…)

(a) Our building is 3,000 sq. m. in total size with xxx dedicated for the manufacturing areas, xxx for the packaging areas, xxx for the storage areas. We also have xxx for the non production areas with 2 washrooms/change rooms for the employees. Production employees access the change rooms and lunchroom areas through a separate entrance (from the office/main entrance), leading directly to the production area. Materials and finished products are delivered and shipped through the warehouse door in the back of the building. A door separates the warehouse and production areas. A corridor in the production areas allows entry to the different manufacturing and packaging rooms. The wash-up room and maintenance room have their own doors and are separated from the production areas by another set of doors to prevent cross-contamination.

(b) Physical areas have been clearly marked for quarantine and released materials and products in the warehouse. Areas for manufacturing, packaging, testing and storage warehouse have been clearly identified and segregated. A SOP is in place to ensure employees working in the manufacturing and packaging areas are restricted from accessing other non-production areas, including outer doors and office areas, except in the case of an emergency.

(c) All floors, walls and ceilings are made of materials that do not shed particles. Surfaces and joints are sealed to prevent contamination from extraneous materials and permit effective cleaning. All floor drains are screened and trapped. All doors, windows, walls, ceilings and floors contain no holes or gaps, except those that are part of the design.

Standard Operating Procedures

Relevant standard operating procedures are established. Yes X No □

List all standard operating procedures (SOPs) (titles and numbers) for this section.

Building, Facilities, Utilities and Operations, SOP PREM 010
Handling of Materials and Goods in the Quarantine and Released areas in the Warehouse, SOP WHSE 002
Personnel flow in the manufacturing and packaging areas, SOP PROD 005
Sanitation and maintenance of the building, SOP MAIN 022
Preventative Maintenance of Production and Non-Production areas, SOP PM 003
Preventative Maintenance of Building exterior, SOP PM 002
Weekly Checks of Ventilation System, SOP PM 008

Deviations and corrective actions

Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable. Detail the corrective action(s) taken and/or to be taken.

Deviation noted: Two entries were missed in the maintenance logs for production room number 2 on October 10 and 12, 2004. The employee involved was identified. Maintenance was performed but entries were missed. The entries were put back in on October 15, 2004 with the appropriate GMP notations (dated and initialled with a brief explanation). Supervisor initialled the entries and employee went through GMP training again (October 22, 2004) on the importance of record keeping and the appropriate way of documenting corrections.

Case Study: QAR Submission (see also Appendix IV)

Supporting documentation
► **Attach a minimum of one photocopy of a completed record(s)/log(s) as outlined in the SOP(s) listed above (see instructions for more details).** ► **Attach supporting documentation such as action plans with timelines for each corrective action identified above.** **List of attachments:** Preventative Maintenance schedule: Annual, quarterly, weekly checks Preventative maintenance Logs, Daily records for the week of October 10, 2004 Weekly Inspection record by supervisor Records for changing materials from quarantine to released Records for the repair of door and ceiling to production room number 2

Premises [Section 45]		
(2) Building is designed to prevent cross-contamination and adulteration of the natural health product(s) by way of: **(a) adequate ventilation, filtration and airflow;** **(b) appropriate plumbing; and** **(c) appropriate water supply for the intended purposes (e.g. production, cleaning or utility functions).**	Yes □ Yes □ Yes □	No □ No □ No □

Premises [Section 45]		
(3) Raw material(s) and finished product(s) are stored under conditions that maintain quality and safety (such as temperature, humidity and light controls).	Yes □	No □

Premises [Section 45]		
(4) Building is designed and maintained to prevent the entry and harbouring of insects and other animals.	Yes □	No □

Equipment [Section 46]		
(5) Equipment is **(a) designed and constructed to prevent contamination of the natural health product(s).** **(b) maintained to prevent contamination of the natural health product(s).**	Yes X Yes X	No □ No □

If yes, describe for (a) and (b) how the equipment complies with NHP GMPs.
If no, provide a rationale (e.g. Not applicable because…)

Production equipment and utensils having direct contact with materials and products are constructed of smooth, non-reactive and non-toxic materials, and are designed to withstand repeated cleaning. They are also designed to minimize the possibility of lubricant or other maintenance materials contaminating the products by ensuring proper equipment design (e.g. tanks, chain drives and transmission gears must be enclosed or properly covered).

A calibration and maintenance program is in place for critical manufacturing, packaging and testing equipment, and records are maintained of this work. Temporary repairs e.g. (with tapes) are avoided. Defective and dirty equipment and utensils are clearly labelled and stored in a separate location. Usage logs for all equipments and utensils are mandatory.

Case Study: QAR Submission (see also Appendix IV)

Equipment [Section 46]		
(6) Procedures are established and followed for the cleaning of the equipment and utensils.	Yes □	No □

Equipment [Section 46]		
(7) Equipment maintenance and calibration procedures are in place to ensure that equipment remains accurate for its intended use.	Yes □	No □

PEOPLE

Personnel [Section 47]		
(8) In meeting company's requirements, individuals in charge of manufacturing, packaging, labelling and/or storage activities have appropriate education, training or experience.	Yes X	No □

If yes, describe how individual(s) meet the requirements to perform their duties relating to the activities, types of natural health product(s) and dosage form(s).
If no, provide a rationale (e.g. Not applicable because...)

The Production Manager has a B.Sc. in Chemistry from University of XYZ in Canada, 3 years in production experience with 2 years as a supervisor and I year as a manager.

He is attending on-going courses of GMPs in Herbal Manufacturing from local institutions and other courses such as Good Documentation Practices, Sanitation programs from trade organizations.

Personnel [Section 47]		
(9) Procedures have been established to ensure that all personnel have appropriate initial and ongoing good manufacturing practices (GMP) training necessary to perform their assigned duties.	Yes □	No □

Quality Assurance [Section 51]		
(10) In meeting company's requirements, the Quality Assurance Person(s) has the appropriate training, experience and technical knowledge.	Yes X	No □

If yes, describe how the Quality Assurance person(s) meet the requirements, and has the qualifications to perform their duties relating to the activities, types of natural health product(s) and dosage form(s).
If no, provide a rationale (e.g. Not applicable because...)

Our company requires the QA Person/Manager to have the following qualifications:

- A minimum of a 3 year degree from a recognized institution in an applied science field
- A minimum of 3 years experience in Quality Assurance
- Training in Quality and Manufacturing related subjects

Please find attached the QAPQ form for details regarding the qualifications of our current Quality Assurance Person/Manager.

Case Study: QAR Submission (see also Appendix IV)

Quality Assurance [Section 51]

(11) Does this site have a Quality Assurance Person(s) responsible for: **(a) approving the materials, methods and procedures;** **(b) approving product release for sale and resale; and** **(c) investigating and recording complaints**	Yes X Yes X Yes X	No □ No □ No □

If yes, describe for (a), (b) and (c) how the quality assurance person complies with NHP GMPs.
If no, provide a rationale (e.g. Not applicable because...)

Ms. Best, our QA Person on site, is responsible to:

Establish and follow procedures to ensure that products conform to specifications and regulatory requirements.

Establish and follow written procedures for sampling, inspecting and testing raw and packaging materials, in-process and finished products.

Approve or reject all raw materials, packaging materials and finished products, including products manufactured by contractors, based upon conformance to respective specifications. (Please see attached Quality Release Procedures SOP QA 005)

Ensure that completed batch records are reviewed and maintained and a decision is made to approve or reject the product prior to distribution.

Access all areas necessary to perform his or her duties.

Approve product reprocessing.

Attest to all his or her decisions by signing and dating all reports.

Destroy returned products unless he or she determines, by assessment or other investigation, that they may be released for resale.

Permit reprocessing of returned products provided that the subsequent product meets specifications.

Maintain records pertaining to returned, reprocessed and redistributed products and include the name and description of the product, lot number, reason for return, quantity returned, date and means of final disposition.

Ensure that laboratories are capable of performing all of the tasks and responsibilities assigned to them.

Maintain laboratory records of tests and investigations.

Set up and follow written procedures for handling product complaints. These procedures include the determination of whether further investigations and corrective actions are required.

Document all complaints with the following information: the name and description of the product, the lot number, the source and nature of the complaint, and any response. When an investigation is conducted, all findings and any follow-up actions are documented in a written record.

PROCESSES

Sanitation Program [Section 48]

(12) A sanitation program has been established at the site.	Yes X	No □

If yes, describe
If no, provide a rationale (e.g. Not applicable because...)

A written Facility Sanitation Program is in place with the following elements:

- cleaning procedures for facilities and processing equipment;
- a list of cleaning and sanitizing agents appropriate for their intended use;

Case Study: QAR Submission (see also Appendix IV)

- cleaning frequencies;
- provisions for storing cleaned equipment to avoid recontamination;
- procedures for the destruction and disposal of waste materials and debris;
- procedures for cleaning lines between the production of different products.
- preventing contamination of other areas by containing or ventilating dusty operations.
- written pest control program outlining effective measures for preventing pest infestations of the building. e.g. an outside contractor has been hired with a monthly program in place.

Sanitation Program [Section 48]		
(13) An employee health and hygiene program has been established at the site to protect the natural health product(s) against adulteration and contamination.	Yes □	No □

Operations [Section 49]		
(14) Material control procedures are in place from the receipt to the release of raw, in-process, packaging, labelling, and reprocessed material(s).	Yes □	No □

Operations [Section 49]		
(15) Critical process controls are in place, where applicable, at the site for:		
(a) manufacturing activities;	Yes X	No □
(b) packaging activities;	Yes X	No □
(c) labelling activities;	Yes X	No □
(d) importing activities.	Yes X	No □

If yes, describe for (a), (b), (c) and (d) where applicable, the critical process controls.
If no, provide a rationale (e.g. Not applicable because…)

For our a) manufacturing, b) packaging, c) labelling and d) importing activities the following process controls are in place:

- Products are formulated to ensure that they adhere to regulatory requirements and claims stated on the label.
- Master production, packaging and labelling documents are created and revised as necessary for each product manufactured at our site. The quality assurance person reviews and approves all master production documents prior to use.
- Batch records are prepared and followed for each batch of product manufactured, packaged and labelled at our site. They are prepared by photocopying the original master production document, identified with the appropriate lot number and contain all records used during each significant step of the manufacturing process of the product.
- Each batch of product manufactured, packaged and labelled is assigned and tracked by an individual lot number.
- We have a change control procedure that allows us to record and evaluate any deviations from written and approved manufacturing, packaging and labelling processes, standards and test methods, with final approval by the person in charge of production and the quality assurance person.
- QA in-process checks are in place through out the manufacturing, packaging and labelling processes and associated documentation is included in the batch record.
- All materials, products, sample, containers, processing lines and major equipment are identified using appropriate labelling and signage at all times to indicate their contents and/or status. (e.g..: Clean; Quarantine; Sampled; Release)
- All rejected materials are stored in a separate section of the warehouse identified with “Reject” labels. Written procedures are in place to dispose of any rejected materials.

Case Study: QAR Submission (see also Appendix IV)

- Written procedures are established for reprocessing batches that do not conform to finished product specifications. The Quality Assurance person is responsible for authorizing the reprocessing of any batch of product.
- All labels are securely stored to prevent mix-ups in our label storage room where only authorized personnel can enter. Labels can only be withdrawn against a packaging order.
- Labelling activities are conducted immediately after filling and sealing to ensure that no mix-ups or mislabelling occurs.
- All bulk products, printed packaging materials and labels are reconciled prior to release of batch.
- Written line clearance procedures are in place for removing all raw, packaging materials and finished products from previous runs.
- Written procedures are in place to ensure that the correct labels and packaging materials are issued and used.
- Each package is identified with a lot number and expiry date that permits determination of the history of the manufacture and control of the lot.
- Production premises are restricted only to authorized personnel who have the appropriate GMP training.
- Imported products are stored properly according to their specified storage requirements.

Operations [Section 49]		
(16) A self inspection program has been established at the site.	Yes □	No □

Operations [Section 49]		
(17) Inspection program(s) for contractors, (e.g. contract testing laboratories, domestic suppliers, foreign suppliers, etc.) have been established.	Yes □	No □

Operations [Section 50]		
(18) Procedures are in place at the site to ensure the effective recall of a product.	Yes X	No □

If yes, describe
If no, provide a rationale (e.g. Not applicable because...)

There is a written SOP for recall outlining the following:

- key personnel responsible for initiating and coordinating recall activities;
- notification to Health Canada.
- Steps to ensure that the recall procedure can be put into operation at any time, during and outside normal working hours;
- steps for implementing a recall (e.g. determining extent of the recall, and means of notifying affected parties);
- maintenance of distribution records to enable tracing of each lot;
- identifying and storing recalled products separately in a secure area until further action is determined;
- assessing and recording the progress and efficacy of the recall, and issuing a final report, including a final reconciliation;
- notification of foreign customers that have imported the lot that is being recalled.

Case Study: QAR Submission (see also Appendix IV)

PRODUCT

Specifications [Section 44]		
(19) Written procedures are in place to assess *raw and/or packaging materials* against written specifications.	Yes □	No □

Specifications [Section 44]		
(20) Written procedures are in place to assess *finished natural health products* against written specifications.	Yes X	No □

If yes, describe
If no, provide a rationale (e.g. Not applicable because…)

Written specifications for all finished products are established.

Written procedures that describe tests to be conducted to ensure the identity, purity and quantity of finished products are available. (When applicable, these procedures should include potency testing.)

We have confirmed that all test methods provide accurate and consistent results.

We have SOPs requiring that each lot of finished products are assessed for compliance with specifications prior to release.

Specifications [Section 44]		
(21) Procedures are in place to ensure that any change(s) in specifications are reflected in the operations and that every change is approved by the quality assurance person. **(Note: any changes to product specifications require a product licence notification and/or amendment)**	Yes □	No □

Stability [Section 52]		
(22) Data from accelerated or real-time stability studies or from similar product formulations are used in the initial determination of the expiration date.	Yes □	No □

Stability [Section 52]		
(23) An on-going stability program is in place at the site.	Yes X	No □

If yes, describe
If no, provide a rationale (e.g. Not applicable because…)

We have an on-going stability program in place at the site which would:

- Provide data and rationale to reasonably ensure that each finished product meets its label claims at the expiry date.

Confirm and adjust the expiry date, when required, on the basis of real-time studies on product stored in the conditions noted on the label, for the period of time indicated by the expiry date.

Display the lot expiry date on the label of each finished product.

Ensure that all packaging and labelling requirements are met, and keep the product free from contamination until the expiry date (e.g. deterioration of packaging material and labelling).

Re-evaluate the product shelf life when significant changes are made to the formulation, process or package that may affect the product's stability.

- Carry out testing appropriate to each product at the pre-set schedule.
- Set out the required number of stability samples for testing purposes.

Case Study: QAR Submission (see also Appendix IV)

Samples [Section 61]

(24) A sample retention program is in place at the site.	Yes X	No □

If yes, describe (including information on the duration of retention, environmental conditions, final trade packages, destruction of samples etc.)
If no, provide a rationale (e.g. Not applicable because...)

The sample retention program at our site includes:

Retain a sample of each lot of a finished product.

Retain samples in their final trade packages or in containers of the same material and construction.

Store samples in the environmental conditions listed on the label.

Ensure that samples are of sufficient size to permit complete testing according to specifications.

Maintain samples for at least one year after the expiry date. Shorter retention times may be approved by applying in writing to NHPD.

Records [Sections 53 to 57]

(25) Required records are maintained as per the *Natural Health Products Regulations*.	Yes X	No □

If yes, for all activities conducted at the site, identify in the boxes below where each of the following records are kept. Please use '**O**' for records maintained on-site, and use '**A**' if you have access to the records but they are kept off site.
If no, provide a rationale (e.g. Not applicable because...)

Record	Manufacturer	Packager	Labeller	Importer
Master production document	O			A
Manufacturing order	O			A
Packaging order	O			A
Labelling order	O			A
Test results: raw material	O			A
Test results: packaging material	O			A
Test results: finished product	O			O
Specifications: raw material	O			A
Specifications: packaging material	O			A
Specifications: finished product	O			O
Stability summary	O			O
Ingredients list	O			O
Products list	O			O
Distribution list	O			O
Complaints	O			O
Sanitation program	O			O
Other (please specify)				

If additional space is required, please attach on a separate sheet.

Case Study: QAR Submission (see also Appendix IV)

Records [Sections 58]		
(26) Batch and lot records for the natural health product(s) are maintained as per the *Natural Health Products Regulations.*	Yes □	No □

Recall Reporting [Section 62]		
(27) Procedures are in place to ensure that the required information is submitted to Health Canada when a recall is initiated.	Yes X	No □

If yes, describe
If no, provide a rationale (e.g. Not applicable because...)

Recall SOP requires us to submit product recall information to NHPD or the appropriate Health Canada Authority within three days of initiating the recall.

The following would be submitted:

- the proper name and the common name of each medicinal ingredient that it contains;
- each brand name under which it is sold;
- its product number;
- the number of each lot or batch recalled;
- the name and address of each manufacturer, importer and distributor of the natural health product;
- the reasons for commencing the recall;
- the quantity manufactured or imported into Canada;
- the quantity that was distributed in Canada;
- the quantity remaining in the possession
- a description of any other actions, as the case may be, that have been taken or to be taken in respect of the recall.

Sterile Products [Sections 59 and 60]		
(28) All sterile products are manufactured and packaged: **(a) in a separate and enclosed area;** **(b) under the supervision of personnel trained in microbiology; and** **(c) using a method scientifically proven to ensure sterility [Sections C.01.064 & C.01.065 of the *Food and Drug Regulations* apply]**	Yes □	No X

If yes, describe
If no, provide a rationale (e.g. Not applicable because...)

This question is not applicable to our site as we are currently not manufacturing, packaging or labelling sterile products.

3C) Annotated Supplementary Quality Assurance Report (*SQAR*) Form for Homeopathic Medicines

Type of Submission:
- **Site Licence Application -** First-time applications
- **Amendment -** Submission for amendment
- **Renewal -** Submission for renewal

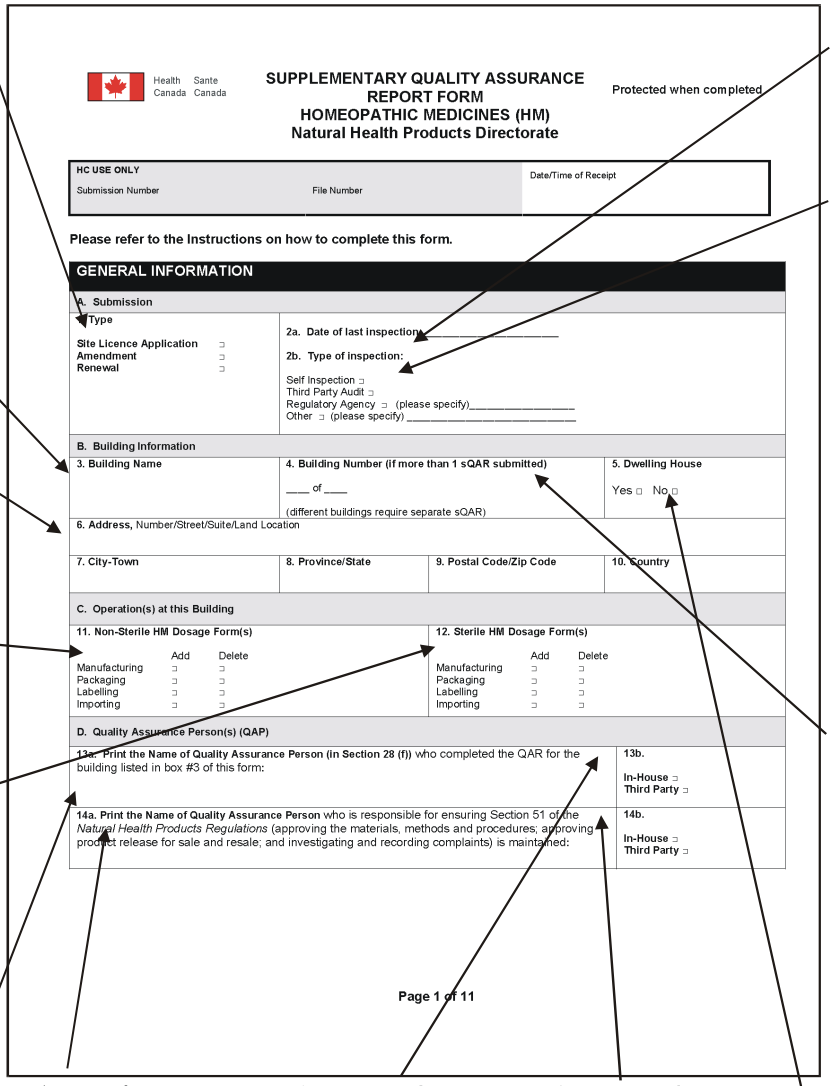
Building Name: Registered name of the building.

Address: Street address, city/town, province/state, postal/zip code, country where the building is located.

Non-Sterile Dosage Form(s): Activity that is performed or will be performed in this building.

Sterile Dosage Form(s): Activity that is being performed or will be performed in this building **Note:** A sterile dosage form is free from microbial contamination.

Refers to Section 28 (f) of the *Natural Health Products Regulations*. **The name of the Quality Assurance Person** (QAP) who completed the QAR for the building listed in box #3 of this form.



Health Canada / Sante Canada

SUPPLEMENTARY QUALITY ASSURANCE REPORT FORM
HOMEOPATHIC MEDICINES (HM)
Natural Health Products Directorate

Protected when completed

HC USE ONLY | Submission Number | File Number | Date/Time of Receipt

Please refer to the Instructions on how to complete this form.

GENERAL INFORMATION

A. Submission
Type
Site Licence Application ☐
Amendment ☐
Renewal ☐
2a. Date of last inspection: _____
2b. Type of inspection:
Self Inspection ☐
Third Party Audit ☐
Regulatory Agency ☐ (please specify)_____
Other ☐ (please specify) _____

B. Building Information
3. Building Name
4. Building Number (if more than 1 sQAR submitted) ___ of ___ (different buildings require separate sQAR)
5. Dwelling House Yes ☐ No ☐
6. Address, Number/Street/Suite/Land Location
7. City-Town
8. Province/State
9. Postal Code/Zip Code
10. Country

C. Operation(s) at this Building
11. Non-Sterile HM Dosage Form(s) — Add / Delete
Manufacturing ☐ ☐
Packaging ☐ ☐
Labelling ☐ ☐
Importing ☐ ☐
12. Sterile HM Dosage Form(s) — Add / Delete
Manufacturing ☐ ☐
Packaging ☐ ☐
Labelling ☐ ☐
Importing ☐ ☐

D. Quality Assurance Person(s) (QAP)
13a. Print the Name of Quality Assurance Person (in Section 28 (f)) who completed the QAR for the building listed in box #3 of this form:
13b. In-House ☐ Third Party ☐
14a. Print the Name of Quality Assurance Person who is responsible for ensuring Section 51 of the *Natural Health Products Regulations* (approving the materials, methods and procedures; approving product release for sale and resale; and investigating and recording complaints) is maintained:
14b. In-House ☐ Third Party ☐

Page 1 of 11

The name of **Quality Assurance Person**(QAP) who is responsible for ensuring Section 51 of the *NHP RegulationS* is maintained. Person identified in box #13a is the individual who is required to sign the Attestation of the QAR. **Note:** Person identified in box # 14a could be the same person as identified in box # 13a

The QAP identified in box #13a is an **in-house** QAP or is a **third party** (auditor) who is independent of the company he/she is auditing andqualified by education, training, and technical knowledge to conduct a natural health product good manufacturing practices site audit.

The QAP identified in box #14a is an **in-house** QAP or is a **third-party** quality assurance person independent of the company he/she is conducting the QA activities for and who is qualified by education, training, and technical knowledge.

Date of last inspection: Date of last inspection at the building identified in box #3.

Type of Inspection:
- **Self inspection -** Inspection conducted internally
- **Third party audit** - Inspection conducted by independant person(s) or organization
- **Regulatory Agency -** Inspection report from a governmental body, such as Health Canada, or from another country
- **Other** - Any other type of audit

Building Number: Building refers to one location at one address. When an applicant carries out activities in more than one building at different addresses, a QAR must be completed for each address.
Designate each building in numerical order (i.e., 1, 2) and complete the respective sections of the form. When one site has more than two buildings, add the required information for the additional building as an attachment.

Dwelling House: Indicate if the building is a place of residence.

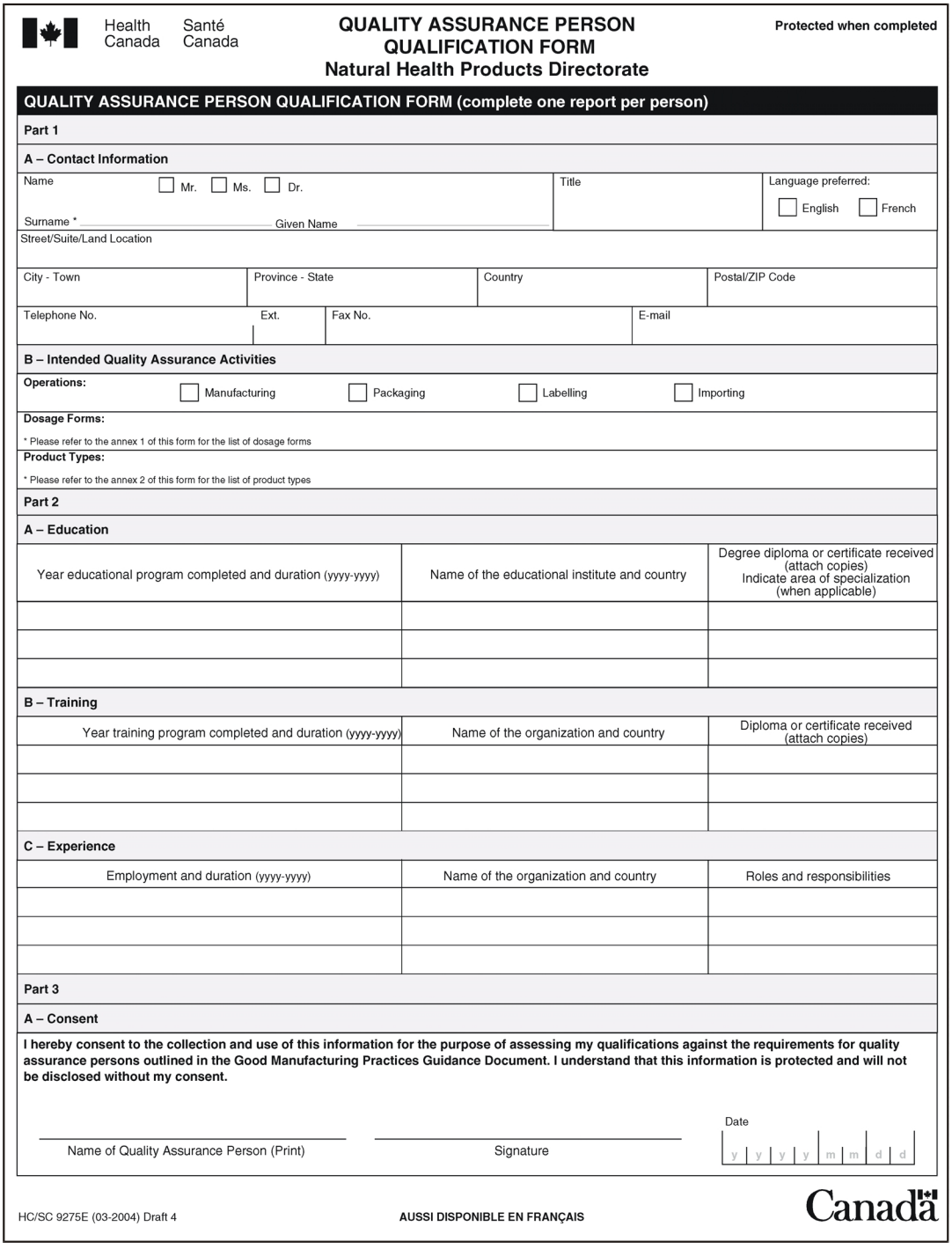
Instructions for Completing the Supplementary Quality Assurance Report (SQAR) Form for Homeopathic Medicines

When dealing with homeopathic medicines, applicants must complete the Quality Assurance Report Form (QAR) and the Supplementary Quality Assurance Report Form (SQAR) for Homeopathic Medicines. These reports are used for self-assessment of the operation against the requirements of Part 3 (Good Manufacturing Practices) of the *Natural Health Products Regulations* and the Good Manufacturing Practices (GMP) for *Natural Health Products Guidance Document.*

Applicant must complete one report per building or location at the same address, and the report must be completed by a person who has the necessary qualifications to assess the operations of the facility.

Please submit **two** copies of SQAR, one original and one photocopy.

D) The Quality Assurance Person Qualification Form



Health Canada / Santé Canada

QUALITY ASSURANCE PERSON QUALIFICATION FORM
Natural Health Products Directorate

Protected when completed

QUALITY ASSURANCE PERSON QUALIFICATION FORM (complete one report per person)

Part 1

A – Contact Information

Name ☐ Mr. ☐ Ms. ☐ Dr. Surname * _____ Given Name _____	Title	Language preferred: ☐ English ☐ French
Street/Suite/Land Location		
City - Town	Province - State	Country	Postal/ZIP Code
Telephone No. Ext.	Fax No.	E-mail

B – Intended Quality Assurance Activities

Operations: ☐ Manufacturing ☐ Packaging ☐ Labelling ☐ Importing

Dosage Forms:

* Please refer to the annex 1 of this form for the list of dosage forms

Product Types:

* Please refer to the annex 2 of this form for the list of product types

Part 2

A – Education

Year educational program completed and duration (yyyy-yyyy)	Name of the educational institute and country	Degree diploma or certificate received (attach copies) Indicate area of specialization (when applicable)

B – Training

Year training program completed and duration (yyyy-yyyy)	Name of the organization and country	Diploma or certificate received (attach copies)

C – Experience

Employment and duration (yyyy-yyyy)	Name of the organization and country	Roles and responsibilities

Part 3

A – Consent

I hereby consent to the collection and use of this information for the purpose of assessing my qualifications against the requirements for quality assurance persons outlined in the Good Manufacturing Practices Guidance Document. I understand that this information is protected and will not be disclosed without my consent.

Name of Quality Assurance Person (Print) _____ Signature _____ Date y y y y m m d d

HC/SC 9275E (03-2004) Draft 4

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Canada

Complete the form, including the **Contact Information**, **Education**, **Training**, and **Experience** for the Quality Assurance Person. Ensure it is signed by the Quality Assurance Person.

Notes:

4. Glossary

The definitions used here apply to the Good Manufacturing Practices (GMPs) and may have different meanings in other contexts.

Assess
Steps taken by the site licence holder to ensure that the requirements in the *Food and Drugs Act,* the *Natural Health Products Regulations* and in-house standards are met. The steps could include, among others, monitoring and testing of raw and/or packaging materials, tracking of production, maintenance of records, and testing of finished products.

Batch
A quantity of product in the processing stage, homogeneous within specified limits, produced according to a single manufacturing order, and as attested by the signatories to the order. In the case of continuous manufacture, the batch corresponds to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

Batch Number
A distinctive combination of numbers and/or letters that specifically identifies a batch, and appears on documents such as the batch record, certificate of analysis.

Batch Record
Production document that captures the quantity and lot number of all materials used, as well as production steps in the manufacturing of a single batch of a natural health product in dosage form.

Bulk Natural Health Product
Unpackaged dosage form, usually in quantities larger than the largest commercially available package size.

Certificate
A legally authenticated written declaration issued by a recognized institution to a person completing a course of study.

Certificate of Analysis
A document signed by a qualified analyst that includes the product name, ingredient listing, lot number of the product, test conducted, test method and results, conclusion of the test (satisfactory or unsatisfactory), name and position of the analyst, and date of issuance.

Certificate of Compliance (CoC)*
A certificate issued by a Regulatory Authority attesting the GMP compliance of a site in that country. In Canada, the CoC is issued by the Inspectorate under the requirements set out in Part C, Division 2 of the *Food and Drug Regulations.*

Certificate of Manufacture
A document issued by a vendor to a distributor or importer that attests that a specific lot of product has been produced according to its master production document. Such certificates include a summary of the current batch documentation, with reference to respective dates of revision, manufacture, and packaging, and are signed and dated by the vendor's authorized quality assurance person.

* see referenced *HPFBI Guidance Document* identified in Section 5.

Critical Process
A process that may cause significant variation in the quality of the finished product.

Diploma
A document issued by an educational institution, such as a university, college, or technical institute, vouching that the recipient has earned a degree or successfully completed a particular course of study.

Distributor
A person who sells a natural health product to another person for the purpose of further sale by that other person.

Dosage Form
The final physical form of the natural health product which may be used by the consumer without requiring any further manufacturing.

Education
The act or process of imparting or acquiring knowledge or skills; the learning of information by instruction, training, or study; can be testified to by a degree, certificate, or diploma.

Experience
Active participation in events or activities leading to the acquisition of knowledge or skills; the knowledge or skills retained from personally observing, encountering, or undergoing something.

Finished Product
A product that has undergone all stages of production, including packaging in its final container and labelling.

Formulate
To prepare components and combine raw materials into a bulk natural health product.

Hazard Analysis and Critical Control Points (HACCP)
An internationally recognized system of food safety methods. It is a systematic approach to the identification, evaluation, and control of food safety hazards.

Homeopathic Medicines
Medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in The *Homeopathic Pharmacopoeia of the United States* (HPUS), the *Homöopathische Arzneibuch* (HAB), the *Pharmacopée Française* (PhF) or the *European Pharmacopoeia*, as amended from time to time, and that are prepared in accordance with these pharmacopoeias.

Importer
A person who imports a natural health product into Canada, for the purpose of sale. This would include bulk natural health products.

In-Process Control
Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the finished product conforms to its specifications. The control of the production environment or equipment may also be regarded as a part of in-process control.

In-Process Product
Any materials or mixture of materials that must, to become a product in dosage form, undergo further processing.

In-Process Testing
The examination or testing of any materials or mixture of materials during the manufacturing process.

ISO (International Organization for Standardization)
A worldwide organization of national standards bodies; ISO is a non-governmental organization that maintains a group of global standards.

Label (n)
Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. Natural health products are included.

Label (v)
To affix the inner or outer label of the natural health product.

Lot
A quantity of any natural health product in dosage form, a raw material or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number which appears on the label of the finished product.

Lot Number
Any combination of letters, figures, or both, by which any natural health product can be traced in manufacture and identified in distribution.

Manufacture
To fabricate or process a product for the purpose of sale.

Manufacturer
A person who fabricates or processes a natural health product for the purpose of sale, but not a pharmacist or other health care practitioner who, at the request of the patient, compounds a natural health product for the purpose of sale to that patient.

Manufacturing Order
Instructions that outline in detail the materials and procedures required to manufacture, prepare, and preserve a single batch of a natural health product in dosage form.

Marketing Authorization
A legal document issued by the Natural Health Products Directorate authorizing the sale of a natural health product in Canada.

Master Formula
A document or set of documents specifying the raw materials with their quantities and the packaging materials, together with a detailed description of the procedures and precautions required to produce a specified quantity of a finished product.

Master Production Document
A document that includes specifications (raw material, packaging material, packaged dosage form), master formula, sampling procedures, and critical processing related standard operating procedures, whether or not these procedures are specifically referenced in the master formula. It also includes a complete list of raw materials used in the manufacture of the product, designated by names or codes; the amount of each raw material required for the theoretical product formulation; manufacturing and process control instructions, and in-process testing requirements, e.g., checks on materials, pre-treatments, sequence of adding materials, mixing time and temperatures; a statement of the principal equipment to be used; a statement of the theoretical weight or measure of the manufactured product, and the acceptable limits beyond which an investigation is required; a description of the finished product containers, closures, and packaging labels; any special precautions to be observed; and dates and times, if applicable, of commencement and completion of significant intermediate stages, such as blending or heating, and of completion of production.

Natural Health Product
A substance set out in Schedule 1 of the *Natural Health Products Regulations* or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine, or a traditional medicine that is manufactured, sold, or represented for use in

a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;

b) restoring or correcting organic functions in humans; or

c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 of the *Natural Health Products Regulations* or any combination of substances that includes a substance set out in Schedule 2. See Appendix 1 of the *Good Manufacturing Practices Guidance Document* for Schedules 1 and 2.

Nosodes
Attenuations of pathological organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles, and yeast; disease products; excretions or secretions.

Observation
A deviation or deficiency of good manufacturing practice noted by an inspector or assessor.

Package (n)
Includes anything in which any food, drug, cosmetic, or device is wholly or partly contained, placed, or packed.

Package (v)
To put a product in its immediate container.

Packaging Material
Labels, printed packaging materials, and those components in direct contact with the dosage form.

Packaging Order
Instructions that outline in detail the materials and special procedures required to package and label a single lot of a product in dosage form.

Potency
The amount per dosage unit of the standardized component(s) which further characterizes the quantity of the ingredient. It is required only when a claim on the potency is to be on the label, or it is required for a specific product, i.e., when literature supports the product with that standardized component. In the Supplementary Good Manufacturing Practices for Homeopathic Medicines, potency refers to the degree of dilution of a homeopathic medicine.

Production
All operations involved in the preparation of a finished product, from receipt of materials, through processing and packaging, to completion of the finished product, including storage.

Purity
The extent to which a raw material or a product in dosage form is free from undesirable or adulterating chemical, biological, or physical entities as defined by specification.

Qualification
To make competent or eligible for an office, position, or task by having the proper or necessary skills, knowledge, credentials, accomplishments, or qualities.

Quality Assurance
All the planned and systematic activities applied within the quality system to provide adequate confidence that the predetermined standards for quality and safety will be met.

Quality Assurance Person
The person who is responsible for assuring the quality of the natural health product before it is made available for sale. This person has the training, experience and technical knowledge relating to the specific activity, i.e., manufacturing, packaging, labelling, and importing.

Quality Assurance Report
A report prepared by either a quality assurance person or a third party auditor who meets the requirements with respect to training, experience and technical knowledge according to section 51(a) (ii) of the *Natural Health Products Regulations.* This report is based on the assessment against the good manufacturing practices regulations and requirements set out in the *Good Manufacturing Practices Guidance Document*. It is considered a self-assessment document and evidence of good manufacturing practices compliance.

Quantity
The amount of medicinal ingredient(s) per dosage unit. It is always required for a product, as it is the amount of medicinal ingredient in the product.

Quarantine
Effective restriction of the availability of material or product for use (physically or by system), until released by the quality assurance person.

Raw Material
Any substance, other than in-process product or packaging material, intended to be used in the manufacture of products, including those that appear in the master formula but that do not appear in the product, such as solvents and processing aids.

Recognized Institution
A Canadian or international educational facility, e.g., a university, college or professional or post-secondary institute, generally approved of or having a secure reputation; credible, reputable, and authoritative.

Reconciliation
A comparison, making due allowance for normal variation, between the amount of product or materials theoretically produced or used and the amount actually produced or used.

Regulatory Authority*
As defined in Section C.01A.001(1) of the *Food and Drug Regulations* (FDR), a government agency or other entity in a Mutual Recognition Agreement (MRA) country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements.

Reprocessing
Subjecting all or part of a batch or lot of an in-process product or finished product to a previous step or alternate manufacturing process due to failure to meet predetermined specifications.

Returned Product
Bulk or finished product sent back to the manufacturer, distributor, or importer.

Risk Classification
GMP Observations (Chapter 4 of the *Good Manufacturing Practices Guidance Document*), that assist the quality assurance person's ability to identify potential risk and take the necessary action.

- Risk 1: Immediate corrective action required
- Risk 2 and Risk 3: Corrective action required

Sampling
Collection of a number of units that comprises representative sample from a designated lot or batch of product.

* see referenced *HPFBI Guidance Document* identified in Section 6.

Sell (Section 2 of the *Food and Drugs Act)*
"Sell" includes offer for sale, expose for sale, have in possession for sale and distribute, regardless of whether the distribution is made for consideration.

Standard Operating Procedures
An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature, e.g., equipment operation, maintenance and cleaning, cleaning of premises and environmental control, sampling and inspection. Certain standard operating procedures may be used to supplement product-specific master production documents.

Third-Party Auditor
An auditor who is independent of the company he or she is auditing and who is qualified by education, training, and experience to conduct a natural health product good manufacturing practices site audit.

Training
To make proficient with specialized instruction and practice.

5. References

The following documents can be found at this site:

Health Canada Website – http://www.healthcanada.ca/nhpd

Natural Health Products Regulations

Site Licence Guidance Document

Good Manufacturing Practices Guidance Document

Natural Health Products Directorate Compliance Policy

Natural Health Products Directorate Compliance Guide

Compliance and Enforcement Policy 001

The Mutual Recognition Agreement (MRA) with Health Product and Food Branch Inspectorate *can be found at the following website:*

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/international_e.html

Appendices

Appendix I: Correspondence with NHPD During the Processing of your Submission

Submission Receipt Acknowledgement

Natural Health Products Directorate
AL: 3301, Qualicum Towers,
2936 Baseline Road
Ottawa, ON K1A OK9

Company Code: 10000
File #: 100000
Submission #: 100000

August 20, 2004

Mr. Jean Gagnon
ABC Limited
11 Herbal Drive
Ottawa, ON
K2H 1B3

Dear Mr. Gagnon:

Re: Application Site Licence
ABC Limited
Date Received by the Natural Health Products Directorate:
2004 - 09 -15 2.00 PM
Natural Health Products Regulation Section: 28

The Natural Health Products Directorate (NHPD), Bureau of Product Review and Assessment (BPRA), thanks you for your submission. This correspondence will serve as acknowledgement of the receipt of your submission.

The company information and contact provided with this submission have been evaluated for quality and completeness and were determined to be deficient as per the Natural Health Products Regulations. At this time, your application is considered incomplete. In order for your application to be processed further, please submit all the following information:

The application form is missing the telephone number, fax number and the e-mail address for Mr. Robert Smith. Please resubmit the application form only to the address below with the missing information included.

The NHPD will retain this submission on file for 15 calendar days in order for all the deficiencies to be addressed. If a written response is not received by the NHPD within 15 days of the date of this letter, this submission will be considered withdrawn. Please remember that the response to the list of deficiencies must be submitted in one consolidated package.

The adequacy of the data submitted to the NHPD has not been assessed at this time and will be determined during the assessment of the submission by the assessment units. As well, a need for data to address additional data gaps may be identified during the assessment. Consequently, further information may be requested by NHPD by means of a processing deficiency notice (PDN) or an information request notice (IRN).

If you have any questions concerning this notice, please contact the submission processor at the below co-ordinates. Please note that File Number and Submission Number (provided at the top right corner of the title page) must be quoted on all correspondence regarding this submission.

Yours truly,

Xxxx Xxxxxxxx
Submission Processor
phone: 613-954-0000
fax: (613) 954-2877

Appendix I: Correspondence with NHPD During the Processing of your Submission

Natural Health Products Directorate
AL: 3301, Qualicum, 2936 Baseline Road
Ottawa, ON
K1A 0K9

Processing Deficiency Notice

Company Code: 10010
File Number: 100000
Submission Number: 100000

August 26, 2004
Mr. Jean Gagnon
11 Herbal Drive
Ottawa, ON
K2H 1B3

Dear Mr. Gagnon:

Re: Processing Deficiency Notice
Site licence Application

This notice is in respect of your submission # 100000, file # 100000 submitted to NHPD on September 15, 2004.

The application form and attachments provided with this submission have been verified by the Bureau of Product Review and Assessment for completeness and were determined to be deficient. At this time, your application is considered incomplete as per section 28 of the *Natural Health Products Regulations*. In order for the processing of your application to be completed, please submit the following information:

- Photocopies of Degrees/Diplomas as referenced in your Quality Assurance Person Qualification form and described in chapter 2 of the Site Licence Guidance Document
- A list of all the SOPs and photocopies of samples of record in use during the last six months

The NHPD will retain this submission on file for 30 calendar days to enable you to address of the deficiencies. If a written response is inadequate or is not received by the NHPD within 30 days of the date of this letter, the submission will be withdrawn. Please remember that the response to the deficiencies must be submitted in one consolidated package. Please note that the File Number and Submission Number (provided at the top right corner of the title page) must be quoted on all correspondence regarding this submission.

The adequacy of the data submitted to the NHPD has not been fully assessed at this time and will be determined during assessment of the submission by the Assessment Division. At this time, further information may be requested as per section 37 of the *Natural Health Products Regulations*.

Should you have any questions concerning the deficiencies identified in this notice, please contact the submission co-ordinator, Xxxxx, at the coordinates below.

Yours truly,

Xxx Xxxxxxx
Site Licensing Submission Co-ordinator
Natural Health Products Directorate
phone: 613-900 0000
fax: 613-900 0001

Letter #2

Appendix I: Correspondence with NHPD During the Processing of your Submission

Natural Health Products Directorate
AL: 3301, Qualicum Towers,
2936 Baseline Road,
Ottawa, ON K1A OK9

Information Request Notice

Company Code: 1xxxxx
File # : 1xxxxx
Sub. No.1xxxxx

September 5, 2004

Mr. Jean Gagnon
ABC Ltd.
11 Herbal Drive
Ottawa, ON K2H 1B3

Dear Mr. Gagnon:

Re: Information Request Notice
Site Licence Application

This is in response to your submission # xxxxx,, file # xxxxx.

The application and attachments provided with this submission are currently being assessed for compliance with Natural Health Products Good Manufacturing Practices and have been determined to be deficient. At this time, NHPD requires further information in order to properly assess your submission. As per [section 37] of the *Natural Health Products Regulations,* please submit all the following information:

- Update on the status of the renovations of the premises and equipment which were to be completed by February 29, 2004

- Samples of records for the following SOPs that were in use during the past six months.
  -SOP 25.0 - Prevention of entry of insects and other small animals into the premises
  -SOP 12.0 - Cleaning the aspirator pump and tank

The NHPD will retain this submission on file for 30 calendar days in order for all of the deficiencies to be addressed. If a written response is inadequate or is not received by the NHPD within 30 days of the date of this letter, the submission will be withdrawn. Please remember that the response to the list of deficiencies must be submitted in one consolidated package. In responding to these issues, please quote the submission # and file # in your response.

If you have any questions concerning the information requested for this submission, please contact the submission co-ordinator at the co-ordinates below.

Yours truly,

Xxx Xxxxxx
Site Licensing Submission Co-ordinator
Natural Health Products Directorate
Phone: (613) 946-2197
Fax: (613) 954-2877

Letter #3

Appendix I: Sample Site Licence 3xxxxx

SITE LICENCE ***LICENCE D'EXPLOITATION***

Licence Number
3xxxxx
Numéro de la licence

This Licence is issued by the Minster of Health under the Authority of section 22 of the Natural Health Products Regulations / *Cette licence est délivrée par le ministre de la Santé conformément à l'article 22 du Règlement sur les produits de santé naturels*

Issued *to/Délivré à* :

Name of Licensee /*Nom du titulaire:* ABC LTD.

Address/*Addresse:* **#11 HERBAL DRIVE**
OTTAWA
ONTARIO
K2H 1B3

to perform the following activities at authorized buildings listed on the Domestic Site Annex and Foreign Site Annex/ *pour exécuter les activités suivantes dans les bâtiments autorisés lister sur Annexe des sites Canadiens et Annexe des sites étrangers :*

ACTIVITIES/*ACTIVITÉS*	**AUTHORIZED ACTIVITIES** / *ACTIVITÉS AUTHORISÉES*	**SPECIFIC AUTHORIZATION** ***AUTORISATION SPÉCIFIQUE***	
		Sterile Dosage Form/*Forme posologique stérile*	**Homeopathic/ Medicine/*Remède Homéopathique***
Manufacturing/*Fabrication*	Yes	No	No
Packaging/*Emballage*	Yes	No	No
Labelling/*Étiquetage*	Yes	No	No
Importing/*Importation*	Yes	No	No

This licence is renewable pursuant to section 36 of the Natural Health Products Regulations. Any changes to the activities authorized by this licence are subject to sections 32 and 33 of the Regulations / *Cette licence est renouvelable annuellement en vertu de l'article 36 du Règlement sur les produits de santé naturels. Tout changement aux activités autorisées par cette licence est régi par les articles 32 et 33 du Règlement.*

Issued/*Délivrée* : Sept. 21, 2004	Amended/*Modifiée* : N/A	Expiry/*Expiration* : Sept. 21, 2005

Annex Attached/ *Annexes jointes:*

.....
Director General, Natural Health Product Directorate/ *Directeur général, Direction des produits de santé naturels*

Appendix I: Sample Site Licence 3xxxxx

SITE LICENCE **Licence Number** ***LICENCE D'EXPLOITATION***

3xxxxx

Numéro de la licence

Canadian Site Annex/*Annexe des sites Canadiens*

The following sites are considered to be in compliance with GMP requirements outlined in PART 3 of Natural Health Products Regulations/*Les sites suivants sont considérés conforme avec les normes des bonnes pratiques de fabrication tel que stipulé dans la partie 3 du Règlement sur les produits de santé naturels*

Building Name/ *Nom du bâtiment:* **Building 8**

Address/*Addresse:* **11 Herbal Drive**	City/*Ville:* **Ottawa**	
Province: **Ontario**	Postal Code/*Code postal:* **K2H 1B3**	Country/*Pays:* **Canada**

ACTIVITIES/*ACTIVITÉS*	**AUTHORIZED ACTIVITIES** / *ACTIVITÉS AUTHORISÉES*	**SPECIFIC AUTHORIZATION/** ***AUTORISATION SPÉCIFIQUE***	
		Sterile Dosage Form/*Forme posologique stérile*	**Homeopathic Medicine/*Remède Homéopathique***
Manufacturing/*Fabrication*	Yes	No	No
Packaging/*Emballage*	Yes	No	No
Labelling/*Étiquetage*	Yes	No	No
Importing/*Importation*	Yes	No	No

Appendix I: Sample Site Licence 3xxxxx

SITE LICENCE **Licence Number** ***LICENCE D'EXPLOITATION***

3xxxxx

Numéro de la licence

Foreign Site Annex/*Annexe des sites étrangers*

The following sites are considered to be in compliance with GMP requirements outlined in PART 3 of Natural Health Products Regulations/*Les sites suivants sont considérés conforme avec les normes des bonnes pratiques de fabrication tel que stipulé dans la partie 3 du Reglement sur les produits de santé naturels*

Foreign Company Name/ Nom de la compagnie étrangère: **CDE Limited (a division of ABC)**
Building Name/Nom du bâtiment: **N/A**
Address/Addresse: **315 Mineral Road** *City/Ville :* **Chicago** *Province/State:* **Illinois**
Postal/Zip Code/Code postal: **97112** *Country/Pays:* **USA**

ACTIVITIES/*ACTIVITÉS*	**AUTHORIZED ACTIVITIES /** *ACTIVITÉS AUTHORISÉES*	**SPECIFIC AUTHORIZATION/** ***AUTORISATION SPÉCIFIQUE***	
		Sterile Dosage Form/*Forme posologique stérile*	**Homeopathic Medicine/*Remède Homéopathique***
Manufacturing/*Fabrication*	Yes	No	No
Packaging/*Emballage*	Yes	No	No
Labelling/*Étiquetage*	Yes	No	No

Appendix II: Application for Alternate Sample Retention Form

APPLICATION FOR ALTERNATE SAMPLE RETENTION	
Health Canada File Number (if known)	Company Code (if known)
Name of Applicant	
Address	
Telephone Number	Fax Number
Name of Product	Product Number (if applicable)
Name of Manufacturer	
Address	
Telephone Number	Fax Number
Name of site where samples are to be retained	
Address	
Contact Person	
Telephone Number	Fax Number
We have formally arranged with the storage site to retain sufficient numbers of samples of lots as per storage conditions indicated on the label, with the same container-closure sold in Canada to allow access by all pertinent regulatory authorities including Health Canada. □ Yes □ No	
We have read and understood Section 61 (1), (2), (3) (see below) under Lot or Batch Samples. 61. (1) Subject to subsection (3), if the Minister has reasonable grounds to believe that a lot or batch of a natural health product made available for sale may result in injury to the health of a purchaser or consumer, the Minister may require the manufacturer, importer or distributor to provide a sample of that lot or batch. (2) The sample shall be of sufficient quantity to enable a determination of whether the lot or batch of the natural health product complies with the specifications for that natural health product. (3) The Minister shall not require a sample of a lot or batch referred to in subsection (1) to be provided if more than one year has elapsed since the expiry date of that natural health product. □ Yes □ No	

We have a written commitment with the responsible person at the storage site that samples will be provided within 48 hours of receiving a request from Health Canada		
Signature, Responsible Officer	Title	Emergency Telephone Number

Appendix III: Recommended Qualifications for Quality Assurance Person(s)

Every manufacturer, packager, labeller and importer shall have a quality assurance person who has the training, experience and technical knowledge relating to the activity conducted and the requirements of Part 3 of the *Natural Health Products Regulation.* It is a company's responsibility to evaluate the appropriate level of education, training and/or experience that personnel must have to qualify them for their assigned tasks.

The following table provides guidance on qualifications (e.g. education, training and experience) for quality assurance persons and serves as a guideline for applicants submitting information regarding the Quality Assurance Person Qualifications Form.

Table 2: Minimum Recommended Qualifications for Quality Assurance Persons*

Education	Training	Experience
Degree, diploma or certificate from a recognized institution in one of the following: • applied science • biochemistry • biology • chemistry • chemical/food engineering • complementary and alternative medicine • food and drug technology • health science • herbology • homeopathy • naturopathic medicine • pharmaceutical technology • traditional herbal medicine	• Food, natural health product or pharmaceutical good manufacturing practices • *Food and Drugs Act* • *Natural Health Products Regulations* • Good manufacturing practices audit • ISO audits • HACCP** audits • Development and review of product specifications • Preparation of standard operating procedures • Record keeping related to quality assurance operations • Product safety assessment • Product recall • Consumer complaint and investigation • Quality assurance and control operations • Employee hygiene • Sanitation programs • Pest management	• Three years experience in quality assurance and control, including approval of raw materials, finished product testing and development of standard operating procedures • ISO audits • HACCP** audits • Good manufacturing practices audits • Product complaint investigation • Manufacturing process for foods, drugs and/or natural health products • Product recall

* The accepted forms of education, training and experience are not limited to those shown in this table; other forms may be acceptable.
** Hazard Analysis and Critical Control Points

Appendix IV: Case Study with Completed Forms

Health Canada / Santé Canada

SITE LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

HC USE ONLY		Date/Time of Receipt
Submission Number	File Number	

Please refer to the Guide for instructions on how to complete this application **Please Print clearly.**

PART 1
APPLICANT OR LICENSEE INFORMATION

A. — APPLICANT OR LICENSEE (This will be the site licence holder)

Applicant/Company Name	Company Code (If known)
ABC Limited	

Address, Street/Suite/Land Location: 11 Herbal Drive

City - Town	Province - State	Country	Postal/ZIP Code
Ottawa	On	Canada	K1H 1B3

B. — CONTACT(S)

Name: [X] Mr. [ ] Ms. [ ] Dr.
Surname: Gagnon | Given Name: Jean | Title: Director | Language preferred: [X] English [ ] French

Company Name (If different from Applicant/Licensee): | Address same as Applicant/Licensee [X]

Street/Suite/Land Location:

City - Town	Province - State	Country	Postal/ZIP Code

Telephone No.: (613) 955-5555 | Ext. | Fax No.: (613) 955-4444 | E-mail: Jean@abcltd.ca

Contact Type: [X] Senior Official in Canada [ ] Contact for this application

Name: [X] Mr. [ ] Ms. [ ] Dr.
Surname: Smith | Given Name: Robert | Title: Production Mgr. | Language preferred: [X] English [ ] French

Company Name (If different from Applicant/Licensee): | Address same as Applicant/Licensee [X]

Street/Suite/Land Location:

City - Town	Province - State	Country	Postal/ZIP Code

Telephone No. | Ext. | Fax No. | E-mail

Contact Type: [ ] Senior Official in Canada [X] Contact for this application

Name: [ ] Mr. [ ] Ms. [ ] Dr.
Surname | Given Name | Title | Language preferred: [ ] English [ ] French

Company Name (If different from Applicant/Licensee): | Address same as Applicant/Licensee [ ]

Street/Suite/Land Location:

City - Town	Province - State	Country	Postal/ZIP Code

Telephone No. | Ext. | Fax No. | E-mail

Contact Type: [ ] Senior Official in Canada [ ] Contact for this application

Appendix IV: Case Study with Completed Forms

PART 2 – SUBMISSION INFORMATION

A – SUBMISSION TYPE

[X] Site Licence Application	Establishment Licence Number (if applicable)	[ ] Amendment	Site Licence No.
[ ] Renewal	Site Licence No.	[ ] Notification	Site Licence No.

(Please check the appropriate box(es) with respect to the notification changes)

[ ] Change in contact person information or company's information

[ ] Change in building, equipment, practice or procedure with respect to which a Quality Assurance Report form was submitted

B – SUBMISSION CONTENT

Type of supporting documents, by volume: check type that is applicable and indicate the volume in which the document is submitted.

Number of Volumes: 2

	Volume #		Volume #
[X] Site Licence application Form	1	[ ] Notification Description Form	
[X] Quality Assurance Report Form	2	[ ] Designated Party Authorization Form	
[X] Quality Assurance Person Qualification Form	2	[ ] Other	
[X] Supplementary Quality Assurance Report Form for Homeopathic Medicines			

PART 3 – CANADIAN SITE INFORMATION

BUILDING INFORMATION (e.g. Building(s) refers to one location at the same address)

BUILDING 1 Dwelling House [ ] Yes [X] No

Building Name: Building 8

Address, Number/Street/Suite/Land Location: 11 Herbal Drive

City - Town	Province	Postal Code	Country
Ottawa	On	K2H 1B3	CANADA

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	[X]	[ ]	[ ]	[ ]
packaging	[X]	[ ]	[ ]	[ ]
labelling	[X]	[ ]	[ ]	[ ]
importing	[X]	[ ]	[ ]	[ ]

Name of Contact Person for this Building [ ] Mr. [X] Ms. [ ] Dr.

Surname: Best Given Name: Mary

Telephone No.	Ext.	Fax No.	E-mail
(613) 955-5555		(613) 955-4444	Best@abcltd.ca

Name of Quality Assurance Person: Mary Best Ref. No.:

[X] Attached Quality Assurance Report Form [ ] Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

BUILDING 2 Dwelling House [ ] Yes [ ] No

Building Name:

Address, Number/Street/Suite/Land Location:

City - Town	Province	Postal Code	Country
			CANADA

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	[ ]	[ ]	[ ]	[ ]
packaging	[ ]	[ ]	[ ]	[ ]
labelling	[ ]	[ ]	[ ]	[ ]
importing	[ ]	[ ]	[ ]	[ ]

Name of Contact Person for this Building [ ] Mr. [ ] Ms. [ ] Dr.

Surname: Given Name:

Telephone No.	Ext.	Fax No.	E-mail

Name of Quality Assurance Person: Ref. No.:

[ ] Attached Quality Assurance Report Form [ ] Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

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Appendix IV: Case Study with Completed Forms

BUILDING 3 Dwelling House ☐ Yes ☐ No

Building Name

Address, Number/Street/Suite/Land Location

City - Town | Province | Postal Code | Country: CANADA

Name of Contact Person for this Building ☐ Mr. ☐ Ms. ☐ Dr.
Surname | Given Name

Telephone No. | Ext. | Fax No. | E-mail

Name of Quality Assurance Person | Ref. No.

☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☐	☐	☐	☐
packaging	☐	☐	☐	☐
labelling	☐	☐	☐	☐
importing	☐	☐	☐	☐

BUILDING 4 Dwelling House ☐ Yes ☐ No

Building Name

Address, Number/Street/Suite/Land Location

City - Town | Province | Postal Code | Country: CANADA

Name of Contact Person for this Building ☐ Mr. ☐ Ms. ☐ Dr.
Surname | Given Name

Telephone No. | Ext. | Fax No. | E-mail

Name of Quality Assurance Person | Ref. No.

☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable)

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☐	☐	☐	☐
packaging	☐	☐	☐	☐
labelling	☐	☐	☐	☐
importing	☐	☐	☐	☐

PART 4 - FOREIGN SITE INFORMATION (FOR IMPORTERS ONLY)

I. FOREIGN COMPANY NAME

Address, Street/Suite/Land Location: 315 Mineral Rd.

City - Town: Chicago | Province - State: Illinois | Country: USA | Postal/ZIP Code

BUILDING INFORMATION (e.g. Building(s) refers to one location at the same address)

BUILDING 1 Dwelling House ☐ Yes ☒ No

Building Name: CDE Limited (A Division of ABC)

Address, Number/Street/Suite/Land Location: 315 Mineral Rd.

City - Town: Chicago | Province: Illinois | Postal/ZIP Code: 97008 | Country: USA

Name of Quality Assurance Person: Andy Mac | Ref. No.

☒ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable) ☐ Other

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☒	☐	☐	☐
packaging	☒	☐	☐	☐
labelling	☒	☐	☐	☐

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Appendix IV: Case Study with Completed Forms

BUILDING 2 Dwelling House ☐ Yes ☐ No

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☐	☐	☐	☐
packaging	☐	☐	☐	☐
labelling	☐	☐	☐	☐

Building Name

Address, Number/Street/Suite/Land Location

City - Town | Province | Postal/ZIP Code | Country

Name of Quality Assurance Person | Ref. No.

☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable) ☐ Other

II. FOREIGN COMPANY NAME

Address, Street/Suite/Land Location

City - Town | Province - State | Country | Postal/ZIP Code

BUILDING INFORMATION (e.g. Building(s) refers to one location at the same address)

BUILDING 1 Dwelling House ☐ Yes ☐ No

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☐	☐	☐	☐
packaging	☐	☐	☐	☐
labelling	☐	☐	☐	☐

Building Name

Address, Number/Street/Suite/Land Location

City - Town | Province | Postal/ZIP Code | Country

Name of Quality Assurance Person | Ref. No.

☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable) ☐ Other

BUILDING 2 Dwelling House ☐ Yes ☐ No

Activity Type

	Add	Delete	Sterile Dosage	Homeopathic Medicines
manufacturing	☐	☐	☐	☐
packaging	☐	☐	☐	☐
labelling	☐	☐	☐	☐

Building Name

Address, Number/Street/Suite/Land Location

City - Town | Province | Postal/ZIP Code | Country

Name of Quality Assurance Person | Ref. No.

☐ Attached Quality Assurance Report Form ☐ Attached Supplementary Quality Assurance Report Form for Homeopathic Medicines (when applicable) ☐ Other

PART 5
ATTESTATION

A – I attest that the building(s), practice(s), procedure(s) used for conducting activities in our facility comply with the good manufacturing practices set out in Part 3 of the *Natural Health Products Regulations*

Name of Quality Assurance Person (Please print): Mary Best

Signature of QA Person: Mary Best

B – I, the undersigned, certify that the information and material in this site licence submission is accurate and complete.

Jean Gagnon
Name of Authorized Senior Official (print)

Jean Gagnon
Signature

Date: 2004 09 15 (yyyy mm dd)

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Appendix V: Site Licence Submission Checklist

No.	Document	Section	Completed (please check)
1.	Site Licence Application	Applicant or Licensee Information	☐
		Submission Information	☐
		Canadian Site Information	☐
		Foreign Site Information (for importers only)	☐
		Name of the Quality Assurance Person	☐
		Attestation	☐
2.	Establishment Licence (EL) (if applicable)	Photocopy of current EL	☐
3.	Quality Assurance Report	General Information: *(Submission; Building Information; Operation(s) at the building; Quality Assurance Person(s))*	☐
		Detailed Quality Assurance Report: *(Places; People; Processes; Products)*	☐
		Attestation	☐
		Application for Alternate Sample Retention (if applicable)	☐
		Attachments (supporting documentation)	☐
4.	Supplementary Quality Assurance Report (if applicable)	General Information: *(Submission; Building Information; Operation(s) at the building; Quality Assurance Person(s))*	☐
		Detailed Quality Assurance Report: *(Places; People; Processes; Products)*	☐
		Attestation	☐
		Attachments (supporting documentation)	☐
5.	Quality Assurance Person Qualification Form	Completed Form *(Contact Information; Intended QA Activities; Education; Training; Experience; Consent)*	☐
		Attachments (supporting documentation)	☐
6.	Designated Party Authorization (if applicable)	Completed Form	☐
7.	Notification Description Form	Completed Form	☐