



## Registration of Natural Health Products (NHPs) in Canada

**Course Objective:** To provide the knowledge needed to successfully register natural health products in Canada.

**Course Description:** The new Natural Health Products (NHP) Regulations came into force on January 1st, 2004. They are designed to ensure ready access to NHPs that are safe, effective and of high quality, while respecting freedom of choice, and philosophical and cultural diversity. All NHPs now require pre-marketing approval by Health Canada. Thorough understanding of the registration requirements is pivotal to ensure success.

This course will focus on the definition and types of NHPs, and the regulatory requirements for product and site licences. Special emphasis will be given to the “Standards of Evidence” required to support label claims. In addition, requirements on Good Manufacturing Practices, Clinical Trials, and Post-marketing surveillance will be described.

**Course Outline:**

- Introduction: The scope of naturopathic medicine and the growth of NHPs
- The Definition of NHP – what products are included?
- Main Components of the NHP regulations
- Product License (PL) application
  - Components of the form
- Demonstration of safety and efficacy
  - Compendial vs. non-compendial
  - Standards of Evidence
- Product specifications
- Labeling requirements
- Site License (SL) application
  - Components of the form
  - The QA Report
  - Attestations
- Good Manufacturing Practices requirements
- Clinical Trials Requirements

- Adverse Reactions Reporting
- Transition periods - Notes on Compliance and Enforcement
- Regulatory Agency Liaison