

# 3<sup>rd</sup> International Summit on **GMP, GCP & Quality Control**

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## Natural health products site licensing in Canada: How to meet the GMPs regulations

This workshop will address site (Establishment) licensing in Canada. It will discuss what a site license is, when it is required, who must hold one, how to apply for a site license and Health Canada (HC) licensing process. In addition, the workshop will discuss the GMP requirements for products manufactured at foreign sites and the acceptable foreign inspection reports. The workshop consists of two presentations and two exercises and anticipates active involvement of the participants.

The event focuses on selected GMP topics, which are the common causes of non-compliance with GMP standards. Specifically, attention will be focused on the site record-keeping requirements.

### Learning Objectives (Benefits)

Upon completion of this workshop, participants will be able to:

- Understand Health Canada NHP Site licensing (GMP) regulations and licensing process
- Understand common cause of non-compliance with GMP standards. (Recognize deficiencies and potential violations of the GMP regulations)
- Help attendees to reassess the current practices at their facilities against the GMP requirements
- At the end of the workshop participants should demonstrate also an improved understanding of the basics of Good Documentation Practices and the record-keeping requirements

### Workshop Contents:

#### A. Presentations:

1. Overview of Natural Health Products Directorate: Good Manufacturing Practices elements.
2. Good Documentation Practices (Records and SOPs requirements)

#### B. Application Exercise

1. Attendees will be divided to small groups to learn on how to establish a SOP Format and Design.
2. Attendees will be given the opportunity to examine samples of Health Canada Information

### Request Notice and the US: FDA inspection Report

#### C. Question & Answer Session

Attendees will have the opportunity to ask the instructor questions. This time can be used to expand on any matter related to HC: NHPs regulations which may be of particular interest to attendees.

### Biography

Mokhalalati has first-hand experience with Health Canada (HC) Natural Health Product Directorate (He is dealing with HC regularly for all aspects pertaining to site and products licensing applications). Dr. Mokhalalati holds a PhD degree in the field of human nutrition from university of London. Since his graduation in 1981, he wrote a number of books and scientific papers, and he worked in various countries for different sectors, including university teaching. In 2001, Dr. Mokhalalati retired from the last job with Abbott laboratories as a head of medical and regulatory affairs department in Saudi Arabia and started his own consultation office in Canada to serve the Food and Drug industry in all aspects of GMP training, site licensing (GMPs), and Natural Health Products registration with Health Canada. Dr. Mokhalalati completed a number of professional services projects locally (with the federal government and private sector) and overseas, where he supported a number of companies in Australia, Hong Kong, India, USA, UK, Saudi Arabia, Jordan, and Brazil in activities pertaining to Health Canada Good Manufacturing Practices Regulations and product licensing. Dr. Mokhalalati registered and approved consultant in the Canadian International Development Agency (CIDA) database of consultants.

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