

## GET THE BIG PICTURE.

Make sure you know the laws and procedures that govern the drug approval process.

Improve your performance through a better understanding of the entire regulatory and review system in Canada.

The Fundamentals of Regulatory Affairs in Canada course is intended to provide participants with a broad overview of Regulatory Affairs and the review process for pharmaceutical products. This course will cover the process of drug development, the Canadian healthcare system, Clinical Trial Applications, New Drug Submissions, submissions for DIN numbers and postmarketing requirements (advertising, labeling and changes to marketed products).



# Call for a Proposal



For more information, or to register for any Pharmahorizons training sessions, visit the pharmahorizons website at:

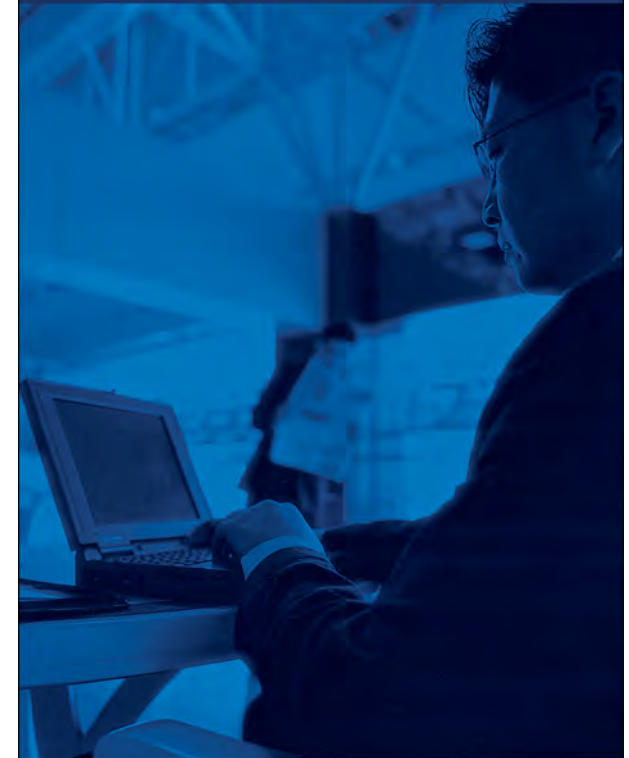
[www.pharmahorizons.com](http://www.pharmahorizons.com)

Or contact Sophie Vadeboncoeur, toll free, at **1-888-514-5858** or by e-mail at [sophie@pharmahorizons.com](mailto:sophie@pharmahorizons.com)

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## Fundamentals of Regulatory Affairs in Canada



On-site programs can be booked at your convenience

[Pharmahorizons.com](http://Pharmahorizons.com)

## Why Attend?

Most executives and managers in pharmaceutical, marketing, sales, quality assurance, medical information and clinical research as well as professionals who are new to regulatory affairs would benefit from a good grasp of the drug approval process.

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## Who Should Attend?

**The seminar is of importance to professionals in:**

- Clinical research
  - Regulatory affairs
  - Quality assurance
  - Marketing and product management
  - Medical information.
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## Instructional Design

**Stephen Gregory, B.A. President,  
Pharmahorizons**

Steve is a noted speaker and nationally recognized training and management consultant. He has designed and delivered highly acclaimed training programs for biotechnology and pharmaceutical companies in Canada, the United States and Southeast Asia.

## Respected and Knowledgeable Facilitator

### Course instructors

**Anne Tomalin, BA, BSc, RAC** is the President of CanReg Inc, one of the world's largest global regulatory consulting companies. She founded CanReg in 1996 after working in regulatory affairs for 26 years at large pharmaceutical companies. Anne has participated as an invited speaker and session chair at many industry meetings during her career, including DIA and RAPS.

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## About CanReg Inc.

CanReg is a company dedicated exclusively to regulatory affairs consulting. More than 100 in-house consultants and staff serve pharmaceutical, biotechnology and medical device clients around the world.



## About Pharmahorizons

Pharmahorizons' focus is on jobs and professional development in pharmaceutical, biotechnology and healthcare industries. It is one of Canada's most popular life science training, recruitment and retention resources.

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## For More Information

To get more facts on this excellent opportunity to learn the laws and procedures that govern the drug approval process, email Sophie at [sophie@pharmahorizons.com](mailto:sophie@pharmahorizons.com) or call toll free at **1-888-514-5858**.



# PROGRAM AGENDA

Course time: 8:30 am - 4:30 pm

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## Day 1

8:00 am:

### Registration & Continental Breakfast

8:30 am:

### Course Commences

- ◆ Regulatory framework for pharmaceuticals
- ◆ The Common Technical Document (CTD)

### 12 noon - 1:00 pm Lunch provided on site

- ◆ Clinical trial applications (CTA)
- ◆ Special access program
- ◆ Good clinical practice
- ◆ Pharmacovigilance
- ◆ Meetings with Therapeutic Products Directorate of Health Canada (TPD)



## Day 2

8:00am - 8:30 am:

### Continental Breakfast

- ◆ New Drug Submissions (NDS)
- ◆ The review process at TPD
- ◆ Priority NDSs
- ◆ NDSs with conditions
- ◆ Abbreviated submissions

### 12 noon - 1:00 pm Lunch provided on site

- ◆ Appeals
- ◆ DIN submissions
- ◆ Electronic submissions
- ◆ Natural health products
- ◆ Post marketing
- ◆ Changes to marketed advertising products
- ◆ Product recalls

