

Make sure your company's "Time-to-Clinic" is a winning performance with no time lost.

Learn the entire Clinical Trial Application (CTA) process from the pros. Explore the components of a CTA and discover tips and techniques to ensure your CTA gets an NOL from the regulators.

All applications to conduct Phase I-III clinical trials in Canada must be submitted to Health Canada (HC) and receive a "No Objection Letter" (NOL) status from the Therapeutic, Biologics or Natural Health Products Directorates.

The Health Canada regulations that govern the Clinical Trial Application (CTA) process are complex. It takes a seasoned hand to prepare a complete and properly worded CTA.

Regulators assess CTAs based on safety and statistical factors.



Call for a proposal

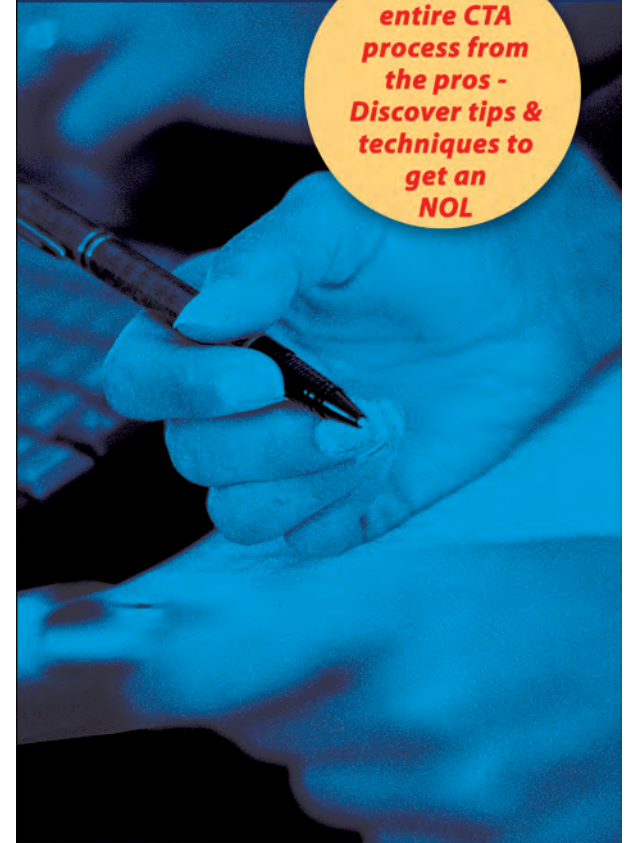


For more information, or to register for any Pharmahorizons training sessions, visit the pharmahorizons website at: www.pharmahorizons.com
Or contact Sophie Vadeboncoeur, toll free, at **1-877-751-9415** or by e-mail at sophie@pharmahorizons.com



Clinical Trial Applications Seminar

Learn the entire CTA process from the pros - Discover tips & techniques to get an NOL



On-site programs can be booked at your convenience



Why Attend

In today's highly competitive and safety conscious environment, no organization can afford to have their Clinical Trial Application (CTA) rejected. A CTA is a vitally important step in the drug development process.

Who Should Attend:

The seminar is of importance to professionals in:

- ◆ Clinical research organizations
 - ◆ Study sponsors
 - ◆ Regulatory professionals
 - ◆ Independent consultants.
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Session Objectives Participants will explore and discuss:

- ◆ How to prepare a CTA in "Common Technical Document" format
- ◆ Identifying and meeting all the components of a CTA and how to describe them effectively
- ◆ Timelines for a CTA (for preparation, for review, to clinic setting)
- ◆ Commitment and maintenance of a CTA
- ◆ How to communicate effectively with Health Canada regarding your CTA
- ◆ Natural health product (NHP) CTA submissions.

Well Respected Training Team

Course instructors

Michelle DeLaCroix runs the CTA Unit at CanReg Inc., one of North America's largest regulatory affairs consulting firms. She has more than 10 years experience in the healthcare industry, including medical, surgical and telemetry specialties.

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 and the United States.

Training At Your Location

Since this is an advanced seminar, it is only offered as an on-site program. The cost depends on the number of participants, location and degree of customization required. Call Sophie at 1-888-514-5858 for a proposal.

Call us about a special team price for not-for-profit institutions such as hospitals. We offer volume discounts.

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.

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 Vadebonceour at ***sophie@pharmahorizons.com*** or call toll free at ***1-888-514-5858***.

PROGRAM AGENDA

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

8:00 am - 8:30 am: Registration & Continental Breakfast, Course Commences

8:30 am - 10:30am

- ◆ A comprehensive overview of the Canadian CTA process (Module I)

10:30 am - 10:45am: Refreshment Break

10:45 am - 12:00 noon

- ◆ The CTA form
- ◆ Small group work
- ◆ Protocol synopsis (PCERT)

12 noon - 1:00 pm: Lunch Provided on Site

1:00 pm - 2:30pm

- ◆ Changes to a CTA and how to address them
- ◆ Notification vs. amendment

2:30 pm - 2:45pm: Refreshment Break

2:45 pm - 4:30pm

- ◆ Case study
- ◆ Q&A and discussion
- ◆ Maintenance of a CTA after NOL is obtained
- ◆ Summary

4:30 pm: Formal portion of the Seminar Concludes

