

Protect consumers and your brand. Learn to meet all the product labeling regulatory requirements in Canada. Avoid costly recalls and delays getting to market.

The labeling of drug products is one of the most sensitive functions done in any pharmaceutical company. Mistakes can result in harm to patients and to the company. Recalls are expensive, and no one wants to have to deal with them. But formal training for label review to meet Canadian regulatory requirements has been virtually nonexistent - until now.



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 **1-888-514-5858** or by e-mail at sophie@pharmahorizons.com



Fundamentals of Pharmaceutical Product Labeling Seminar

Learn to avoid recalls & delays getting to market!



On-site programs can be booked at your convenience



Why Attend

Those responsible for reviewing labels in today's highly competitive and safety conscious environment need systematic training to determine exactly what the regulations permit and exclude in pharmaceutical labeling.

Who Should Attend?

This seminar is of importance to anyone involved in the review of labels for pharmaceutical products from the following functional areas:

- ◆ Regulatory affairs
 - ◆ Legal
 - ◆ Medical
 - ◆ Marketing
 - ◆ Quality assurance
 - ◆ Pharmacovigilance/drug safety.
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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

Session Objectives Participants will explore and discuss:

- ◆ Industry standards for label review
 - ◆ Requirements from the Food and Drug Regulations for label requirements
 - ◆ Labeling of narcotic, controlled and targeted drugs
 - ◆ Labeling of parenteral drugs, including small containers
 - ◆ Labeling of blisters and other inner packaging
 - ◆ Structured Product Labeling (SPL)
 - ◆ The new product monograph template and package inserts
 - ◆ Bar codes and newer mechanisms for tracing product.
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Well Respected Training Team Course instructor

Anne Tomalin, B.A., B.Sc., R.A.C., President, CanReg Anne has over 31 years of experience in regulatory affairs at three international pharmaceutical companies with pharmaceuticals, over-the-counter (OTC) products, and medical devices. Anne teaches Post Graduate courses in Regulatory Affairs at Humber College in Toronto.

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.

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

PROGRAM AGENDA

Course time: 8:00 am - 4:30 pm

Morning:

8:00 am - 8:30 am

Continental Breakfast, Seminar Commences

- ◆ The importance of labels
- ◆ Setting up a label docket system

10:30 am

Refreshment Break

- ◆ Labeling regulations and guidances

12 Noon - 1:00 pm

Lunch provided on site



Afternoon:

1:00 pm

- ◆ Case Studies
- ◆ New product monograph template

2:30 pm

Refreshment Break

- ◆ Industry standards and regulatory practices
- ◆ Structured Product Labeling (SPL)
- ◆ Bar codes and other tracing mechanisms
- ◆ Wrap-up

4:30 pm

Formal portion of the seminar concludes

