



## ***The Challenge of Change: Working with the Post-NOC Guidances***



### ***About the Symposium***

This one-day symposium will focus on the final Post-NOC Guidance documents and provide industry with a chance to have questions addressed by Health Canada and to have industry speakers share their experience.

### ***Who Should Attend?***

Novice and experienced Regulatory Affairs Professionals in the pharmaceutical and biotechnology industries, along with Operations and various functions involved with implementing post-NOC changes.

***March 1, 2010***

**The Westin Prince Hotel**  
900 York Mills Road  
Toronto, On, M3B 3H2



## **AGENDA**

### **Monday, March 1**

- 8:00 – 8:30**      ***Registration and Continental Breakfast***
- 8:30 – 8:35      Welcoming Remarks
- 8:35 – 9:20      Overview of Framework and Process – *Joyce Pon*  
*Senior Policy Analyst, Health Canada*
- 9:20 – 9:45      Industry Experience with Quality Post-NOC Changes ( Pharmaceuticals) – *Dean Callaghan*  
*Regulatory Affairs Manager, CMC, AstraZeneca*
- 9:45 – 10:15      ***Morning Break***
- 10:15-11:15      Q&A Session, TPD Quality – *Randy Duhaime*  
*Senior Policy Analyst, Health Canada*
- 11:15-11:40      Industry Experience with Quality Post-NOC Changes (Biologics) – *Daniela Decina,*  
*Senior RA Manager, Amgen Canada Inc*
- 11:40 – 12:40**      ***Lunch***
- 12:40 – 1:40      Q&A Session, BGTD Quality – *Hugo Hamel, Senior Biologist/Evaluator, Health Canada*  
& *Harold Rode, Rode Biologics Consulting Inc.*
- 1:40 – 2:10      ***Afternoon Break***
- 2:10 – 2:35      Industry Experience with Post-NOC Safety and Efficacy Changes – *Anne Tomalin*  
*President, CanReg Inc.*
- 2:35 – 3:35      Q&A Session, Safety and Efficacy – *Lisa Kelly*  
*Assessment Officer, Health Canada*
- 3:35 – 4:15      NOC/C Guidance – *Marcin Boruk*  
*Senior Policy Analyst, Health Canada*
- 4:15 – 4:45      eCTD Q&A Session: Post NOC Issues from SIPD – *Vianney Caron, Project Lead, TPD e-Review*  
& *Irena Pastorekova, Regulatory Information Officer, Health Canada*
- 4:45 – 5:00      Closing Remarks



## **ACCOMMODATION AND TRAVEL**

### **The Westin Prince Hotel**

900 York Mills Road  
Toronto, On, M3B 3H2

For reservations, call **1-800-937-8461** and mention you are with CAPRA to get the convention rate.  
Reservations must be guaranteed with a credit card or advanced deposit.

**Convention rate: \$149**

**Rate is subject to availability.**

## **REGISTRATION AND FEE**

**FEE** (*Includes symposium materials, breaks and lunch*):

CAPRA Member or Government Employee: \$395 (\$376.19 plus \$18.81 GST)

Non-member: \$445 (\$423.81 plus \$21.19 GST) (GST Registration No. R124015116)

### **REGISTRATION PROCEDURE:**

Registration will be accepted by FAX or ON LINE at [www.capra.ca/meetings.html](http://www.capra.ca/meetings.html). Credit card payment is available only with on-line registration prior to the registration deadline. (On the payment site, please use the name and address that match the card.)

**Please Note:** Registrations will be accepted up to **February 22, 2010**.

After February 22, 2010, participants may be substituted, but no refunds will be issued.

### **Disclaimer**

CAPRA reserves the right to make amendments to the conference (including but not limited to identity of speakers, topics, locations, timing of speakers) without notice to you. In the event that the conference is cancelled for any reason whatsoever, such reason not within the control of CAPRA, CAPRA shall not be liable for any cost or loss otherwise incurred.



*The Challenge of Change: Working with the Post-NOC Guidances*

*March 1, 2010*

**FAX REGISTRATION FORM**

CAPRA Member / Government Employee: Yes \_\_\_ No \_\_\_

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Company: \_\_\_\_\_

Telephone: \_\_\_\_\_

Address: \_\_\_\_\_

Fax: \_\_\_\_\_

\_\_\_\_\_

Email: \_\_\_\_\_

\_\_\_\_\_

Do you wish a vegetarian meal? Yes \_\_\_ No \_\_\_

Fax this registration form to 905-946-8971.

**Registration will be confirmed by e-mail or fax within 5 days.**

Follow up with a cheque by mail. (Credit card numbers cannot be processed by fax or mail.) **Payment must be received prior to the event.** Mail cheque and a copy of the registration form to:

CAPRA/ACPR  
7030 Woodbine Avenue, Suite 500  
Markham, ON. L3R 6G2  
(T) 905-943-2977  
(F) 905-946-8971

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