DIA Canadian Pharmacovigilance and Risk Management Meeting

April 6 | Hilton Toronto | Ontario, Canada

PROGRAM CO-CHAIRS:

Marcia Bailey, RN, BScN, MHS
Senior Specialist, Pharmacovigilance and Medical Information
Otsuka Canada Pharmaceutical Inc., Canada

Rita Cassola, RPh
Executive Director PV
Certus PV Services Inc., Canada

Colin D'Cunha, MHS, FRCPC
Director, Global Medical Affairs,
Apotex Inc., Canada

Marc F. Poitras, PhD, MBA
Scientific Manager, Marketed Pharmaceuticals and Medical Devices Bureau
Health Canada

Ljubica Ivanisevic, PhD
Scientific Evaluator
Health Canada

Overview

Hear from expert pharmaceutical, biotechnology, and regulatory personnel about Regulatory Guidance Document Updates (Pharmacovigilance, Risk Management and Drug Safety), how Vanessa's Law came into play and where it is going, Pharmacovigilance Agreement, eReporting, Special Product Area, and much more.

Who Should Attend

Professionals involved in:

- Drug Safety/Pharmacovigilance
- Risk Management
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Research
- Data Analysis
- Pharmacoepidemiology
- Medical Information
- Health Outcomes

Highlights

- Interactive Sessions
- Question and Answer Session with Health Canada
- Numerous Networking Opportunities

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Describe the current Canadian regulatory framework for pharmacovigilance
- Discuss current Pharmacovigilance issues facing Marketing Authorization Holders in Canada
- Discuss Vanessa's Law including why the legislation came into play, and the impact it will have
- Discuss operational challenges of implementing benefit-risk analyses and risk management plans

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for 6.5 contact hours or .65 continuing education units (CEU's). Type of activity: Knowledge UAN: 0286-0000-16-061-L05-P

ACPE Credit Requests MUST BE SUBMITTED by Monday, May 23, 2016

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity.** Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 0.7 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Statement of Credit

If you would like to receive a statement of credit, you must attend the meeting, sign in at the registration desk, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **Wednesday, April 20, 2016**. To access My Transcript:

- Visit **DIAglobal.org**, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the conference (and/or tutorial, if applicable).

The online evaluation closes on Wednesday, April 27, 2016.

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosure statements will be included in the meeting materials.

View DIA's Grievance Policy at DIAglobal.org/CE.

DIA'S CERTIFICATE PROGRAM

This program is part of DIA's Certificate Program and is awarded the following:

- Clinical Research Certificate Program: 4 Elective Units
- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
- Regulatory Affairs Certificate Program: 4 Elective Units

For more information go to **DIAglobal.org/certificateprograms**

WEDNESDAY, APRIL 6

7:15AM–5:15PM **Registration**

7:15–8:15AM Continental Breakfast and Networking

8:15–8:30AM

Welcome and Opening Remarks

Marcia Bailey, RN, BScN, MHS
Senior Specialist, Pharmacovigilance and Medical Information
Otsuka Canada Pharmaceutical Inc., Canada

Rita Cassola, RPh
Executive Director PV
Certus PV Services Inc., Canada

8:30–10:30AM

Session 1: New Developments and Updates from Health Canada

Session Chair:

Marcia Bailey, RN, BScN, MHS
Senior Specialist, Pharmacovigilance and Medical Information
Otsuka Canada Pharmaceutical Inc., Canada

Gain a general overview of Vanessa's Law (Bill C-17) and its potential impact on industry. Updates regarding Health Canada's Risk Communication Process, specific Reporting Guidance Documents, and the Transparency Initiatives will also be presented.

Vanessa's Law - An Industry Perspective

Karyn Pellatt-Caron, LLB
Corporate Counsel
Otsuka Canada Pharmaceutical Inc., Canada

Proactive Pharmacovigilance - Risk Management Planning

Rania Mouchantaf, PhD
Proactive Pharmacovigilance-Risk Management Planning
Health Canada

Health Canada Transparency Initiatives – Safety Review (In Progress and Summaries)

Alain Musende, PhD
Manager, Therapeutic Effectiveness and Policy Bureau
Health Canada
(presentation will be via Webex)

Health Canada Risk Communication Process Updates

Patricia Carruthers-Czyzewski
Manager, Risk Communication Section
Health Canada

10:30–11:00AM Refreshment Break and Networking

11:00AM–12:00PM

Session 2: Inspectorate Update

Session Chair:

Rita Cassola, RPh
Executive Director PV
Certus PV Services Inc., Canada

A representitive from the Inspectorate in Ontario Region will provide an overview of the current fiscal year as well as a look into what is coming in the future. Additionally, the Inspectorate will discuss what's new, provide observations, and give reminders to the industry.

Inspectorate Update

Katarina Susnjar
Regulatory Compliance Specialist, Inspector Program
Health Canada

12:00–1:30PM Luncheon and Networking

1:30–3:00PM

Session 3: Wired and Wireless in Cyberspace (eReporting)

Session Chair:

Marcia Bailey, RN, BScN, MHS
Senior Specialist, Pharmacovigilance and Medical Information
Otsuka Canada Pharmaceutical Inc., Canada

Learn how some small companies are utilizing their website options in eReporting. Bill C17 and eReporting next steps will also be discussed.

eReporting

Bill Wilson
Business Lead, Canada Vigilance Project
Health Canada
(presentation will be via Webex)

An Industry Perspective on E2B Implementation with Canada Vigilance

Quynh Duong, BSN, RN, MSc
Manager, Medical Information and Pharmacovigilance
Lundbeck Canada, Canada

3:00–3:30PM Refreshment Break and Networking

3:30–5:00PM

Session 4: Special Topics

Session Chair:

Colin D'Cunha, MHS, FRCPC
Director, Global Medical Affairs
Apotex Inc., Canada

Learn about current changes for drug safety professionals in their day-to-day practices. Topics discussed will include drug interchangeability, the evolving Biosimilars landscape in Canada, and the upcoming changes in consumer product framework.

Drug Interchangeability – Understanding the Science and Navigating Forward

Yu Chung Tsang
Chief Science Officer, Biopharmaceutics and Biostatistics
Apotex Inc., Canada

The Consumer Health Product Framework

Kristin Willemsen, MS
Director of Scientific and Regulatory Affairs
Consumer Health Products Canada

Second Entry Biologics

Colin D'Cunha, MHS, FRCPC
Director, Global Medical Affairs
Apotex Inc., Canada

5:00–5:15PM

Closing Remarks

Colin D'Cunha, MHS, FRCPC
Director, Global Medical Affairs
Apotex Inc., Canada

5:15PM

Meeting Adjourned