DIA

Canadian Pharmacovigilance and Risk Management Strategies Conference

October 16 | Ottawa Marriott Hotel | Ottawa, Ontario, Canada

PROGRAM CHAIR

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

PROGRAM COMMITTEE

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

Colin D'Cunha, MD, 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

DIA's *Canadian Pharmacovigilance and Risk Management Strategies Conference* is the premier place to hear from expert pharmaceutical, biotechnology, and regulatory personnel about Global Regulatory Guidance Document updates (pharmacovigilance, risk management, and drug safety), gain new perspectives from the Inspectorate, and discuss patient support programs and PV responsibilities. Join in on an exclusive session with the Canadian regulator, touching on a host of current topics including the management of Canada Vigilance Adverse Reaction Online Database duplicate safety reports.

Who Should Attend

Professionals involved in:

- Advertising and Promotion
- Biotechnology
- Clinical Data Management/eClinical
- CMC
- Combination Products
- Clinical Safety and Pharmacovigilance
- Clinical Research
- Medical Devices and Diagnostics
- Pharmacology
- Regulatory Affairs

Revised: 10/02/2017 For the most up to date program information, please visit DIAglobal.org/XXX

Schedule At-A-Glance

MONDAY | OCTOBER 16

7:00AM-5:00PM	Registration
7:00-8:00AM	Continental Breakfast and Networking
8:00-8:15AM	**Opening Remarks**
8:15-8:30AM	**Welcome Remarks**
8:30-10:00AM	**Session 1:** What's New and What's Hot in Pharmacovigilance
10:00-10:30AM	Refreshment and Networking Break
10:30-11:30AM	**Session 2:** Identifying Canada Vigilance Database: Duplicate Reports and Global/Local Literature Reporting
11:30AM-12:30PM	**Session 3:** Round Table with Inspector
12:30-1:30PM	Luncheon and Networking
1:30-3:00PM	**Session 4:** Health Canada's Review of the Draft Guidance on Annual Reporting and the Updated Guidance on ADR Reporting; Bill C-17 Updates
3:00-3:30PM	Refreshment and Networking Break
3:30-4:30PM	**Session 5:** Privacy Round Table
4:30-5:30PM	**Session 6:** AE reporting in Patient Support Program
5:30PM	**CHEO Event/Reception**

Learning objectives

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

- Describe the current Canadian regulatory framework for pharmacovigilance
- Examine current Pharmacovigilance issues facing Marketing Authorization Holders in Canada
- Discuss proposed changes to Vanessa's Law
- Identify strategies for implementing benefit-risk analyses and risk management plans

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The online evaluation will close on **Tuesday, November 8, 2017**.

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MONDAY | OCTOBER 16

7:00AM-5:30PM — **Registration**

7:00-8:00AM — **Continental Breakfast**

8:00-8:15AM — **Opening Remarks**

Sudip Parikh, PhD
Senior Vice President and Managing Director
DIA Americas

8:15-8:30AM — **Welcome Remarks**

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

8:30-10:00AM — **Session 1**
What's New and What's Hot in Pharmacovigilance

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

In this session, you will learn about new/ongoing national, international initiatives to strengthen postmarket surveillance activities. Representatives from Regulatory Agencies and industry will describe and discuss the progress of the implementation and the challenges anticipated and encountered. You will learn, among other things, how leveraging pharmacovigilance databases could facilitate the detection, assessment, and confirmation of safety signals.

Modernizing Pharmacovigilance in Canada

Melissa J. Hunt, MSc
Scientific Manager
Health Canada

Real World Evidence: How Can We Use it Effectively to Inform Decision-Making

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Early Access and Risk Management, Visiting Scientist, MIT Center for Biomedical Innovation
QuintilesIMS, United Kingdom

New Developments in Postmarketing Drug Safety

Gerald J. Dal Pan
Director, Office of Surveillance and Epidemiology
CDER, FDA

10:00-10:30AM — **Refreshment and Networking Break**

10:30-11:30AM — **Session 2**
Identifying Canada Vigilance Database: Duplicate Reports and Global/Local Literature Reporting

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

Examine the issue of duplicate reports in the Canada Vigilance Database. Additionally, local literature reporting challenges will be discussed. How Canada Vigilance Database duplicate reports are identified and managed will be reviewed as well as sources for duplication that safety professionals should be aware of. Finally, how you target local journals or databases for local literature reporting will be revealed.

Canada Vigilance Online Database and Scientific Literature Reporting

Adriana Ziff, RPh
Director, Drug Safety/Pharmacovigilance and Product Information, Medical Sciences
Purdue Pharma Canada

Canada Vigilance Program: Duplicate Checking and Quality Assurance Activities

Sophie Sommerer
Director, Marketed Health Products Safety and Effectiveness Information Bureau
Health Canada

11:30AM-12:30PM — **Session 3**
Round Table with Inspector

Session Chair
Rita Cassola, BPharm, RPh
Executive Director PV
Certus PV Services Inc.

Sophie Lafrance, Corporate Regulatory Compliance and Enforcement Advisor at Health Canada, will provide an update on the GVP inspection program in Canada, with examples of recent inspection findings.

Sophie Lafrance
Corporate Regulatory Compliance and Enforcement Advisor, Regulatory Operations and Regions Branch
Health Canada

DAY ONE | WEDNESDAY, OCTOBER 18

12:30-1:30PM — **Luncheon and Networking**

1:30-3:00PM

Session 4
Health Canada's Review of the Draft Guidance on Annual Reporting and the Updated Guidance on ADR Reporting; Bill C-17 Updates

Session Chair

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

During this session, Health Canada will review two guidance documents. Updates to Bill C-17 (Vanessa's Law) will be discussed. Topics addressed will include an overview of the new recall powers of Health Canada, how life science companies can ensure their current process for reporting to regulatory authorities is updated to meet the new requirements, a description of new reporting requirements for companies, and a review of the implementation timeline.

Update on Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

Anne Tomalin, RAC
President
Therapeutic Products, Inc.

Revised Canadian Guidelines for Adverse Reaction and Summary Reporting

Sarah Clayman
Regulator Project Manager,
Health Products and Food Branch
Health Canada

Bruce Wozny, MA
Senior Policy Officer
Health Canada

3:00-3:30PM — **Refreshment and Networking Break**

3:30-4:30PM

Session 5
Privacy Round Table

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

This session will provide a perspective on Privacy considerations in Canada whilst undertaking Pharmacovigilance activities. Relevant legislation will be discussed along with best practice examples.

Privacy Case Studies/Challenges in Pharmacovigilance Activities from the Perspective of Industry

Agnes Jankowicz, MSc
Executive Director, PV
Certus PV Services Inc., Canada

Legal Perspectives and Considerations in Pharmacovigilance Activities

Eileen Tan, JD
Legal Council
Aptoex Inc., Canada

4:30-5:30PM

Session 6
AE Reporting in Patient Support Program

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

Discuss challenges encountered by the industry in the management of Patient Support Programs, from the planning step to receiving, processing, and analyzing safety information derived from these programs.

Maha Hadj-Omar, MD, MSc
Director, Global Medical Safety
Pharmascience Inc.

5:30PM

CHEO Event/Reception

This year, we are partnering with the Children's Hospital of Eastern Ontario and Ottawa Children's Treatment Centre (CHEO- OCTC) to kick off the *DIA Annual Canadian Meeting* with a community outreach activity! Help us say 'thank you' by supporting the leaders of tomorrow at CHEO-OCTC, whose focus is on research and exceptional patient and family centered care. CHEO-OCTC seeks to continually improve the quality and the efficiency of all activities through research, benchmarking, learning, and evidence-based practices.


SAVE THE DATE!
DIA 2018
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