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
## Schedule At-A-Glance

### MONDAY | OCTOBER 16

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 Health Canada’s Review of the Draft Guidance on Annual Reporting and the Updated Guidance on ADR Reporting; Bill C-17 Updates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

Continuing Education Credits

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 .8 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.

If you would like to receive a statement of credit, you must attend the conference, sign in at the DIA registration desk upon arrival, 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 beginning Tuesday, November 1, 2017.

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

To view DIA’s Grievance Policy, visit DIAglobal.org/CE.

DIA Disclosure Policy

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. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.
### MONDAY | OCTOBER 16

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00AM-5:30PM</td>
<td>Registration</td>
</tr>
<tr>
<td>7:00-8:00AM</td>
<td>Continental Breakfast</td>
</tr>
</tbody>
</table>
| 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.  

<table>
<thead>
<tr>
<th>Update on Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)</th>
<th>Revised Canadian Guidelines for Adverse Reaction and Summary Reporting</th>
</tr>
</thead>
</table>
| Anne Tomalin, RAC  
President  
Therapeutic Products, Inc. | 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  
Aptex 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.  

<table>
<thead>
<tr>
<th>Privacy Case Studies/Challenges in Pharmacovigilance Activities from the Perspective of Industry</th>
<th>Legal Perspectives and Considerations in Pharmacovigilance Activities</th>
</tr>
</thead>
</table>
| Agnes Jankowicz, MSc  
Executive Director, PV  
Certus PV Services Inc., Canada | Eileen Tan, JD  
Legal Council  
Aptex 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
Boston, MA | June 24-28
DIAglobal.org/DIA2018