DIA

Annual Canadian Meeting

October 16: Short Courses | October 17-18: Meeting
Ottawa Marriott, Ottawa, Ontario

PROGRAM CO-CHAIRS

Marilena Bassi, MA
Director of Office of Planning, Performance and Review Services
Health Canada

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Senior Manager, Regulatory Affairs (Canada)
Pendopharm, Division of Pharmascience

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Matthew Ryan
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Health Canada

Overview

2017 marks the sesquicentennial for Canada. Canada is celebrating 150 years of Confederation! Join us at the DIA Annual Canadian Meeting as we explore how Canada's past has shaped the Canadian health care ecosystem of today and tomorrow.

The *DIA Annual Canadian Meeting* will reflect on the evolution of Canada's health system by bringing together key thought leaders from industry, academia, regulators, and Health Canada. Expert speakers will discuss in-depth how collaboration can support new regulatory processes, innovation, and access, as well as trends in clinical research and operations, and developing transparency and engagement initiatives.

Highlights

- Keynote Address on celebrating the sesquicentennial for Canada
- Key insight from Health Canada and future regulations
- Round Table Discussions with expert leaders on today's hot topics
- Networking Reception with numerous exhibiting companies showcasing their latest services and solutions

Who Should Attend

Professionals involved in:

- Regulatory
- Policy
- Clinical trial disclosure policies and compliance
- Clinical operations
- Clinical Research
- Medical writing
- Medical communications
- Legal
- Market access

Schedule At-A-Glance

SHORT COURSES | MONDAY, OCTOBER 16	
7:30AM-5:00PM	Registration
7:30-8:30AM	Short Course Continental Breakfast
8:30AM-5:00PM	**Short Course 1:** Quality Stream
8:30AM-5:00PM	**Short Course 2:** ICH Clinical Safety and Efficacy Stream
5:30PM	**CHEO Event/Reception**

DAY ONE | TUESDAY, OCTOBER 17	
7:30AM-5:00PM	Registration
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking
8:30-9:00AM	**Welcome and Opening Remarks**
9:00-10:00AM	**Session 1:** Keynote Address: Collaborating for a Better Tomorrow-A Focus on Improving Access to Child-Friendly Medicines
10:00-10:30AM	Refreshments, Exhibits, and Networking Break
10:30AM-12:00PM	**Session 2:** Health Canada Policy Priorities: Regulatory Review of Drugs/Devices, Cannabis, and the Controlled Drugs and Substance Strategy
12:00-1:30PM	Networking Luncheon
1:30-3:00PM	**Session 3:** Concurrent Breakout Sessions **Track A:** Postmarket Pharmacovigilance **Track B:** Biosimilars: Evolving Perspectives **Track C:** Medical Devices - A Global Perspective
3:00-3:30PM	Refreshments, Exhibits, and Networking Break
3:30-5:00PM	**Session 4:** Concurrent Breakout Sessions **Track A:** International Work Sharing and Collaboration Initiatives **Track B:** Market Access: Implications for and Piloting the Alignment of HTA, HC Reviews, and Comprehensive Economic and Trade Agreement (CETA) **Track C:** IDMP
5:00-6:00PM	Networking and Exhibitor Reception

DAY TWO | WEDNESDAY, OCTOBER 18	
7:30AM-3:00PM	Registration
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking
8:30-10:00AM	**Session 5:** Concurrent Breakout Sessions **Track A:** Clinical Trial Transparency **Track B:** Health Canada Policy Activities and Transparency Updates **Track C:** Medical Communication Compliance, Including Use of Social Media
10:00-10:30AM	Refreshments, Exhibits and Networking Break
10:30AM-12:00PM	**Session 6:** Concurrent Breakout Sessions **Track A:** Perspectives on Continuous Manufacturing Approaches **Track B:** Real-World Data **Track C:** Postmarket Considerations: Including PV Inspections, Global Drug and Device Challenges, and Vanessa's Law
12:00-1:30PM	Networking Luncheon
1:30-3:00PM	**Session 7:** Future of Personalized Health – Tomorrow's Promises – Today's Challenges

Learning objectives

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

- Describe the current and evolving regulatory environment in Canada
- Discuss regulatory agency priorities for 2018 and their impact on the health care system
- Summarize methods and approaches used in clinical trials, patient engagement, supply chain, and manufacturing
- Discuss more in-depth approaches on international harmonization, worksharing, and adoption of guidelines
- Describe the various levels of transparency and postmarket activities that are underway

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Short Course 1: Quality Stream: .8 CEUs

Short Course 2: ICH Clinical Safety and Efficacy Stream: .8 CEUs

Meeting: 1.1 CEUs

The online evaluation closes on **Wednesday, November 8**.

This event is approved by the Regulatory Affairs Professionals Society for 12 RAC credits.

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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.

SHORT COURSES | MONDAY, OCTOBER 16

7:30AM-5:00PM — **Registration**

7:30-8:30AM — **Short Course Continental Breakfast**

8:30AM-5:00PM

Short Course 1
Quality Stream

Featured Topics
- ICH Introduction
- Q3D: Impurities: Guideline for Elemental Impurities
- M7: Assessment and Control of DNA Reactive Impurities
- Q9: Application of Quality Risk Management in Product Life Cycle: From Product Development to Post-Approval Changes
- Q10: Pharmaceutical Quality System
- Q11 Questions and Answers Document: Selection and Justification of Starting Materials for the Manufacture of Drug Substances

Learning Objectives
At the conclusion of this short course, participants should be able to:

- Understand the ICH process and how ICH guidelines are developed and implemented in Canada
- Recognize the value that ICH brings to drug regulation in Canada
- Describe and understand key ICH safety and efficacy guidelines
- Recognize how and when to use the guidelines throughout the life cycle of a drug product

Instructors

Celia Lourenco
Director, Bureau of Gastroenterology Infection and Viral Diseases
Health Canada

Alison Ingham, PhD
Team Leader, Generic Drugs Quality DivisionHealth Canada

Nick Orphanos
Senior Policy Analyst
Health Canada

Alisa Vespa, PhD
Assessment Officer
Health Canada

Gary Condran
Associate Director
Health Canada

Amirthini Rajkumar, PhD
Team Leader/ Advisor
Health Canada

Stephen McCaul
Drug Inspection Supervisor, Regulatory Operations and Regions Branch
Health Canada

8:30AM-5:00PM

Short Course 2
ICH Clinical Safety and Efficacy Stream

Featured Topics
- ICH Introduction
- E9: Addendum to Defining Appropriate Estimand for a Clinical Trial/Sensitivity Analyses
- E11: Addendum to Paediatric Drug Development
- M4E(R2): Enhancing the Format and Structure of Benefit-Risk Information in ICH
- E15, E16, and E18: Pharmacogenomics
- S9: Nonclinical Evaluation for Anticancer Pharmaceuticals

Learning Objectives
At the conclusion of this short course, participants should be able to:

- Understand the ICH process and how ICH guidelines are developed and implemented in Canada
- Recognize the value that ICH brings to drug regulation in Canada
- Describe and understand key ICH safety and efficacy guidelines
- Recognize how and when to use the guidelines throughout the life cycle of a drug product

Instructors

Ariel E. Arias
Senior Advisor, Centre for Biologics Evaluation, BGTD
Health Canada

Catherine Njue, PhD
Biostatistics Advisor
Health Canada

Agnes V. Klein, DrPH
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products
Health Canada

Jian Wang, MD, PhD
Chief, Clinical Evaluation Division, Haematology/Oncology, HPFB
Health Canada

Alisa Vespa, PhD
Assessment Officer
Health Canada

Kader Kourad, MD, PhD
Senior Clinical Reviewer
Health Canada

Nashwa Irfan, PhD
Associate Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate
Health Canada

MONDAY, OCTOBER 16

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.

DAY ONE | TUESDAY, OCTOBER 17

7:30AM-5:00PM

Registration

7:30-8:30AM

Continental Breakfast

8:30-9:00AM

Opening Remarks

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

Program Co-Chairs

Marilena Bassi, MA
Director, Therapeutic Products Directorate
Health Canada

Deirdre Cozier
Senior Manager, Regulatory Affairs (Canada)
Pendopharm, Division of Pharmascience, Canada

9:00-10:00AM

Session 1

Keynote Address: Collaborating for a Better Tomorrow-A Focus on Improving Access to Child-Friendly Medicines

Session Chair

Deirdre Cozier
Director, Regulatory Labelling Advertising and Operations (Canada)
Pharmascience, Canada

The access to health care is a defining value for all Canadians. Canada enjoys a rich history in developing and bringing life-saving drugs both domestically and internationally. This presentation will raise awareness on the importance of having pediatric formulations available in Canada. Modifying adult formulations to suit the needs of children bears certain risks. Learn how a non-profit organization is pioneering an innovative and collaborative cross-industry approach to meet the needs of Canada's sick children. Suitable commercially available pediatric formulations can spell the difference between successful treatment or therapeutic failure.

Keynote Speaker

Andréa Gilpin, PhD, MBA
General Manager
The Rosalind and Morris Goodman Family Pediatric Formulations Centre of the CHU Sainte-Justine

10:00-10:30AM

Refreshments, Exhibits, and Networking Break

DAY ONE | TUESDAY, OCTOBER 17

10:30AM-12:00PM

Session 2

Health Canada Policy Priorities: Regulatory Review of Drugs/Devices, Opioids, Cannabis, and the Controlled Drugs and Substance Strategy

Session Chair
Marilena Bassi, MA
Director, Therapeutic Products Directorate
Health Canada

Senior officials from Health Canada will discuss current departmental policy and regulatory priorities including initiatives to modernize regulatory review processes, the proposed legalization of cannabis, and the federal government's renewal of the controlled drugs and substance strategy.

Overview of Health Canada's Regulatory Review of Drugs and Devices
Evelyn Soo
A/Manager
Health Canada

Proposed Cannabis Legalization
Chris Rose
Director, Cannabis Legalization and Regulatory Branch
Health Canada

Updating the Controlled Drugs and Substances Strategy
Michelle Boudreau
Director General, Controlled Substances Directorate, Health Environments and Consumer Safety Branch
Health Canada

Panel Discussion

12:00-1:30PM

Networking Luncheon

1:30-3:00PM

Session 3

Concurrent Breakout Sessions

TRACK A
Postmarket Pharmacovigilance

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

Adverse Drug Reactions (ADR) reporting is one of the cornerstones of pharmacovigilance. Harmonization of ADR reporting practices nationally and internationally brings its own challenges. Listen in as representatives from Health Canada and the Industry discuss the challenges associated with ADR reporting in Canada and abroad. You will learn the similarities and differences between different ADR reporting regulations in Canada, US, EU, and Asia, and their impact on the ability to monitor drug safety.

Understanding Challenges in Safety Reporting in Asia – The Emerging Regulatory Market: Comparison with US and EU

Mugdha Chopra, DDS
Associate Vice President, US PV and Clinical Safety
APCER Life Sciences

Pre-Market Pharmacovigilance and its Challenges: Canadian Regulator's Perspective

Hoda Eid, MSc, PhD
Manager, Adverse Drug Reactions Division
Office of Clinical Trials
Health Canada

Canadian Industry Perspective on Challenges Regarding ADR Reporting for Marketed Health Products

Caroline Croteau, MS, RPh
Country Safety Lead
Pfizer Canada Inc

TRACK B
Biosimilars: Evolving Perspectives

Session Chair
Loretta Del Bosco
Director, Regulatory Affairs Quality Assurance Operations
AbbVie Corporation, Canada

This session will provide an overview from the two key North American Regulators (Health Canada and FDA) as well as from the Alliance for Safe Biologic Medicines on the exciting and evolving landscape of Biosimilars. Being at the forefront of the biosimilar discussion is key to the future of our healthcare system in Canada (and abroad) and this session will highlight key concepts and challenges.

Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, Office of New Drugs
CDER, FDA

Understanding Canadian Prescriber Perspectives on Key Considerations for Biologics and Biosimilars

Harry Gewanter, MD, FAAP, FACR
Chairman
Alliance for Safe Biologic Medicines

Biosimilars: An Update on Health Canada Activities

Stephanie Hardy
Senior Policy Analyst
Health Canada

TRACK C
Pharmacovigilance for Medical Devices – A Global Perspective

Session Chair
Maggie Graham
Senior Policy Analyst, Natural and Non-Prescription Health Products Directorate
Health Canada

Pharmacovigilance Challenges and Complexities in Medical Devices: US and EU Perspective

Sanjeev Miglani, MD
Vice President-PV and Clinical Safety North America and Global Medical Affairs
APCER Life Sciences

Canadian Perspective on the Challenges on Postmarket Surveillance for Medical Devices

Patrick Fandja
Manager, Medical Devices Section
Health Canada

Postmarket Surveillance – Industry Perspective

Patrick Caines, MBA, PhD
Director, Quality and Compliance
Baxter Healthcare, Canada

DAY ONE | TUESDAY, OCTOBER 17

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

3:30-5:00PM — **Session 4**
Concurrent Breakout Sessions

TRACK A International Work Sharing and Collaboration Initiatives	TRACK B Market Access: Implications for and Piloting the Alignment of HTA, HC Reviews, and Comprehensive Economic and Trade Agreement (CETA)	TRACK C IDMP
Session Chair **Nancy Shadeed** Manager, International Affairs Division, Therapeutic Products Directorate Health Canada This session will include updates and information on various pharmaceutical and medical device initiatives the Health Products and Food Branch is engaged in. The session will cover the work sharing project that Health Canada is conducting with the TGA – Australia. **Update on Health Products and Food Branch International Activities** **Mary Hill** Manager, Policy Development, International Affairs Health Canada **International Medical Devices Regulatory Forum** **Nancy Shadeed** Manager, International Affairs Division, Therapeutic Products Directorate Health Canada **ICH Return on Investment Project** **Representative Invited** **International Work Sharing Project – New Chemical Entities** **Andy Hua** Senior Policy Analyst Health Canada	**Session Chair** **Keith McIntosh** Executive Director, Scientific and Regulatory Affairs Innovative Medicines Canada This session will focus on regulatory policies realted to market access. You will learn about various approaches for HTA and regulatory approvals in Canada, and hear directly from Health Canada the work underway to streamline and coordinate these processes. The session will examine the implication of CETA on pharmaceutical protection, including what benefits CETA may bring to Canadian consumers, patients, and the economy. **Piloting the Alignment of HTA and HC Reviews** **Kelly Lehman** Associate Director Health Canada **The Implication of CETA on Pharmaceutical Patent Protection** **Cheryl Cheung** Intellectual Property Counsel Pharmascience	**Session Co-Chairs** **Maggie Graham** Senior Policy Analyst, Natural and Non-Prescription Health Products Directorate Health Canada **Donald Palmer, MA** Director, Product Strategy and Regulatory Informatics ACUTA LLC The ISO IDMP standard, and the European implementation of it, present a number of challenges in terms of the data that must be collected, managed, and submitted to the agencies. Explore how companies can – and should already be starting to – approach IDMP implmentation. Speakers will address how to design new processes for handling IDMP requirements and how to react to evolving requirements. **IDMP: Incrememental Data, More Processes** **Joel Finkle** Director, Regulatory Innovation ACUTA **IDMP Overview and a Regulators Perspective** **Vikesh Srivastava** Associate Director, Business Informatics Division, HPFB Health Canada **IDMP Overview and a Regulators Perspective** **Vikesh Srivastava** Associate Director, Business Informatics Division, HPFB Health Canada **Industry Perception and Action on IDMP Standards: US and EU** **Brooke L. Casselberry, MSRA, RAC** Partner IDENTIFICA

5:00-6:00PM — **Networking and Exhibitor Reception**

DAY TWO | WEDNESDAY, OCTOBER 18

7:30AM-3:00PM — **Registration**

7:30-8:30AM — **Continental Breakfast and Networking**

8:30-10:00AM — **Session 5**
Concurrent Breakout Sessions

TRACK A
Clinical Trial Transparency

Session Chair
Lorella Garofalo, PhD
Director, Regulatory Affairs,
Worldwide Safety and Regulatory-Innovative
Pfizer Canada, Inc

Transparency in regulatory decision making is a global growing trend with regulatory authorities adopting transparency policies that include requirements for disclosure of clinical trial information and data. This session will provide an overview of current regulatory requirements for disclosure of data from clinical studies in the US and EU as well as Health Canada's initiative to publicly release clinical information concerning the safety and efficacy of drugs and safety and effectiveness of medical devices. Industry transparency efforts and challenges encountered in operationalizing requirements as well as the implications for study participant confidentiality and compliance with privacy regulations in multiple jurisdictions will also be discussed.

Health Canada's Regulatory Proposal and Policy on the Public Release of Clinical Information in Drug Submissions and Medical Device Applications

Andre Molgat, PhD
Senior Regulatory Affairs Officer,
Resource Management and Operations Directorate, HPFB
Health Canada

Legal Considerations with Disclosure of Clinical Data

Yolande Dufresne
TORYS LLP

TRACK B
Health Canada Policy Activities and Transparency Updates

Session Chair
Karen Feltmate
President
Redstone Health Group Inc.

This session provides an opportunity for Health Canada to provide an update on key policy and regulatory activities. The department has a number of priorities which fall under its mandate, a few of which were discussed by senior government officials during the opening plenaries. This session delves deeper into additional policy and regulatory issues being led by the department. Leaders within the Health Products and Food Branch will provide timely updates on these initiatives, including outlining the policy objectives, the specific actions being implemented, and the applicable timelines. Whether you are in academia, industry, a not-for-profit, or a regulator, this information will help build your overall knowledge of issues affecting your work and the broader Canadian population as a whole.

Update on Premarket Transparency Initiatives for Drugs and Medical Devices

Laura Johnson
Project Manager Office of Planning, Performance and Review Services, Therapeutic Products Directorate, Health Products and Food Branch
Health Canada

Anti-Microbial Resistance: An Overview of Health Canada's Activities

Luyce Galand
Associate Director Bureau of Gastroenterology, Infectious and Viral Diseases, Therapeutic Products Directorate, Health Products and Food Branch
Health Canada

Regulatory Foresight: Anticipating the Health Needs of Canadians

Ed Morgan
Director General, Policy, Planning and International Affairs Directorate, Health Products and Food Branch
Health Canada

Elizabeth Toller
Director, Strategic Horizontal Policy Division, Policy, Planning and International Affairs Directorate, Health Products and Food Branch
Health Canada

TRACK C
Medical Communication Compliance, Including Use of Social Media

Session Chair
Rania Gaspo, BPharm, PhD
Director, Global Therapy Area Lead,
External Medical Communications
Pfizer Canada Inc

This session will discuss medical communication compliance from the Americas perspective. Canadian medical information websites are important resources to communicate balanced and accurate medical information to health care providers on prescription medicines, while social media can be used by medical information departments as a strategic channel to increase awareness. Join this session to learn how to effectively leverage your companies communication channels.

Canada Medical Information (MI) Industry Websites: How Usable Are They Across The Industry? A Bonus: The Impact Of Social Media Posts Within Pfizer Canada, Mexico, and Brazil

Rania Gaspo, BPharm, PhD
Director, Global Therapy Area Lead,
External Medical Communications
Pfizer Canada Inc

How To Determine Whether Your Activities Related To Medical Communications Cross into The Realm Of Drug Advertising

Patrick Massad, BPharm
Deputy Commissioner
PAAB

What are the Possible Applications of Social Media Within Medical Communications? What To Consider?

Mai-Loan Leha, BPharm, MSc
Medical Information, Canada Lead
Bristol-Myers Squibb

DAY TWO | WEDNESDAY, OCTOBER 18

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

10:30AM-12:00PM — **Session 6**
Concurrent Breakout Sessions

TRACK A
Perspectives on Continuous Manufacturing Approaches

Session Chair
Loretta Del Bosco
Director, Regulatory Affairs Quality Assurance Operations
AbbVie Corporation

This session will provide the Regulator and Industry perspectives on continuous manufacturing approaches. From initial formulation and process development activities to manufacturing, the session will highlight key lessons learned and future opportunities in this exciting area of pharmaceutical products.This session will also have updates from Health Canada on several key regulatory quality guidelines for the regulation of pharmaceuticals.

A Risk-Based Approach to Development and Manufacture of a New Chemical Entity Using Continuous Manufacturing (PCMM)

John Groskoph, MBA
Executive Director, New Products CMC, Global CMC
Pfizer Inc

Continuous Manufacturing of Biological Therapeutics: Current Technology Trends and Their Regulatory Impact

Daniela Decina, MSc
Senior Director, Regulatory Affairs, CMC
Mapi Group, Canada

Update on Health Canada's Quality Guidance for NDSs and ANDSs and on the Use of EDQM's Certificates of Suitability (CEPs) within the Canadian Regulatory Framework

Alison Ingham, PhD
Team Leader, Generic Drugs Quality Division
Health Canada

TRACK B
Real-World Data

Session Chair
Lisa Chartrand
Director, Regulatory Affairs and Quality Management
Hoffmann-La Roche Ltd., Canada

We hear a lot lately about real-world data and how it will revolutionize the way we think about evidence. As ICH have reflected on this concept already, it is time now for industry, regulators, and patients in Canada to start thinking about how this evidence will be used, how it will foster research and innovation, how it will help with regulatory decision-making throughout the product's life cycle and ideally, from the patient's perspective, and how it could expedite access of medicines by looking at partnerships with industry, as well as government stakeholders to explore its full potential.

Real World Evidence in Regulatory Decision-Making

Michael Duong, PhD
Director, Evidence Generation, Medical Affairs
Hoffmann-La Roche Ltd.

Should Real-World Data Impact Regulatory Decision-Making: A Patient's Perspective

Barry D. Stein
President and CEO
Colorectal Cancer, Canada

Health Canada: The Enhanced Use of Real-World Data

Basanti Ghosh, PhD, MBA
Office of Pharmacopeidemiology and Data Analytics (OPEDA), HPFB Marketed Health Products Directorate/DPSC de DGPSA
Health Canada

Vikesh Srivastava
Associate Director, Business Informatics Division, Health Products and Food Branch
Health Canada

TRACK C
Postmarket Considerations: Including PV Inspections, Global Drug and Device Challenges, and Vanessa's Law

Session Chair
Lorella Garofalo, PhD
Worldwide Safety and Regulatory-Innovative
Pfizer Canada, Inc

Amendments to the Canadian Food and Drugs Act under Bill C-17 have resulted in a broadening of Health Canada's (HC) powers in particular concerning the collection of post-market safety information. This session will provide an overview of the ongoing modernization and renewal efforts being undertaken by Health Canada on its Good Pharmacovigilance Program (GVP) and in addition discuss recent trends in GVP inspections. An update by HC on Bill C-17 related regulations and the Industry perspective on the impact, benefit and cost of implementing Bill C-17 requirements based on current proposals will also be presented.

Updates on the Good Pharmacovigilance Practices Inspections

Sophie Lafrance
Corporate Regulatory Compliance and Enforcement Advisor
Health Canada

Vanessa's Law - Costs and Benefits of Implementation

Rocelyn DelCarmen
Director, Regulatory Affairs and Quality Assurance
Astrazeneca Canada Inc.

Vanessa's Law – Update on Implementation

Debra Haltrecht
Manager - Policy Development, Office of Legislative and Regulatory Modernization
Health Canada

DAY TWO | WEDNESDAY, OCTOBER

12:00-1:30PM	**Networking Luncheon**
1:30-3:00PM	**Session 7** Future of Personalized Health - Tomorrow's Promises - Today's Challenges **Session Co-Chairs** **Marc F. Poitras, PhD, MBA** Scientific Manager, Marketed Pharmaceuticals and Medical Devices Bureau Health Canada **Anu-Shukla Jones** Health Canada Personalized Health promises to leverage modern technology to revolutionize the way we approach disease prevention, diagnosis, and treatment. However, the implementation of tools and approaches to fully unlock the benefits of Personalized Health brings numerous challenges that society must address before it can become a reality. This session will provide two key perspectives on which and how new targeted health solutions can contribute to a cost-effective and sustainable health care system and accessing the right therapy for the right patient with the fewest barriers. **Christopher McCabe, PhD** Executive Director and CEO Institute of Health Economics, Canada **Kathleen Barnard** Save Your Skin Foundation, Canada
3:00PM	**Meeting Adjourned**