DIA Annual Canadian Meeting

Short Courses: October 29 | Conference 30-31 | Ottawa Marriott | Ottawa, ON

PROGRAM COMMITTEE CO-CHAIRS

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

Karen Feltmate
President
Redstone Health Group, Inc., Canada

PROGRAM COMMITTEE

Marilena Bassi, MA
Director, Therapeutic Products Directorate
Health Canada

Lisa Chartrand
Director, Regulatory Affairs and Quality Management
Hoffmann La-Roche Limited, Canada

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

Fiona Frappier, PhD
Senior Policy Analyst
Health Canada

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

Melissa Hunt, MSc
Acting Director
Health Canada

Rania Mouchantaf, MD, PhD
Manager
Marketed Health Product Directorate, Health Canada

Lissa Murseli
Manager
Health Canada

Polina Ostrovsky
Policy Analyst
Health Canada

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

Overview

The DIA Annual Canadian Meeting will deliver a comprehensive overview of the current bio-pharma and device landscape in Canada, while sharing insights into Canada's broader role in global healthcare product development. From policy updates and priorities shared directly from Health Canada, to sessions on international work sharing and partnerships to key regulatory and clinical considerations for drugs and devices, you will have the exclusive opportunity to address the current issues and opportunities in Canada and across the globe. Bringing together key stakeholders from the drug (innovator and generic/biosimilar)/, device and Patient Self Care industries, regulatory agencies, and academia, this meeting will discuss/analyze the relevant challenges and opportunities for professionals working in the field in Canada. This year's meeting will feature preconference short courses, plenary sessions, multi-track breakout sessions and multiple networking opportunities.

Highlights

- To ensure you are on top of all the new and trending regulatory changes and how they may impact your work environment
- Hear directly from knowledgeable experts from Health Canada (and other regulatory agencies), Academia and Industry about current and future regulatory opportunities and challenges in Canada, including insights on biologics, medical devices, personalized medicine and pre/post-market pharmacovigilance
- Discuss key R2D2 topics
- Describe the current and evolving regulatory environment in Canada
- Discuss more in-depth, approaches on international harmonization, work sharing, and adoption of guidelines

Target Audience:

Professionals in pharmaceutical and device industries, regulatory agencies, and academia involved in:

- Clinical Data Management/EClinical
- Comparative Effectiveness/Health Technology Assessment
- Clinical Safety/Pharmacovigilance
- Clinical Research
- Document Management/ESubmissions
- Medical Communications
- Outsourcing
- Project Management
- Public Policy/Law/Corporate Compliance
- Quality Assurance Control
- Regulatory Affairs
- Research and Development
- Statistics

Schedule At-A-Glance

SHORT COURSE | MONDAY OCTOBER 29		ROOM
7:00AM-5:00PM	Short Course Registration	Lower Level Foyer
8:00AM-12:00PM	**Short Course 1:** Policy and Regulatory Development at the Health Products and Food Branch (HPFB): From Conception to Realization and the Role of Stakeholders	Laurier
1:00-5:00PM	**Short Course 2:** Regulatory Renewal: Statistical Principles as Part of Regulatory Decision-Making	Laurier
5:30-6:30PM	CHEO-OCTC Event and Networking Reception	Lower Level Foyer

DAY ONE | TUESDAY OCTOBER 30		ROOM
7:30AM-5:30PM	Registration	Alta Vista
7:30-8:30AM	Continental Breakfast and Networking	Victoria Ballroom Foyer
8:15-8:30AM	Mobile App Tutorial	Victoria Ballroom North/South
8:30-9:15AM	**Welcome and Opening Remarks from Health Canada Senior Official**	Victoria Ballroom North/South
9:15-10:00AM	**Session 1:** Keynote Address	Victoria Ballroom North/South
10:00-10:30AM	Refreshment, Exhibits, and Networking Break	Victoria Ballroom Foyer
10:30AM-12:00PM	**Session 2:** Perspectives in Regulatory Cooperation	Victoria Ballroom North/South
12:00-1:30PM	Luncheon, Exhibits, and Networking	Cartier I-III
1:30-3:00PM	**Session 3:** Breakout Sessions	
	Track A: Exploring New Pathways to Market	Victoria Ballroom North
	Track B: Canadian Trends in Fostering Clinical Trial Research	Victoria Ballroom South
	Track C: Digital Health: Transforming Processes with Technology	Laurier
3:00-3:30PM	Refreshment, Exhibits, and Networking Break	Victoria Ballroom Foyer
3:30-5:00PM	**Session 4:** Breakout Sessions	
	Track A: Regulatory Renewal: More on the Regulatory Changes Implemented and Being Proposed	Victoria Ballroom North
	Track B: Patient Care, Patient Voice, and Patient Engagement	Victoria Ballroom South
	Track C: Risk Minimization and Evaluation of Their Impact: Challenges and Approaches	Laurier
5:00-6:00PM	Networking Reception	Victoria Ballroom Foyer

DAY TWO | WEDNESDAY OCTOBER 31		ROOM
7:30AM-3:00PM	Registration	Alta Vista
7:30-8:30AM	Continental Breakfast and Networking	Victoria Ballroom Foyer
8:30-10:00AM	**Session 5:** Breakout Sessions	
	Track A: Cybersecurity	Victoria Ballroom North
	Track B: Responsible On-Boarding of Precision Medicine: Why Bytes and Spit Aren't Enough	Victoria Ballroom South
	Track C: Regulatory Considerations for Small- and Medium-Sized Enterprises	Laurier
10:00-10:30AM	Refreshment, Exhibits, and Networking Break	Victoria Ballroom Foyer
10:30AM-12:00PM	**Session 6:** Breakout Sessions	
	Track A: Innovative Labeling Policies, Guidances, and Solutions for Self-Care Products	Victoria Ballroom North
	Track B: Emerging Technologies and Therapies	Victoria Ballroom South
	Track C: Best Practices in Policy Development and Direction	Laurier
12:00-1:30PM	Luncheon, Exhibits, Networking, and Speaker Round Tables	Cartier I-III
1:30-3:00PM	**Session 7:** Breakout Sessions	
	Track A: International Collaborations and Updates	Victoria Ballroom North
	Track B: Pharmacovigilance: To Detect or Not to Detect	Victoria Ballroom South
	Track C: Leveraging Partnerships	Laurier

Learning Objectives

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

- Describe the current and evolving regulatory environment in Canada
- Summarize methods and approaches in various aspects of clinical trials, patient engagement, and market access
- Discuss more in-depth, approaches on international harmonization, worksharing, and adoption of guidelines
- Review the various levels of transparency and post-market activities that are underway

Continuing Education Credit

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 1.8 CEUs for this meeting. Participants must complete the entire conference 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 for the conference, you must sign in each day 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 Monday, November 12, 2018.

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CLINICAL TRIALS ONTARIO

SHORT COURSES | MONDAY OCTOBER 29

7:00AM-5:00PM — **Short Course Registration**

8:00AM-12:00PM — **Short Course 1:** Policy and Regulatory Development at the Health Products and Food Branch (HPFB): From Conception to Realization and the Role of Stakeholders

This short course will give an overview of how the regulatory process unfolds in HPFB and how the Branch develops supporting policy, guidance documents, and processes. The session will describe the regulatory and policy processes, how comments are sought from stakeholders and incorporated in policy and regulatory decision-making, some lessons learned, and best practices in these areas, including case examples from both Health Canada and Industry.

Introduction and Overview
Marilena Bassi, MA, Director, Therapeutic Products Directorate, Health Canada

Regulatory Development Process
Alicia Li, Senior Policy Analyst, Health Canada

Policy/Guidance Development Process
Ruth Hansson, Policy Analyst, Health Canada

Working Case Study – Tamper-Resistance Products
Nadia Giancaspro, Senior Policy Analyst, Health Canada

Industry/Stakeholders Perspective
Kristin Willemsen, MS, Director of Scientific and Regulatory Affairs, Consumer Health Products Canada

1:00-5:00PM — **Short Course 2:** Regulatory Renewal: Statistical Principles as Part of Regulatory Decision Making

This short course will uncover the regulatory principles and guidances which are used by Health Canada statisticians as part of the overall review process. In addition, new statistical principles being explored as part of developing new clinical study designs will be discussed. Case studies will help the lay regulatory professional work through "thinking like a statistician."

Catherine Njue, PhD, Biostatistics Advisor - Clinical Trials, Health Canada

Andrew Raven, Manager, Biostatics, Health Canada

Melanie Poulin-Costello, MSc, PStat, Biostatistics Site Head, Hoffmann-La Roche Ltd., Canada

5:30-6:30PM — **CHEO-OCTC Event and Networking Reception**

DIA is pleased to partner again 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! Focusing 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. Join us in creating trick-or-treat bags for the children of CHEO-OCTC as we network over refreshments. Attendees of the *Canadian Pharmacovigilance and Risk Management Strategies Conference* and *DIA Annual Canadian Meeting* are invited to attend.

DAY ONE | TUESDAY OCTOBER 30

7:30AM-5:30PM — **Registration**

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

8:15-8:30AM — **Mobile App Tutorial**

8:30-9:15AM

Welcome and Opening Remarks from Health Canada Senior Official

Session Co-Chairs
Marc Poitras, PhD, MBA, Scientific Manager, Marketed Pharmaceuticals and Medical Devices Bureau, Health Canada

Karen Feltmate, President, Redstone Health Group, Inc., Canada

Pierre Sabourin, MBA, Assistant Deputy Minister, Health Products and Food Branch, Health Canada

9:15-10:00AM

Session 1: Keynote Address

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

There are a myriad of regulatory changes in the works and in the wings, from Patented Medicine pricing reviews, new collaborations with HTA reviewers and other regulators, to review and approval process improvements. While both exciting and at times maybe frightening, these changes should ultimately ease our access to innovative medicines. Hear from a key stakeholder in the telecommunications industry (also heavily regulated) about his experience, lessons learned, and how to keep your focus on the right outcomes.

Working Through Regulatory Transformation: Lessons Learned from a Related Industry
Robert Ghiz, President and CEO, The Canadian Wireless Telecommunications Association (CWTA), Canada

Panelists
Pierre Sabourin, MBA, Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Karen Feltmate, President, Redstone Health Group, Inc., Canada

10:00-10:30AM

Refreshment, Exhibits, and Networking Break

10:30AM-12:00PM

Session 2: Perspectives in Regulatory Cooperation

Session Co-Chairs
Marc Poitras, PhD, MBA, Scientific Manager, Marketed Pharmaceuticals and Medical Devices Bureau, Health Canada

Karen Feltmate, President, Redstone Health Group, Inc., Canada

This session will provide a high-level context for the transformations in our regulations. From the Treasury Board of Canada Secretariat to the international arena, to the HTAs/Provinces/Territories at home. From the Treasury Board of Canada Secretariat to the international arena, to the HTAs/Provinces/Territories at home. The industry perspective will also be presented to complete a fulsome review of Regulatory Cooperation in evolution.

David K. Lee, LLB, Chief Regulatory Officer for Health Product and Food Branch, Health Canada

Canada's Regulatory Modernization Agenda
Jeannine Ritchot, MA, Executive Director of the Regulatory Policy and Cooperation Directorate, Treasury Board of Canada Secretariat, Canada

Brian O'Rourke, President and Chief Executive Officer, Canadian Agency for Drugs and Technologies in Health, Canada

Industry Perspectives on Regulatory Cooperation
Kristin Willemsen, MS, Director of Scientific and Regulatory Affairs, Consumer Health Products Canada

12:00-1:30PM

Luncheon, Exhibits, and Networking

1:30-3:00PM

Session 3: Breakout Sessions

Track A: Exploring New Pathways to Market

Session Chair
Melissa Hunt, MSc, Acting Director, Health Canada

This session will explore factors associated with regulatory approval timing in Canada as well as initiatives underway to explore different pathways to market in Canada. This session will include perspectives from both industry and Health Canada. Specific topics that will be discussed include factors associated with filing and approval for new drugs in Canada, international worksharing and use of foreign reviews/decisions at Health Canada, and how Health Canada is exploring engagement earlier in drug development.

Factors Associated with Regulatory Filing and Approval Timelines of New Medicines
Sarah Lussier Hoskyn, MA, Senior Analyst, Regulatory Affairs and Market Access, Innovative Medicines Canada, Canada

Early Scientific Advice at Health Canada
Megan Bettle, PhD, Director, Regulatory Review of Drugs and Devices, Health Canada

International Work Sharing at Health Canada
W. Craig Simon, PhD, Associate Director, Bureau of Metabolism, Oncology, and Reproductive Sciences, Health Canada

The Proposed Use of a Foreign Decision Pathway
Léo Bouthillier, PhD, Director, Bureau of Cardiology, Allergy, and Neurological Sciences, Health Canada

Track B: Canadian Trends in Fostering Clinical Trial Research

Session Chair
Fiona Frappier, PhD, Senior Policy Analyst, Health Canada

The session will provide an overview of key initiatives to enhance the number and quality of trials underway in Canada. Factors impacting the clinical trials environment and opportunities to improve our healthcare innovation capabilities in Canada will be identified and described. Key outlooks will be reflected from provincial, contract research organization, and national coordinating center perspectives.

Clinical Trials: The Changing Landscape - Understanding and Adapting
Susan Marlin, MSc, President and CEO, Clinical Trials Ontario, Canada

Enhancing Research Participant Protection in Canada Through Accreditation
Janice E. Parente, PhD, President and CEO, Orion Human Research Accreditation, Canada

Update on International Clinical Data Sharing Initiatives
Marcin Boruk, MSc, MBA, Senior Policy Analyst, Health Canada

Track C: Digital Health: Transforming Processes with Technology

Session Chair
Karen Feltmate, President, Redstone Health Group, Inc., Canada

This session will discuss technology-driven approaches to collecting and managing data through the drug development lifecycle. It is easier than ever to generate data, but appropriate tools and processes are necessary to make best use of this data and keep it protected.

The Shifting Landscapes of Clinical Trials
Marta Motta, Global Director of Client Solutions, Welocalize Life Sciences

Daniel Zikovitz, PhD, Principal Digital Solutions Architect, GE Healthcare Canada, Canada

Shanti Gidwani, RN, MSN, MHA, CHE, National Director, Healthcare, Cisco Systems Canada

3:00-3:30PM

Refreshment, Exhibits, and Networking Break

3:30-5:00PM

Session 4: Breakout Sessions

Track A: Regulatory Renewal: More on the Regulatory Changes Implemented and Being Proposed

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

Following on from Session 3A, given the unprecedented number of regulatory changes being proposed in the last year (and in the next few years to come) which affect various stages of a product's lifecycle in Canada, this session will summarize, consolidate, clarify, and help to ensure as an industry and consumers that we are all prepared.

Regulatory Changes Under the F&DA: Where We Are Now and Where We're Going
Kristen Beausoleil, Manager, Economic Analysis, Office of Legislative and Regulatory Modernization, Health Canada

Industry Impact Regulatory Changes
Jared Rhines, General Manager, AKCEA Therapeutics Canada Inc., Canada

Proposal for the Environmental Risk Assessment of Medicinal Ingredients in Human and Veterinary Drugs
Julie Chateauvert, MS, Senior Scientific Project Coordination Biologist, Health Canada

Track B: Patient Care, Patient Voice, and Patient Engagement

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

This session will give an overview of perspectives, best practices, and lessons learned on how to keep the patient voice in the heart of program design.

Special Access Program Renewal Follow-Up from Stakeholder Consultations – Patient Perspective
Marilena Bassi, MA, Director, Therapeutic Products Directorate, Health Canada

Using Patient Perspectives to Frame Health Technology Assessments
Sarah Berglas, Patient Engagement Officer, CADTH, Canada

Using Patient Perspectives to Frame Health Technology Assessments
Shelina Karmali, Executive Director, Canadian Treatment Action Council, Canada

The Patient Experience and Regulatory Decision-Making
Katherine Soltys, MD, Director, Health Canada

Track C: Risk Minimization and Evaluation of Their Impact: Challenges and Approaches

Session Chair
Rania Mouchantaf, MD, PhD, Manager, Marketed Health Product Directorate, Health Canada

In parallel with the global adoption of risk management planning, progress has been made in recent years in the area of risk minimization measures and evaluating effectiveness of such measures. These areas are now considered an integral part of pharmacovigilance in Canada and internationally. Moreover, in view of the broad range of pharmacovigilance activities that are now at the disposal of both the regulator and manufacturers, it is now timely to determine if such post-market processes are meeting their goals.

Therapeutic Risk Minimization: Designing for Dissemination, Sustainability, and Impact
Meredith Smith, PhD, MPA, Global Risk Management Officer, Amgen

Evaluation of the Effectiveness of Risk Minimization Activities
Yola Moride, PhD, FISPE, Full Professor, Faculty of Pharmacy Université de Montréal, Canada

Pharmacovigilance, Risk Minimization, and Evaluation of its Impact: International Perspectives and Best Practices
Rachel Sobel, DrPH, MPH, FISPE, Senior Director, Epidemiology - Group Lead, Pfizer Inc

5:00-6:00PM

Networking Reception

DAY TWO | WEDNESDAY, OCTOBER 31

7:30AM-3:00PM — **Registration**

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

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

Track A: Cybersecurity

Session Chair
Marc Lamoureux, Manager, Digital Health Division, Medical Devices Bureau, Health Canada

Health Canada, as the federal regulator of medical device safety and effectiveness, will now be considering cybersecurity vulnerabilities in medical devices as a potential risk to patients that manufacturers of medical devices must mitigate or eliminate. This session will describe the regulatory approach Health Canada is taking, what safety standards are relevant for this topic, and examples of industry approaches to medical device cybersecurity.

Medical Device Cybersecurity: A Health Canada Perspective
Marc Lamoureux, Manager, Digital Health Division, Medical Devices Bureau Health Canada

Cybersecurity Considerations for Medical Devices
Laura Élan, PE, RAC, Senior Manager, Cybersecurity, CSA Group

Product Security Overview from a Medical Device Manufacturer **Colin Morgan, CISS, CISM, GPEN**, Director Product Security and Service, Johnson & Johnson

Track B: Responsible On-Boarding of Precision Medicine: Why Bytes and Spit Aren't Enough

Session Chair
Andrew Atkinson, Manager, Emerging Sciences Policy, Health Canada

In this session, the responsible introduction of personalized medicine will be explored including opportunities for cost savings, as well as mitigating the economic impacts of high cost treatments.

Personalized Healthcare: Unlocking the Data – Are We Ready?
Michael Duong, Director, Evidence Generation, Medical Affairs, Hoffmann-La Roche Limited, Canada

Rated P/G: The Importance of Phenotype in a World of Genomic Data
Kathleen Hodgkinson, PhD, Associate Professor of Medicine, Memorial University, Canada

Health Technology Assessment for Reimbursement of Emerging Precision Medicine Technologies
Wendy J. Ungar, MSc, PhD, Senior Scientist, The Hospital for Sick Children Research Institute, Canada

Track C: Regulatory Considerations for Small- and Medium-Sized Enterprises

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

This session will allow for a better understanding of the challenges and opportunities faced by small- and medium-sized enterprises as they navigate the present and most importantly, the future in Canada. Whether you are from a large global or a small/medium-sized company, this session will provide transferable insights.

Changes in the Regulatory Environment: Four Pillars of Impact for Small- and Medium-Sized Enterprises
Tammy Mitchell-Moore, Associate Director, Regulatory Affairs, Eisai Limited, Canada

Case Study: Practical Approach for a Small Company as a Product Goes Through the Health Canada Process
Joe O'Neill, CEO, Accelera Pharma Canada, Canada

Global R&D at Small Companies - Impact and Benefits of Harmonized Guidelines
Yatika Kohli PhD, MBA, Vice President, Regulatory Affairs and Project Office, Medicago Inc., Canada

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

10:30AM-12:00PM

Session 6: Breakout Sessions

Track A: Innovative Labeling Policies, Guidances, and Solutions for Self-Care Products

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

In February 2018, Health Canada set out ambitious plans to execute the Self-Care Framework under existing legal statues, beginning with improving labeling for NHPs by adapting Facts Table style labeling. This announcement comes at a time when the consumer health product industry is actively working to adapt Facts Table labeling to all marketed OTCs in retail by June 2021. Necessity is the mother of convention. Packaging size limitations and timing constraints have created an environment where highly innovative approaches to packaging and labeling policy are needed to ensure that consumers have the information they need at the point of sale.

Self-Care Products Framework Update
Matthew Bown, Senior Policy Advisor, Natural and Non-Prescription Products Directorate, Health Canada

Plain Language Labeling for OTCs
Jason DiMuzo, Label Review Coordinator, Non-Prescription Drugs Evaluation Division, Canada

PLL Implementation and Solutions for the Future
James Lee, Director, Innovation Solutions Group, Jones Packaging, Canada

Track B: Emerging Technologies and Therapies

Session Chair
Fiona Frappier, PhD, Senior Policy Analyst, Health Canada

Emerging technologies have started to disrupt whole industries and in doing so are demonstrating their role as amplifiers for solutions in health outcomes. This session will describe lessons learned in bringing novel therapies through to market. Strategic elements of technology transfer, securing intellectual property, and financing in the Canadian context will focus on overcoming the first valley of death. Key enablers and thought leaders will provide examples of emerging technology companies and spin offs they have shepherded through critical steps.

Regulation of Advanced Cell Therapies for Regenerative Medicine
Nadine Kolas, PhD, Senior Policy Analyst, Health Canada

Collaborating to Get Through the Valley(s) of Death in Regenerative Medicine
Síofradh McMahon, MSc, Senior Manager, Clinical Translation and Regulatory Affairs, Centre for Commercialization of Regenerative Medicine (CCRM), Canada

Open Science Opportunities for Development and Commercialization of Novel Therapies
Maxwell Morgan, JD, LLM, Lead Legal and Policy Advisor, Structural Genomics Consortium (SGC), Canada

Track C: Best Practices in Policy Development and Direction

Session Chair
Lissa Murseli, Manager, Health Canada

This session will give an overview of relevant policy areas in Canada, such as cannabis and/or opioids. Speakers will highlight key policy areas that are underway or emerging. The session will describe some lessons learned or best practices in these policy areas, including engagement of relevant players in the policy development process.

Citizen-Focused Drug Policy Development: Working with (and for) People with Lived and Living Experience with Drug Use
Ian Hodges, Manager, Policy Development (Canadian Drugs and Substances Strategy), Office of Drug Policy and Science, Controlled Substances Directorate, Health Canada

Proactive Monitoring: A New Approach to Health Canada's Oversight of Health Products Advertising
Alain Musende, PhD, Manager, Regulatory Advertising Section, Marketed Health Products Directorate, Canada

A Discussion of Innovation and Collaboration Frameworks for Medical Cannabis
Setu Purohit, JD, Co-Founder, President, Chief Legal Officer, Avicanna Inc., Canada

12:00-1:30PM — **Luncheon, Exhibits, Networking, and Speaker Round Tables**

1:30-3:00PM — **Session 7**

Track A: International Collaborations and Updates

Session Chair
Ed Morgan, Director General, Policy, Planning and International Affairs, Health Canada

This session will outline the importance of collaborating internationally to help protect and enhance the health of Canadians. The purpose of this session is to provide an update on international collaborative files including, but not limited to: Regulatory Cooperation Council (RCC), Comprehensive Economic and Trade Agreement (CETA), European Union, Trans-Pacific Partnership (TPP) etc.; Update on International Council for Harmonisation (ICH); Update on medical devices; Industry perspective. Collaboration: ICH and IPRP

International Collaboration: ICH and IPRP
Celia Lourenco, PharmD, Interim Senior Executive Director, Therapeutic Products Directorate, Health Canada

Overview: ICH Training Activities and APEC Regulatory Harmonization Steering Committee
Michelle Limoli, PharmD, Senior International Health Science Advisor, CBER, FDA

Health Canada's International Collaboration with Regulatory Counterparts
Mary Hill, BScPT, BID, Manager, International Unit, Health Canada

Track B: Pharmacovigilance: To Detect or Not to Detect

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

Identifying new potential risks and ongoing monitoring of identified risks constitute the essence of all pharmacovigilance activities throughout the product lifecycle. In this session, experts in the field will discuss different aspects of pharmacovigilance/signal detection including different signal management tools for different product lines.

Insight into Different Signal Management Tools: New Regulatory Perspectives
Sanjeev Miglani, MD, Founder and Director, AWINSA Life Sciences

EU and US Approaches Towards Signal Detection in Vaccines
Mugdha Chopra, DDS, Co-Founder and Director, AWINSA Life Sciences

Pharmacovigilance Analysis of Product Confusion Errors and Issues in Canada - A Pharmacovigilance Assessment
Zsuzsanna Gesztesi, MD, Director, Patient Safety and Medical Information, AstraZeneca Canada Inc., Canada

Track C: Leveraging Partnerships

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

As the regulatory revisions and reforms evolve and the regulatory system strives to meet Canadian healthcare needs, new partnerships between related and unrelated stakeholders are forming. This session will allow for a better understanding and insight into the challenges and opportunities faced by various partnerships including Health Canada, HTAs, Third Parties, and Industry.

Health Canada: Expanding Collaboration with Health Partners
Kelly Robinson, MSc, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Health Canada

Help Me Help You: Strategic Partnerships to Streamline Product Development
Lauren Neighbours, PhD, RAC, Head of Regulatory Affairs, PSI CRO, United States

Building, Sustaining, and Enduring Partnerships: A New Kind of Math
Heather Logan, Vice President, Pharmaceutical Reviews, Canadian Agency for Drugs and Technologies in Health, Canada

3:00PM — **Conference Adjourns**

DIA
Annual Canadian Meeting
Exhibitor Directory

October 30-31, 2018 | Ottawa Marriott Hotel
Ottawa, Ontario, Canada

Alliance for Safe Biologic Medicines — Table 5

Contact: Michael Reilly
michael@safebiologics.org
www.safebiologics.org
Twitter Handle: @SafeBiologics

ASBM is an organization of patients, physicians, pharmacists, manufacturers of innovator biologics and biosimilars, and researchers working together to ensure patient safety is at the forefront of the biosimilars policy discussion. With more than 140 members worldwide, ASBM serves as a resource center as policies are developed and implemented.

Canadian Consumer Product and Pharmaceutical Safety (CCPPS) — Table 4

Phone: +1.844.253.4852
business@ccpps.ca
www.ccpps.ca
www.linkedin.com/company/ccpps

Canadian Consumer Product and Pharmaceutical Safety Inc. (CCPPS) is a non-profit organization that offers geographic- and product-specific data on the misuse, abuse, diversion and the associated consequences for prescription and illicit drugs. This is accomplished through an exclusive partnership with the RADARS® System.

Certus PV Services Inc. — Table 8

Contact: Rita Cassola/Agnes Jankowicz
Phone: +1.905.306.3448
contact@certuspv.com
www.certuspv.com

Certus PV provides pre-approval and post-market pharmacovigilance (PV) expertise for pharmaceutical drugs, biologics, radiopharmaceutical drugs, natural health products, medical devices and cosmetics. Our services include ICSR processing and Aggregate Reports, Risk Management, GVP Audit and Inspection support, Literature screening and PV training.

Innomar Strategies — Table 3

Contact: Mary Speagle
mspeagle@tpireg.com
www.tpireg.com
www.linkedin.com/company/innomar-strategies

Innomar Strategies delivers end-to-end commercialization solutions to improve product access, increase supply chain efficiency and enhance patient care. Regulatory and strategic consulting, patient support programs, nursing and clinical services, and specialty pharmacy and logistics are just a few of our key areas of specialization.

LORENZ International LLC — Table 7

Contact: Yaprak Eisinger
www.lorenz.cc/email
www.lorenz.cc
www.linkedin.com/company/lorenz-life-sciences-ltd.

LORENZ Life Sciences Group has an array of RIM solutions geared towards industry, health authorities and academia which enable enforcing compliance globally. LORENZ's portfolio offers Product Registration/IDMP, Submission Assembly, Validation and Management, Publishing/eCTD, Regulatory Planning and Tracking products and related services.

Mapi Lifesciences Canada Inc., an ICON plc Company — Table 6

Contact: Hetal Mokashi
hetal.mokashi@iconplc.com
www.iconplc.com
www.linkedin.com/company/icon-plc-2
Twitter Handle: @ICONplc

Mapi Lifesciences Canada Inc. is an ICON plc company. ICON is a global provider of strategic regulatory affairs services to the pharmaceutical, biotechnology and medical device industries. ICON specializes in strategic development, management and analysis of programmes supporting clinical development, operating from 97 locations in 38 countries.

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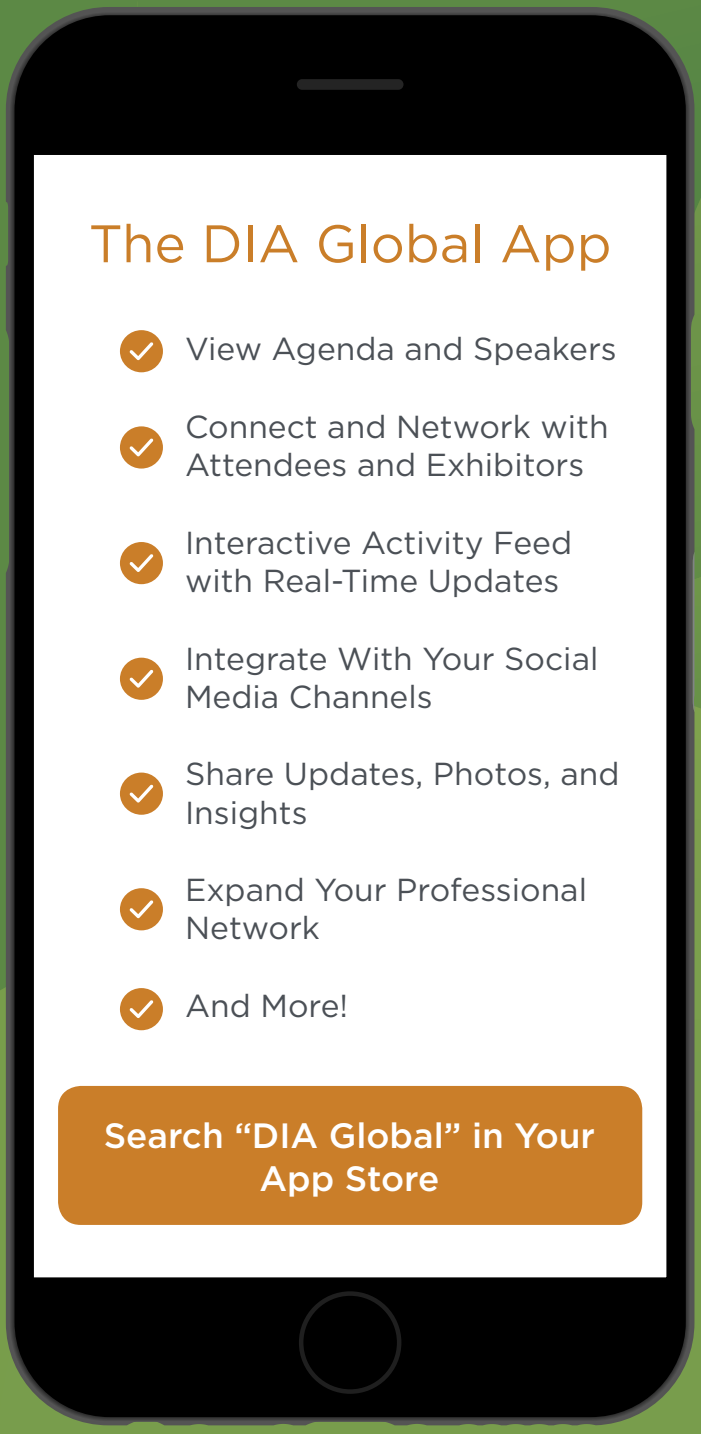

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