DIA Annual Canadian Meeting 2015

Tutorials: October 26 | Meeting: October 27-28

Marriott Ottawa | Ottawa, Ontario, Canada

As of October 15, 2015

PROGRAM CHAIRS:

Karen Feltmate
President
Redstone Health Group, Inc.

Matthew Ryan
Senior Policy Analyst
Policy, Planning and International Affairs Directorate
Health Canada

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

PROGRAM COMMITTEE:

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

Rocelyn DelCarmen
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AstraZeneca, Inc.

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Health Canada

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A New Era in Regulatory Affairs - Building Capabilities to Support Innovation, Transparency, Quality and Safety of Health Products in Canada

OVERVIEW:

As the Canadian health care system continues to evolve, the need for transparency is playing an important role in the development and management of new and existing medicines and devices. Numerous stakeholders are working to build regulatory capabilities that will help to promote innovation and to maintain high standards of quality and safety of important therapies and medicines in Canada.

The DIA Annual Canadian Meeting 2015 will bring together key thought leaders and experts, representing various stakeholders, to explore what this new era of regulatory affairs means to the Canadian health care and biopharmaceutical industries.

This year's meeting will feature plenary sessions, multi-track breakout sessions, networking opportunities, tutorials, and tabletop exhibiting opportunities.

HIGHLIGHTS:

Keynote Address

Alex Mackenzie, MD
Physician, Division of Endocrinology
Children's Hospital of Eastern Ontario (CHEO) Research Institute
Professor, Department of Pediatrics, Faculty of Medicine, University of Ottawa

Closing Remarks

Simon Kennedy
Deputy Minister of Health
Health Canada

LEARNING OBJECTIVES:

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

- Describe the current and evolving regulatory environment in Canada
- Recognize the challenges faced by various Canadian stakeholders in the development, regulation, and harmonization of accessing the state-of-the-art medicines and devices within a global context
- Discuss new technologies and efficiencies to support drug and device development
- Describe quality measures to support improved inspections and manufacturing practices

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CONTINUING EDUCATION CREDIT ALLOCATION

Tutorials:
- Tutorial 1: Plain Language Labeling: Implementing Health Canada's Guidance for Industry: IACET: .3 CEUs
- Tutorial 2: Strategies for Efficient Submission Preparation: IACET: .3 CEUs

Meeting:
- IACET: 1.1 CEUs
- Pharmacy:
- Keynote Address, Sessions 1 and 2: 3 contact hours or .3 CEUs, 0286-0000-15-128-L04-P
- Session 3: Track B: Implementation of Health Canada's Revised Guidance for Industry: Review of Drug Brand Names: 1.5 contact hours or .15 CEUs, 0286-0000-15-129-L04-P
- Session 4: Track A: Premarket Transparency in the Review of Health Products: 1.5 contact hours or .15 CEUs, 0286-0000-15-130-L04-P
- Session 4: Track C: Safety Surveillance of Scientific Literature for Medical Devices, Drugs and Combination Products: 1.5 contact hours or .15 CEUs, 0286-0000-15-131-L04-P
- Session 5: Track A: Challenges with Increasingly Smaller and Specific Patient Populations in Oncology: 1.5 contact hours or .15 CEUs, 0286-0000-15-132-L01-P
- Session 5: Track B: Regulatory Information and Data Standards for Improved Health Product Safety: 1.5 contact hours or .15 CEUs, 0286-0000-15-133-L04-P
- Session 6: Track A: Postmarket Transparency for Health Products: 1.5 contact hours or .15 CEUs, 0286-0000-15-134-L04-P

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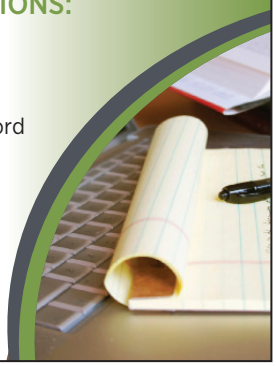

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MONDAY, OCTOBER 26

7:30-8:30AM **TUTORIAL REGISTRATION**

8:30AM-12:00PM **TUTORIAL #1: PLAIN LANGUAGE LABELING: IMPLEMENTING HEALTH CANADA'S GUIDANCE FOR INDUSTRY**

INSTRUCTORS:

Madeleine Marshall
Manager, Policy Division, Bureau of Policy, Science and International Programs, Health Products and Food Branch
Health Canada

Christine Leroux
Senior Project Manager, Therapeutic Products Directorate
Health Canada

Rocelyn DelCarmen
Director, Regulatory Affairs
AstraZeneca, Inc.

Bradlee Zrudlo
Product Evaluation Officer, Therapeutic Products Directorate
Health Canada

Helen Leask, PhD
Founding Partner
SCRIPT

This tutorial will review Health Canada's requirements for Plain Language Labeling and will offer an opportunity to work on concrete examples and provide tips and strategies to facilitate the implementation of Health Canada's Guidance for Industry. The tutorial will also provide an opportunity to discuss/reflect on the experience gained so far and to address questions/concerns regarding the implementation.

LEARNING OBJECTIVES:

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

- Explain the principles and concepts of Plain Language Labeling
- Describe Health Canada's requirements for Plain Language Labeling
- Prepare drug label and packaging documents according to Health Canada's Guidance for Industry

Please note that lunch is not served on Tutorial Day

12:30-1:30PM **TUTORIAL REGISTRATION**

1:30-5:00PM **TUTORIAL #2: STRATEGIES FOR EFFICIENT SUBMISSION PREPARATION**

INSTRUCTORS:

Heather Cherry
A/Senior Regulatory Project Manager, Therapeutic Products Directorate
Health Canada

Kristen Zorn
Senior Regulatory Project Manager, Therapeutic Products Directorate
Health Canada

Shih-Miin Loo
Senior Regulatory Affairs Officer, Biologic and Genetic Therapies Directorate
Health Canada

Christine McRoberts
Regulatory Project Officer
Natural and Non-prescription Health Products Directorate
Health Canada

Brian Melanson
Senior Regulatory Project Manager, Natural and Non-Prescription Health Products Directorate
Health Canada

This tutorial will cover innovative and generic drugs, both prescription and non-prescription, biological drugs and radiopharmaceuticals, and natural health products, with a focus on effective tips and strategies for preparing submissions to Health Canada. Common roadblocks to an efficient submission process will be discussed, along with strategies to avoid them in future. The tutorial will comprise of an overview of these key strategies and commonly observed deficiencies for each of the product areas, followed by a question and answer session.

LEARNING OBJECTIVES:

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

- Identify common submission deficiencies and barriers to an efficient review process
- Describe how industry can improve the quality of submissions filed to Health Canada
- Apply advice from Health Canada on preparing submissions with fewer deficiencies to allow for a more efficient screening process and smoother transition into review

TUESDAY, OCTOBER 27

7:30AM-6:00PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30-8:40AM OPENING REMARKS

DIA:

Julie Y. Ho
Associate Director, Business and Market Development
DIA

PROGRAM CO-CHAIRS:

Matthew Ryan
Senior Policy Analyst
Policy, Planning and International Affairs Directorate
Health Canada

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

8:40-9:10AM KEYNOTE ADDRESS

Rare Diseases in Canada; Diagnostic Therapeutic and Regulatory Challenges

Alex Mackenzie, MD
Physician, Division of Endocrinology, Children's Hospital of Eastern Ontario (CHEO) Research Institute
Professor, Department of Pediatrics, Faculty of Medicine, University of Ottawa

Rare diseases have in the past few years emerged from the shadows into the Canada's collective consciousness. The appreciation of their overall frequency, the degree to which they are undiagnosed, and even more so untreated, has identified them as one of Canada's greatest unmet medical and societal needs. Nonetheless, the Canadian rare diseases landscape is changing in Canada with its international lead in rare disease diagnostics and recent launch of a national rare disease strategy.

The keynote presentation will review these developments and the unique therapeutic challenges facing this aggregate common problem, outlining approaches and options for moving the diagnosis and care for rare diseases forward.

9:10-10:30AM SESSION 1: PLENARY SESSION: NEW ERA OF REGULATORY AFFAIRS – PART I

SESSION CHAIR:

Matthew Ryan
Senior Policy Analyst
Policy, Planning and International Affairs Directorate
Health Canada

With the passage of Bill C-17 (Vanessa's law), the need for industry to enhance transparency of their review and evaluation of product safety profiles post launch is key. Similarly, regulators need to evaluate new data in a timely way to make critical decisions and take necessary actions. Many more changes in the pipeline such as anticipating drug shortages, a Consumer Product Framework, a new guidance for Subsequent Entry Biologics and Orphan Drugs share the need for increased transparency...all of which in turn are driving changes in how we do business, including processes, technical skills and people skills.

In this two-part plenary session, you will hear from a variety of stakeholders on how they are experiencing this new era and how they are responding to new requirements. Learn how their organizations are preparing themselves to comply with the new regulations in order to continuously improve the safety of medications and optimize the health care of Canadian patients.

SPEAKERS:

Regulatory Perspective on Openness and Transparency

Heidi Jackson
Director, Office of Transparency and Openness / Directrice
Bureau de la transparence et l'ouverture
Health Canada / Santé Canada

Industry Perspective

Andrew Casey
President and Chief Executive Officer
Biotech Canada

Patient Organization Perspective

Katharina Kovacs-Burns, PhD, MSc, MHSA
Director
Best Medicines Coalition

Panel Q&A

10:30-11:00AM **REFRESHMENT AND NETWORKING BREAK**

11:00AM-12:15PM **SESSION 2: PLENARY SESSION: NEW ERA OF REGULATORY AFFAIRS – PART II**

SESSION CHAIR:

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

With the passage of Bill C-17 (Vanessa's law), the need for industry to enhance transparency of their review and evaluation of product safety profiles post launch is key. Similarly, regulators need to evaluate new data in a timely way to make critical decisions and take necessary actions. Many more changes in the pipeline such as anticipating drug shortages, a Consumer Product Framework, a new guidance for Subsequent Entry Biologics and Orphan Drugs share the need for increased transparency...all of which in turn are driving changes in how we do business, including processes, technical skills and people skills.

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SPEAKERS:

Consumer Health Products Advocate Perspective

Kristin Willemsen
Director Scientific and Regulatory Affairs
Consumer Healthcare Products Canada

Medical Devices Perspective

Brian Lewis
President & CEO
MEDEC

Generics Perspective

Mathi Mathivanan
Director, Regulatory Affairs
Teva Canada
Vice-Chair of the Scientific Advisory Committee, CGPA

Panel Q&A

12:15-1:30PM **LUNCHEON AND NETWORKING**

1:30-3:00PM **SESSION 3: CONCURRENT TRACK BREAKOUT SESSIONS**

TRACK A - REGULATORY LEADERSHIP

The Importance of a Timely and Efficient Regulatory System and a Proposed Path for Success

SESSION CHAIR:

Rocelyn DelCarmen
Director, Regulatory Affairs
AstraZeneca, Inc.

To enable new innovations to be readily available to Canadians, a timely and efficient regulatory system is supportive. During this session, speakers from Industry and Regulatory Authorities will discuss this and offer proposals for the Canadian system to further enhance its effectiveness.

SPEAKERS:

Enhancing the Regulatory Approval Process Through Timeliness, Efficiency, and Predictability

Keith McIntosh
Executive Director, Scientific & Regulatory Affairs
Rx & D

Impact of Time to Drug Approval on Potential Years of Life Lost and The Compelling Need for Improved Trial and Regulatory Efficiency

David J. Stewart, MD, FRCPC
Head, Division of Medical Oncology
University of Ottawa/The Ottawa Hospital

John-Peter Bradford
Executive Director
Life-Saving Therapies Network

Finding Efficiencies, Continuous Improvement, Keeping up with Change

Martin McLean
Regulatory Project Manager
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada

Maxine Yu
Regulatory Project Manager, Health Products and Food Branch
Health Canada

TRACK B - LABELING AND ADVERTISING & PROMOTION

Implementation of Health Canada's Revised Guidance for Industry: Review of Drug Brand Names

SESSION CHAIRS:

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

Margaret Zimmermann
Manager – Patient Safety Section
Health Canada

On June 13, 2015, Health Canada's *Guidance for Industry: Review of Drug Brand Names* became effective. This session will walk through the revised guidance document providing information on what constitutes a brand name, brand name changes requiring an assessment, and the information to be provided to Health Canada in demonstrating the acceptability of a proposed brand name. Industry/Health Canada Perspective on the implementation of the Guidelines will be also be presented.

SPEAKERS:

Overview of the Revised Guidance

Margaret Zimmerman
Manager, Policy & Partnership
Marketed Health Products Directorate
Health Canada

Perspective from a Labeling Reviewer

Ana Nesic
Regulatory Affairs Specialist, Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Products and Food Branch
Health Canada

Implementation of the Revised Guidance

Tharany Ganesh
Senior Manager, Regulatory Affairs
AstraZeneca Canada, Inc.

TRACK C - CLINICAL PRACTICE

DIA Adaptive Design Scientific Working Group Best Practices Team: Objectives and Case Studies

SESSION CHAIRS:

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

Eva R. Miller, PhD
Senior Director, Biostatistics
inVentiv Health Clinical

Members of the DIA Adaptive Design Scientific Working Group (ADSWG) Best Practices team are senior statisticians from the FDA and industry who endeavor to identify gaps in implementation of adaptive trials, and promote the broader use of adaptive design by applying best practices. Adaptive designs have not grown to be as large a proportion of total clinical trials undertaken as advocates would have hoped. Barriers to adoption include concerns about regulatory acceptance, the time involved in planning, simulations, communications and teamwork, extra considerations for DMCs, and availability of appropriate software for planning, simulations, and implementation. In this session, representatives from the working group will summarize the committee's objectives and current practices and evolving issues related to the use of adaptive trials, and consider what went well and what was learned from a number of case studies. The speakers will share successes and best practices for adaptive designs.

Goals and Objectives of DIA ADSWG Best Practices Case Studies Subteam and Two Successful Case Studies

Eva R. Miller, PhD
Senior Director, Biostatistics
inVentiv Health Clinical

Adaptive Design Case Studies: Selecting the Best Dose and Adjusting the Sample Size in a Confirmatory Trial

Yannis Jemiai, PhD
Vice President Consulting and Software
Cytel Inc.

Health Canada Perspective of Adaptive Trial Designs

Norman Viner, MD
Chief, Clinical Trials Division, The Biologics and Genetic Therapies Directorate
Health Canada

3:00-3:30PM REFRESHMENT AND NETWORKING BREAK

3:30-5:00PM SESSION 4: CONCURRENT TRACK BREAKOUT SESSIONS

TRACK A - TRANSPARENCY AND OVERSIGHT

Premarket Transparency in the Review of Health Products

SESSION CHAIR:

Maggie Graham
Senior Policy Analyst
Natural and Non-Prescription Health Product Directorate
Health Canada

Regulators are becoming more open and transparent about the decisions they are taking and the information that is made publicly available. This session will provide an overview of Health Canada's premarket transparency initiatives as it relates to in the evaluation of health products, impacts to patient safety, and the industry perspective.

SPEAKERS:

Submissions Under Review and Regulatory Decision Summaries: Premarket Transparency in the Health Products and Food Branch

Laura Johnson
Project Manager
Health Canada

Impact of Transparency Initiatives

Laurie Proulx
Steering Committee Member
Canadian Arthritis Patient Alliance

Retrospective Analysis of Health Canada's Summary Basis of Decisions Database

Mukesh Kumar
Regulatory Affairs Associate
Regxia, Inc.
Humber-RAC Group

TRACK B - REGULATORY INFORMATION AND DATA STANDARDS

Recent Trends in Regulatory Information Standards

SESSION CHAIR:

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

From the eCTD to structured content, the pharmaceutical industry depends on massive amounts of critical data to ensure patient safety and regulatory compliance. The management and use of these data is crucial in ensuring that Health Canada meets its obligations to the Canadian population and can either enhance or hinder a firm's ability to maintain compliance. This session will overview the recent trends in regulatory information standards and the challenges faced by the regulator and the industry in the collection and maintenance of these data.

SPEAKERS:

Regulatory Enrollment Process

Vianney Caron
Manager, Electronic Regulatory Activities
Health Canada

Structured Content

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

Regulatory Information Management – An Industry Perspective

Craig Anderson
Co-Chair Group on Electronic Regulatory Activities (GERA)
Pharmaceutical Regulatory Operations Consultant

TRACK C - PHARMACOVIGILANCE AND RISK MANAGEMENT

Safety Surveillance of Scientific Literature for Medical Devices, Drugs, and Combination Products

SESSION CHAIR:

Ljubica Ivanisevic
Scientific Evaluator
Health Canada

The session will discuss approaches and methodologies used to screen scientific literature in order to enhance the ability to identify important safety signals. Representatives from Health Canada and Industry will discuss specific methods used/challenges/pitfalls with regards to safety surveillance of medical devices, drugs and combination products.

SPEAKERS:

Safety Surveillance of Scientific Literature Related to Combination Products

Robert F. Reder, MD
Senior Medical Director
Abbvie

ABSTRACT CO-AUTHORS (NOT PRESENTING):
Khaudeja Bano, Abbvie
Shelly Naylor, Abbvie

Health Canada Approach to Safety Signal Detection through the Scientific Literature for Medical Devices

Rana Filfil, PhD
Senior Scientific Evaluator, Marketed Health Products Directorate
Health Canada

Health Canada Approach to Safety Signal Detection through the Scientific Literature for Pharmaceutical Products

David Duguay, PhD
Scientific Evaluator, Marketed Health Products Directorate
Health Canada

5:00-6:00PM NETWORKING RECEPTION

WEDNESDAY, OCTOBER 28

7:30AM-12:00PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30AM-10:00AM **SESSION 5: CONCURRENT TRACK BREAKOUT SESSIONS**

TRACK A - REGULATORY LEADERSHIP

Challenges with Increasingly Smaller and Specific Patient Populations in Oncology

SESSION CHAIR:

Vratislav Hadrava
Vice President and Medical Director
Global Innovative Products
Pfizer Canada, Inc.

Development of new generations of innovative medicines is focusing on more and more specific molecular targets and on more and more specific patient populations. It is particularly evident in Oncology with increasingly specific and narrowed lines of therapies. The challenges associated with this trend are not dissimilar from those in rare disease and personalized medicine areas. In this session we will hear how regulators, industry and clinicians/researchers are seeing these challenges and their possible solutions.

SPEAKERS:

Health Canada Perspective

Kelly Robinson
Acting Director, Bureau of Metabolism, Oncology and Reproductive Sciences
Health Canada

Health Technology Assessment (HTA) Perspective

Mona Sabharwal
Executive Director
pCODR (pan-Canadian Oncology Drug Review) at CADTH

Industry Perspective

Christine Mormont, PhD
Director, Medical Affairs - Oncology
Merck Canada Inc.

TRACK B - REGULATORY INFORMATION AND DATA STANDARDS

Regulatory Information and Data Standards for Improved Health Product Safety

SESSION CHAIR:

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceutical

Information transparency is becoming ever important to improve drug quality to the benefit of the patients. This session will explore various approaches and regulatory programs for harmonizing and utilizing regulatory information management to increase data transparency, quality, safety surveillance, and risk management throughout the product life cycle of medicinal products and specialized product lines.

SPEAKERS:

Health Canada's Harmonized Approach to Biological Health Product Safety: Blood, Blood Products and Cells, Tissues and Organs

Bruce Gordon
Senior Scientific Evaluator
Health Canada

The EMA, Transparency and Product Safety – Has This Helped the Individual Patient?

Miranda Dollen
Vice President, Pharmacovigilance
Mapi Group
EEA Qualified Person for Pharmacovigilance

Increase RIM's Information Transparency Via the 'Single Place of Truth'

Olaf Schoepke, PhD
Director of Strategic Development
Samarind Ltd.

TRACK C - SCIENCE, QUALITY, AND GOOD MANUFACTURING PRACTICES

Good Manufacturing Practices: Compliance Trends and Initiatives

SESSION CHAIR:

Maggie Graham
Senior Policy Analyst
Natural and Non-Prescription Health Product Directorate
Health Canada

Over the last several years, the drug manufacturing industry, like many others, has evolved a complex, networked approach to manufacturing. Recent trends and transparency initiatives related to inspections will be discussed from the regulator and industry perspective.

SPEAKERS:

Compliance and Enforcement Trends and Initiatives

Sara O'Connor
Director, Office of Business Transformation
Health Canada

Daniel McLean
Senior Policy Advisor
Health Canada

Industry Perspective

Sandra Usik
Associate Director
Reg. Affairs, Quality & Compliance
Eli Lilly Canada, Inc.

10:00-10:30AM **REFRESHMENT AND NETWORKING BREAK**

10:30AM-12:00PM SESSION 6: CONCURRENT TRACK BREAKOUT SESSIONS

TRACK A - TRANSPARENCY AND OVERSIGHT

Postmarket Transparency for Health Products

SESSION CHAIR:

Maggie Graham
Senior Policy Analyst
Natural and Non-Prescription Health Product Directorate
Health Canada

Over time, there is a progression in the knowledge about a health product. Regulators are using this knowledge to inform post-market work that considers the full life cycle of a health product. This session will provide an overview of Health Canada's post-market transparency initiatives as it relates to post-market review of health products and an industry perspective.

SPEAKERS:

Postmarket Transparency

Denis Mulhall
Executive Director, Information Management and Technology, Health Products and Food Branch
Health Canada

Postmarket Transparency

Matthew Bown
Associate Director, Marketed Health Products Directorate
Health Canada

Industry Perspective

Anne Tomalin, RAC
President
Therapeutic Products Inc.

TRACK B - LABELING AND ADVERTISING & PROMOTION

The Product Monograph Project

SESSION CHAIR:

Vratislav Hadrava
Vice President and Medical Director
Global Innovative Products
Pfizer Canada, Inc.

This session will provide an overview of the ongoing review of the Product Monograph content and format including areas of the monograph under examination and proposals for a new format. This session will also provide insight from two stakeholders who contributed to the consultation phase of this project, PAAB and the industry as discussed within an Rx&D sub-committee. Rx&D will provide insights into the critical importance of the Product Monograph, efforts made to ensure the accuracy and international consistency of the content, and the industry perspective on recent Health Canada proposals affecting the Product Monograph. PAAB will speak to the implications of the various proposed changes to the Product Monograph, including the streamlined referencing process, and how they could affect the review process for advertising drugs.

SPEAKERS:

The Health Canada Product Monograph Project

Madeleine Marshall
Manager, Policy Division, Bureau of Policy, Science and International Programs, Health Products and Food Branch
Health Canada

Overview of Industry Comments on the Product Monograph

Sandra Wainwright
Director, Regulatory Affairs
Merck Canada Inc.

Implications For Advertising And Promotions Campaigns Based On The Proposed Product Monograph Changes

Jennifer Carroll
Reviewer/Training
Pharmaceutical Advertising Advisory Board (PAAB)

TRACK C - PHARMACOVIGILANCE AND RISK MANAGEMENT

Pharmacovigilance Systems/Models and eReporting

SESSION CHAIR:

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceutical

The session will discuss different pharmacovigilance systems/models used by the industry for the continuous monitoring of therapeutic health products. The session will also include an update from Health Canada and a Q&A on eReporting.

SPEAKERS:

Designing a Pharmacovigilance System - Options and Strategies

Miranda Dollen
Vice President, Pharmacovigilance
Mapi Group
EEA Qualified Person for Pharmacovigilance

A Look at a Hybrid Pharmacovigilance System

Diana Basmadjian
Associate Director, Pharmacovigilance and Medical Information
Sanofi Aventis

Q&A: eReporting

Mary Raphael
Acting Director, Marketed Health Products Safety and Effectiveness information Bureau
Health Canada

Valerie Bergeron
Adverse Reaction Terminology Specialist
Marketed Health Products Directorate
Health Canada

12:00-1:30PM LUNCHEON AND NETWORKING

1:30-3:00PM **SESSION 7: PLENARY SESSION: INTERNATIONAL UPDATE**

SESSION CHAIR:

Louise Déry
Director, Policy, Planning and International Affairs Directorate
Health Canada

In this session, we will reflect on some of the gains made in Canada, with respect to advancement in clinical research investment, and will discuss future opportunities to make Canada more competitive in the areas of research, investment, and innovation within the international arena.

A representative from Health Canada will also discuss Canada's involvement with ICH, highlighting new updates, governance, guidance, and future projects.

The meeting will close with remarks from the Deputy Minister of Health at Health Canada.

SPEAKERS:

Advancement in Clinical Research Investment and Future Innovation in Canada

Ed Dybka
President
AstraZeneca Canada

ICH Updates

Celia Lourenco, PhD
Director of Bureau of Gastroenterology Infection and Viral Diseases
Therapeutic Products Directorate
Health Canada

Update from the Australian Therapeutic Goods Administration (TGA)

Diane Wilkinson
Assistant Director
Regulatory Reform and Coordination Section
Complementary Medicines Branch
Australian Therapeutic Goods Administration (TGA)

Closing Remarks

Simon Kennedy
Deputy Minister of Health
Health Canada

3:00PM **MEETING ADJOURNS**

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