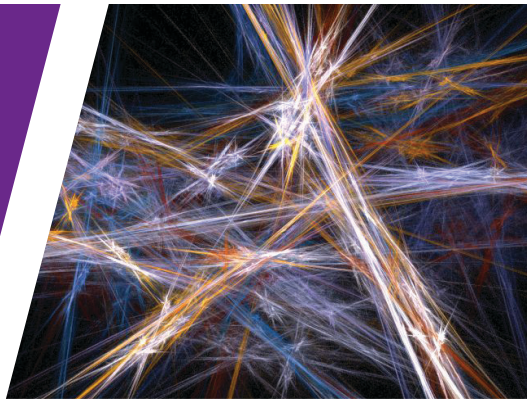
DIA's Annual Canadian Meeting: New Realities/New Frontiers

Tutorials: October 28 | Meeting: October 29–30

Ottawa, Ontario, Canada



PROGRAM CO-CHAIRS

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

Matthew Ryan
Senior Advisor, Director General's Office,
Therapeutic Product's Directorate HPFB
Health Canada

PROGRAM COMMITTEE

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AstraZeneca Inc.

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Redstone Health Group, Inc.

Stephen Li
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Paul Litowitz
Associate Director, Bureau of Metabolism, Oncology and Reproductive Sciences Therapeutic Products Directorate, HPFB
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Co Pham
Scientific Manager, HPFB
Health Canada

Andrew Storey
Vice President,
Regulatory Affairs, US/Canada
AbbVie

OVERVIEW

Today's patient reality is driving change in drug development and regulations. Drug companies are exploring new technologies bringing to the forefront modern novel products revolutionizing the global and local approach to medicine. Widespread advancements in areas of personalized medicines and cell therapies, promising patient benefits, are being studied. Additionally, a number of blockbuster drugs' patents are expiring allowing for the introduction of generic drugs and subsequent entry biologics. This places an increased importance on driving pipelines forward in an efficient manner taking into consideration the ever changing regulatory environment. This has driven innovative development that can address critical disease areas, and will ultimately maximize benefits to patients. In line with New Realities, Heath Canada continues to modernize activities including a new pathway for initiatives such as the authorization of drugs for rare diseases. There is recognition of the need to provide the patient and the health care professionals with increased accessibility to drug information and comprehension of drug labels. This meeting will explore how patients, health care professionals, industry and the regulator continue to evolve and liaise. Through this continuous evolution, the need to embrace changes to drug development, regulatory requirements, encourage global collaborations and transparency while placing patient safety and greater access to efficacious drugs at the forefront.

TARGET AUDIENCE

Professionals involved in:

- Regulatory Affairs
- Policy/Pharmacoeconomics
- Clinical Development
- Drug Safety/Pharmacovigilance
- Patient Safety
- Medical Communications
- Quality Operations

LEARNING OBJECTIVES

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

- Describe the current regulatory environment
- Recognize the challenges faced by industry and regulators in the drug development, market access, and in the regulation in Canada
- Identify new ways of thinking about worldwide advancements in patient benefits and implementing them for Canada
- Discuss the evolution of drug development and regulatory requirements while encouraging global collaboration
- Explain the need to provide patient and health care professionals with increased accessibility to drug information in order to make informed decisions

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- Tutorial 1: The Emerging PV Landscape in Canada: .3 IACET CEUs
- Tutorial 2: Trends in Health Canada Inspections: .3 IACET CEUs
- DIA Canadian Annual Meeting 2013: New Realities/New Frontiers: 1.2 IACET CEUs

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- Clinical Safety and Pharmacovigilance: 4 Elective Units
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TUTORIALS | **MONDAY, OCTOBER 28**

11:00 AM – 1:30 PM TUTORIAL REGISTRATION

1:30 – 5:00 PM TUTORIAL #1

The Emerging PV Landscape in Canada

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

This tutorial will focus on four emerging areas of change in pharmacovigilance (PV) and present them within a Canadian context. The first area deals with the new good pharmacovigilance practice (GVP) Inspection guidelines and policy that have been released by Health Canada and become effective September, 2013. Areas of change from previous inspection model will be highlighted.

The second area in this tutorial will focus on the recently announced acceptability of Periodic Benefit Risk Evaluation Reports (PBRERs) to meet the requirements for Canadian Summary reports in Canada. Focus will be on how these reports differ from PSURs and how to begin to develop these new format reports for Canadian submission.

The third emerging area of change that will be reviewed is the development of the PV Master File, a new concept recently introduced by Europe, and the associated PV Quality System. We will review how to set up a PV Master File in Canadian context and how to set up a robust PV Quality System. Discussion will focus on implementing the Master file concept and maintaining it over time. We will discuss the benefits of moving in this direction for Canada only and within the context of a global PV environment.

The fourth area will overview the Risk Management Plans (RMPs) in Canada, their current status and general considerations when submitting them, background on Drug Utilization Research and describe Health Canada expectations when designing them, and applied overview of some common Health Canada Risk Management Plan review comments will be provided.

Rita Cassola, B.Pharm. Hons.
Senior Director, Pharmacovigilance
OptumInsight

Blair MacKenzie
Senior Compliance Officer
Compliance and Enforcement Inspectorate Program
Prairie Region – Alberta
Health Canada

Rania Mouchantaf
Scientific Evaluator
Health Canada

TARGET AUDIENCE:

Pharmacovigilance, Medical Information and Regulatory staff interested in meeting the new PV challenges developing globally. QA, Medical and Clinical Research staff will also find this of interest as there are areas that touch on these discipline areas. Those in Project Management, General Management and Marketing will obtain a good understanding of the ongoing changes within the PV environment and how they impact industry.

TUTORIAL OBJECTIVES:

At the conclusion of this tutorial, participants should be able to:
- Explain the changes in the new GVP Inspection process and the expectations that come with these changes
- Describe how the new Periodic Benefit Risk Evaluation Report (PBRER) will replace the PSUR (Periodic Safety Update Report) and if it meets or does not meet the Canadian requirements for an Annual Summary Report
- Discuss the use of the Pharmacovigilance Master File and how to build a file moving forward
- Discuss the status, design and expectations regarding Risk Management Plans in Canada.

1:30 – 5:00 PM TUTORIAL #2

Trends in Health Canada Inspections

Rocelyn DelCarmen
Director,
Regulatory Affairs and Quality Assurance
AstraZeneca, Inc.

This tutorial will focus on recent trends in Health Canada Inspections from the perspective of the Inspectorate and the Industry it regulates.

Following an overview of the Inspectorate and the inspection strategy for drugs, biologics and medical devices, the Inspectorate and Industry will discuss emerging trends.

For GMP and medical devices inspections, the Inspectorate will present a summary of top observations, including examples on GMP, medical devices and clinical trial inspections. Industry speakers will discuss how recent Inspection observations have changed their operational practices in Canada and globally.

Additionally, HPFBI will provide Industry with advice on areas considered "grey space".

Julie Calendino
Senior Corporate Regulatory Compliance and Enforcement Advisor, Medical Device Compliance
Health Canada

Linda Jack, PhD
Director, Regulatory Affairs and Quality Management
Group Leader PDR
US Marketed Products
Hoffmann-LaRoche Limited

Andrei Baume
Senior Compliance Specialist
Drug GMP Inspection Unit
HPFB Inspectorate
Health Canada

TARGET AUDIENCE:

Professionals involved with leading and participating in Health Canada inspections, e.g. Quality Assurance, Quality Compliance, Quality Operations, Supply Management and Regulatory Affairs. Professionals with an interest in quality system frameworks for drugs and medical devices in Canada. Those in Project Management and General Management can get an understanding of the recent trends within the GMP environment and how they can impact Industry operational aspects.

TUTORIAL OBJECTIVES:

At the conclusion of this tutorial, participants should be able to:
- Discuss the HPFBI's current mandate and operations for GMP oversight in the areas of drugs, biologics and medical devices manufacturing, importing and distribution
- Describe how Industry should prepare for drug and medical device inspections by gaining knowledge of recent inspection findings and issues and how some companies have adapted operations to respond
- Apply advice from the Inspectorate on managing topics that drug and medical device manufacturers, importers and distributors seek clarity on drugs, biologics and medical devices.

4:00 – 5:00 PM MEETING REGISTRATION

MEETING DAY 1 | **TUESDAY, OCTOBER 29**

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 8:45 AM OPENING REMARKS

8:45 – 9:00 AM WELCOME

Welcome Speaker:

Kathryn McDade
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

9:00 – 10:30 PM PLENARY SESSION 1

International Regulatory Cooperation: Trends and Impacts

Co-Chairs:

Matthew Ryan
Senior Advisor, Director General's Office, Therapeutic Product's Directorate HPFB, Health Canada

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

Hear from key leaders from international regulators on current trends, activities and the future of collaboration amongst key agencies. International cooperation is having a shifting impact on public policy and drug regulation, and will continue to shape and impact agency activities. Learn about these key initiatives, where agencies are focusing their activities and how interagency collaboration is evolving now and into the future. Attendees will hear about the impacts of these new realities of international regulatory cooperation and what this means for key stakeholders in the development and regulation of health products.

Speaker:

Health Canada Perspective

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

EMA Perspective

Sabine Haubenrisser, MSC, PhD
Liaison Official at the FDA
International and European Cooperation
EMA European Medicine Agency

Embedment of Health Canada National Visiting Expert (NVE) in Pharmacovigilance at European Medicines Agency - Pilot Project (Via Video Communications)

Christopher Turner, MD FRCPC
Health Canada National Visiting Expert (NVE)
Health Canada

10:30 – 11:00 AM REFRESHMENT BREAK IN THE EXHIBIT AREA

11:00 AM – 12:30 PM PLENARY SESSION 2

Stakeholder Perspective

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

Matthew Ryan
Senior Advisor, Director General's Office, Therapeutic Product's Directorate HPFB, Health Canada

In today's reality, companies are doing business internationally. While they are seeking to bring their products to global markets with unified research and development approach, they are facing national laws and diversified regulations and requirements in both the R&D phase as well as in the post approval surveillance and commercialization phase. After the regulator's perspective, this plenary session will provide an opportunity for industry representatives from different businesses to brief the audience on the involvement of stakeholders in the regulatory harmonization process, on challenges and opportunities, and how it may impact their future.

Regulatory Harmonisation - Industry Perspective

Peter Honig, MD, MP
Head Global Regulatory Affairs
Patient Safety and Quality Assurance
AstraZeneca

International Regulatory Cooperation: Trends and Impacts for Academic Sponsors

Alison Urton
Investigational New Drug Program
& Audit and Monitoring Group
NCIC Clinical Trials Group
Professor, Department of Oncology
Queens University

A Survivor's Story

Norma Beauchamp
Breast and Thyroid Cancer
Patient Advocate

12:30 – 1:30 PM LUNCHEON

1:30 – 3:00 PM SESSION 3

TRACK 1 - NEW FRONTIERS

Harmonizing in the Post-Approval Pharmacovigilance: Challenges and Opportunities

Session Chairperson

Vratislav Hadrava
Director, Regulatory Affairs
Pfizer

Pharmacovigilance is a rapidly evolving and increasingly global field. Government and Industry are often criticised for taking action in one jurisdiction not always harmonized to action in another. With the near instantaneous dissemination of information and the different global regulatory practices with respect to risk management, the regulators and the pharmaceutical industry are faced with challenges in trying to find the best way to manage risk while at the same time meeting expectations from various stakeholders. This session will provide the perspective of Health Canada, Industry and other stakeholders to provide understanding and appreciation of the current practices, consumers' expectations, challenges and opportunities for change. The expectations of global harmonisation will also be explored.

Challenges and Opportunities in Post Market Pharmacovigilance - A Canadian Perspective
Melissa Hunt
Scientific Manager
Health Canada

Context Matters
Dianne Azzarello
Senior Director, Pharmacovigilence and Regulatory Affairs
Celgene, Inc.

Harmonizing in the Post-Approval Pharmacovigilance: Challenges and Opportunities
Yola Moride, PhD, FISPE
Associate Professor, Faculty of Pharmacy
Universite de Montreal

TRACK 2 - COMMUNICATIONS

Social Media

Session Chairperson

Deirdre Cozier
Manager, Regulatory Operations, Policy & Intelligence
sanofi-aventis, Inc.

The increasing popularity of social media networks is changing consumer behavior. An entire generation now communicates via tweets, pins and IMs. Consumer endorsement has a powerful, and near instantaneous, effect on company strategy. This has required the business community to adapt to this technology and engage their customers in more personal and virtual ways. In an industry as tightly regulated as pharmaceuticals, the use of social media platforms to engage, inform and promote raises some unique challenges. This session will explore the uses of social media both from an industry and regulator perspective. From R&D, to internal collaboration and compliance considerations, the 3 speakers will share best practices and provide valuable tips to ensure that your use of social media platforms is successful.

Harnessing Power of SMAC (Social Media, Mobility, Analytics and Cloud) to Drive Transformation in Clinical R&D
Susant Mallick
Head, Clinical Standards and Analytics, Center of Excellence in Life Sciences
Cognizant Technology Solutions Corporation

Social Media as Health Communication Tools in Canada
Brenda M. Gryfe
Director, Canadian Regulatory Affairs
Optuminsight, Inc.

Regulatory Considerations of Using Social Media
Alain Musende, PhD
Head, Regulatory Advertising Unit
Health Canada

TRACK 3 - NEW REALITIES

Regulatory-Driven Research Networks: A New Frontier in Pharmacovigilance Worldwide

Session Chairperson

Co Pham
Scientific Manager, HPFB
Health Canada

Finding solutions for public health problems and optimizing patient's wellness is impacting the development of drugs as well as their post approval surveillance. From translational medicine bringing research scientists and industry together, to research networks responding to the need for real-world knowledge about drug safety and effectiveness, this session will explore how real world settings are impacting regulatory decision making and undertaking high quality post-market research.

Importance of Real-World Drug Safety & Effectiveness Research to Regulatory Decision-Making in Postmarket
Scott Sawler
Director General, MHPD
Health Canada

Update on the Drug Safety and Effectiveness Network Post-Implementation
Robert Peterson
Executive Director, DSEN
Canadian Institute of Health Research (CIHR)

Knowledge Translation / Translational Medicine
Sharon Strauss, MD MSc FRCPC
Division Director, Geriatric Medicine; Professor
University of Toronto

3:00 – 3:30 PM REFRESHMENT BREAK IN THE EXHIBIT AREA

3:30 – 5:00 PM SESSION 4

TRACK 1 - NEW FRONTIERS

Update on ICH: What you Need to Know

Session Chairperson

Andrew Storey
Vice President
Regulatory Affairs, US/Canada
AbbVie

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved to respond to the increasingly global face of drug development, so that the benefits of international harmonization for better global health can be realized worldwide. From CTD to MedDRA to the many Quality guidelines now available, there has been significant revolution as a result of the organization's output. ICH has been particularly prolific of late producing some key and much anticipated documents that will have a major impact on regulators and industry.

During this session, a panel will review some of the key developments and publications, the involvement of Health Canada, and some of the changes contemplated for ICH as it assesses new ways to add even more value in future.

International Conference on Harmonization – Updates on Health Canada's Involvement
Mike Ward
Manager, International Programs Division
Health Canada

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

RMPs
Rania Mouchantaf
Scientific Evaluator
Health Canada

PBRERs
Vicky Hogan
Director, Office of Risk Management and Science, M H P D
Health Canada

Industry Perspective
Sarah Frise
Director Patient Safety &
Medical Information
Astrazeneca

TRACK 2 - COMMUNICATIONS

Support Programs: The Pursuit of Patient Advocacy

Session Chairperson

Karen Feltmate
President
Redstone Health Group, Inc.

Patient support programs have been around in one form or another for many years. However with a significant number of molecules going off patent and the complexity of some of the new medications be they drug, device or a combination drug/device, manufacturers are turning to these programs with increasing attention. This session will explore what drivers prompt new programs, their format and their deliverables. We will hear what are best practices, what factors need to be considered and monitored and even some of the pitfalls that can be avoided. Finally, we will also hear the patients' perspective on whether these programs are value added – or not.

Patient Support Programs: Safety Reporting and Other Regulatory Considerations
Diana Basmadjian
Associate Director
Sanofi

Leveraging the Patient Journey: Why it Matters
Grace Soyao
Founder & Chief Executive Officer
Self Care Catalysts, Inc.

Patient Support Programs: Is there a magic bullet?
Susanne Cookson
President
Cookson James Loyalty

TRACK 3 - NEW REALITIES

An Update on the Legislative and Regulatory Modernization Initiative

Session Chairperson

Rocelyn DelCarmen
Director, Regulatory Affairs and Quality Assurance
AstraZeneca, Inc.

Hear an update from Health Canada's Office of Legislative and Regulatory Modernization on the status of the regulatory roadmap activities. Get Health Canada and Industry's insight about topics that will likely be addressed as the next phase of the roadmap is tackled, including topics such as product classification (e.g. Drug vs OTC vs NHP) and the resetting of Divisions 1 and 8 of the FDA & R.

Priorities for Upcoming LRM initiatives - the Perspective of Consumer Health Products Manufacturers
Anuradha Rao HBSc, MSc
Scientific and Regulatory Affairs Officer
Consumer Health Products, Canada

Update on Regulatory Modernization in HPFB
Barbara Wong
Senior Policy Analyst
Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Health Canada

Priorities for upcoming LRM initiatives – the Perspective of Multi-national innovative Pharmaceutical Companies
Loretta Del Bosco
Director, Regulatory Affairs and Quality Assurance Operations
AbbVie Corporation

5:00 – 6:00 PM NETWORKING RECEPTION

MEETING DAY 2 | **WEDNESDAY, OCTOBER 30**

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 10:00 AM SESSION 5

TRACK 1 - NEW FRONTIERS

IT Modernization

Session Chairperson

Paul Litowitz
Associate Director, Bureau of Metabolism, Oncology and Reproductive Sciences, Therapeutic Products Directorate, HPFB
Health Canada

This session will present the overall features of IT modernization in the areas of HC website, e signature and the electronic Gateway for Market Authorization Holders and Clinical Trial Sponsors. Discussion will focus on the objectives achieved so far and the challenges of modernization moving ahead for regulators and impact on the industry.

A goal of collaboration for Health Canada and the FDA is to better align regulatory systems, reduce unnecessary duplication's and differences, and to the extent feasible, better leverage technologies and resources to help both agencies meet public health missions within the parameters allowed by prevailing laws and regulations subject to available human and financial resources. This session aims to provide updates in regard to the implementation of an electronic platform to support the review process, the implementation of the common electronic submission gateway as well as discussion in regard to industry's adoption of digital identities and SAFE signatures.

Update on eSubmisions at Health Canada
Vianney Caron
Manager Electronic Regulatory Activities
T PD, Health Canada

FDA Electronic Gateway
Michael Fauntleroy
Program Manager, CBER, FDA

Health Canada and US FDA Common Electronic Submission Gateway
Vikesh Srivastava
Associate Director, Business Informatics Resource, Health Canada

Adoption of Digital Identities
Janet McDougall, MSc,
President, McDougall Scientific

TRACK 2 - COMMUNICATIONS

Plain Language Labeling in the Regulatory System: Consumer- and Patient- Centered Information

Session Chairperson

Vratislav Hadrava
Director, Regulatory Affairs
Pfizer

The Plain Language Labeling initiative is a part of the Canadian Regulatory Modernization. Its main objectives are improving safe and effective use of medicines, reducing preventable medication errors and supporting Canadians in making informed choices about their medications/ health products. The labels also represent the key interface between the Canadian consumers and patients at one hand and Health Canada and the Manufacturers at the other hand. System wide collaboration is key to the success of this initiative. This session will review the key elements of the ongoing projects, explore their alignment with the needs of the Canadian public and other regulatory jurisdictions, and provide perspective of the Consumers/Patients, Health Canada and Industry.

Medication Incidents and Plain Language Labeling
Sylvia Hyland, RPh
Vice President and
Chief Operating Officer
Institute for Safe Medication Practices Canada (ISMP Canada)
Partner in the Canadian Medication Incident Reporting and Prevention System

Plain Language Labeling for Consumer Health Products
Robert White, CAE, MSc, MBA
Director of Scientific and Regulatory Affairs
Consumer Health Products Canada

Update: Plain Language Labeling
Madeleine Marshall
Unit Manager
Health Canada, TPD
Policy Division

TRACK 3 - NEW REALITIES

Managing Drug Shortages

Session Chairperson

Sandra Alderdice
Regulatory Affairs Supervisor, Office of Regulatory Affairs, BGTD
Health Canada

The management of a drug shortage involves collaborative efforts by multiple stakeholders and authorities to minimize patient impact. This session will explore how drug shortages across Canada are managed. It will provide an overview of significant global regulatory and legislative developments shaping supply chain management. It will consider how drug shortages can be avoided by monitoring real compliance data and increasing organizational communication. Finally, this session will look at public health issues involving shortages and illustrate a case example highlighting how the Public Health Agency of Canada, Health Canada and manufacturers around the world worked together to find alternative products.

Managing Drug Shortages by Monitoring Real Compliance Data: Global Developments Affecting Drug Supply Chains
Mujadala Abdul-Majid
Senior Regulatory Analyst
3E Company

Addressing Drug Shortages in Canada
Etienne Ouimette
Director, Strategic Horizontal Policy Division
Health Canada

Drug Shortages and Public Health : A Case Study of BCG Vaccine
Cathy Parker
Acting Senior Executive Director, BGTD
Health Canada

10:00 – 10:30 AM REFRESHMENT BREAK

10:30 AM – 12:00 PM SESSION 6

TRACK 1 - NEW FRONTIERS

New Business Models

Session Co-Chairpersons

Geoffrey Saroea
Senior Medical Affairs Advisor
Novartis Consumer Health

Chanez Kebache
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

Drug development used to have a fairly predictable timeline and process. This is not true today. The increasing cost of drug development has spawned new business partnerships/mergers to help carry the cost and lower the burden and risk of failure. Indeed, drugs themselves are being combined with devices and as well available in various patient selection tests. This session will review how industry and regulators are managing the regulatory complexities of these new development models. The speakers will provide insight from their experience in working through these new models and highlight key learnings.

Critical Path to Ensure Regulatory Compliance During Merger & Acquisitions
Silvia Mamber
Pharmacovigilance Manager
Valeant

Companion Diagnostics in Canada: Regulatory Considerations
Katherine M. Soltys M.D.
Manager, Oncology Division Bureau of Metabolism, Oncology & Reproductive SciencesTherapeutic Products Directorate
Health Canada

Drug-Device Combinations- Regulatory and Other Considerations
Mary C. Speagle
Executive Director
Canadian Regulatory Affairs
OptumInsight

TRACK 2 - COMMUNICATIONS

Making Clinical Trial Information More Available: Why..What.. and How?

Session Chairperson

Paul Litowitz
Associate Director, Bureau of Metabolism, Oncology and Reproductive Sciences, Therapeutic Products Directorate, HPFB
Health Canada

Making clinical trial information publicly accessible in registries has been identified as a key means of enhancing transparency. Various organizations, domestic and international, are currently engaged in initiatives to encourage or require registration and disclosure of clinical trial information. Regulators, industry, industry associations, medical journals, public funding agencies, patient groups and the World Health Organization (WHO) have all initiated efforts to promote transparency of clinical trials. Currently, there is no formal consensus on international norms and standards for reporting the findings of clinical trials. Clinical trial medical informatics aims to achieve the best possible support of patient care and outcome by acquiring, generating and sharing ongoing in trial information.

Saving Lives and Reducing Waste: Update on Sharing of Clinical Trial Information
An-Wen Chan
Assistant Professor and Phelan Scientist WCRI
University of Toronto, Women's College Hospital

New Clinical Trial Data Base
Joel Raymond
Manager, Office of Clinical Trials
Health Canada

Clinical Trials Information at the Research Centre Level
Andrew Arnold MBBS, FRCPC, MRCP
Escarpment Cancer Research Institute
Professor, Department of Oncology
McMaster University
Head of Clinical Trials
Juravinski Cancer Centre

TRACK 3 - NEW REALITIES

Cool Tools in Medical Devices

Session Chairperson

Carolyne Desrosiers
Manager, Regulatory Projects
Lundbeck, Inc.

The term *medical device* covers a vast range of equipment, from simple tongue depressors to haemodialysis machines. Like medicines and other health technologies, they are essential for patient care.

On the global front, the International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.

In Canada, the booming mobile app economy is quickly expanding into the health industry. There's a growing list of health-oriented apps and sensors that regular individuals can buy, from pedometers and heart-rate monitoring apps to general wellness-tracking apps. We're getting medically wired both at the professional and consumer end and the regulation of these medical devices is a vast and rapidly evolving field.

International Medical Device Regulations Forum - Update
Nancy Shadeed
Special Advisor
International Programs Division
Health Canada

Software Regulated as a Medical Device
Colin Foster
Regulatory Information Officer
Health Canada

Monitoring your Health "There is no place like home"
Nicholas Zamora, BSc, MBA, CHE
Chief Clinical Advisor
TELUS Health

12:00 – 1:00 PM LUNCHEON

1:00 – 2:30 PM PLENARY SESSION 7

It's BIG and It's Coming

Karen Feltmate
President
Redstone Health Group, Inc.

Matthew Ryan
Senior Advisor, Director General's Office, Therapeutic Product's Directorate HPFB, Health Canada

This is a session you will not want to miss! Qualified speakers will address imminent significant changes for industry and regulators alike. Topics such as strategic risk management, Class Action Law Suits and patient Home Care/ Palliative Care will be presented with key insights on how and when their impact will be made.

Class Action Law Suits

Jill Daley
Associate
Norton Rose Fulbright Canada LLP

Randy Sutton
Associate
Norton Rose Fulbright Canada LLP

Patient Home Care/Palliative Care

Jeff Myers, MD, MSEd, CCFP
W. Gifford Jones Professor in Palliative Care
Head and Associate Professor – Division of Palliative Care
Department of Family and Community Medicine
University of Toronto
Head – Palliative Care Consult Team
Sunnybrook Health Sciences Centre

The Future of Risk Governance

Supriya Sharma, MD, MPH, FRCPC
Senior Medical Advisor
Assistant Deputy Minister's Office
Health Products and Food Branch
Health Canada

2:30 – 3:00 PM WRAP-UP

3:00 PM MEETING ADJOURNED

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