5th Canadian Annual Meeting
Blueprint for an Evolving Regulatory Environment for Pharmaceuticals in Canada

Tutorials: October 28, 2007
Conference: October 29 – 30, 2007 | **Ottawa Congress Centre, Ottawa, Ontario, Canada**

Issues of Interest Facing Health Canada, the Pharmaceutical Industry, Health Academia, and the Health Care System

PROGRAM CHAIRS

Rav Kumar, PhD
Vice President, Regulatory and Development Operations
GlaxoSmithKline Canada

Supriya Sharma, MD, MPH, FRCPC
Director General
Therapeutic Products Directorate
Health Canada

PROGRAM COMMITTEE

Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Services Bureau, Marketed Health Products Directorate, Health Canada

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Vice President, Product Development
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Associate Director, Office of Clinical Trials
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David Krakovsky, BScPhM, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline, Inc., Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate, Health Canada

Anne Tomalin
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Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Canada

PROGRAM ADVISORS

Agnes V. Klein, MD
Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Canada

Mohammed Razdar Khan
Director
Synergex Consulting, Canada

OVERVIEW

DIA's 5th Canadian Annual Meeting will cover a number of important issues facing Health Canada, the Pharmaceutical Industry, Health Academia and the Health Care System. These include: Health Canada's proposed new Life Cycle approach to the regulation of drug products – "Progressive Licensing Framework," as well as Risk Management and Safety Signal Detection. The meeting will also cover Sustainability of Canada's Healthcare System and Public demand for more information and greater transparency. As electronic information flow continues to increase, application of technology to the development and regulation of pharmaceutical products, e.g., eCTD will also be discussed.

REGULATORY AFFAIRS/CLINICAL TRIALS

SAFETY/PHARMACOVIGILANCE

SCIENCE AND TECHNOLOGY

TUTORIALS

Sunday, October 28, 1:30-5:00 PM *(See page 3 for details. Register on page 10.)*

#1 Preparing a Complete Quality Overall Summary (QOS) and Quality Module

#2 Practical Aspects of eCTD Preparation – From Efficient Content Development to the Compliant eCTD Lifecycle

TARGET AUDIENCE

This program will benefit individuals involved in:

- **Regulatory affairs**
- **Policy/pharmacoeconomics**
- **Clinical research**
- **Drug safety/pharmacovigilance**
- **Drug development**
- **Plant operations**
- **Quality assurance**
- **Marketing**
- **Academia**

CONTACT INFORMATION

For information about this meeting, contact **Joanne Wallace | Phone +1-215-442-6180 or email Joanne.Wallace@diahome.org**
For information about exhibiting, contact **Jeff Korn | Phone +1-215-442-6184 or email Jeff.Korn@diahome.org**

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

Continuing Education

DIA's 5th Annual Canadian Meeting

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 10.5 contact hours or 1.05 continuing education units (CEUs). 286-000-07-024-L04.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded 1.4 continuing education units (CEUs) to participants who successfully complete this program.

- **Tutorials are each approved for 0.3 IACET CEUs.**
- **The opening plenary session will not offer credit.**

The following tracks will offer these additional continuing education credits:

Monday, 1:30-3:00 (1.5 credit/contact hours)
Track 1 – No Credit
Track 2 – Pharmacy
Track 3 – No Credit

Monday, 3:30-5:00 (1.5 credit/contact hours)
Track 1 – No credit
Track 2 – Pharmacy
Track 3 – No credit

Tuesday, 9:00-10:30 (1.5 credit/contact hours)
Track 1 – No credit
Track 2 – Pharmacy
Track 3 – No credit

Tuesday, 11:00-12:30 (1.5 credit/contact hours)
Track 1 – Pharmacy
Track 2 – Pharmacy
Track 3 – No credit

Tuesday, 1:30-3:00 (1.5 credit/contact hours)
Track 1 – Pharmacy
Track 2 – Pharmacy
Track 3 – No credit

To receive a statement of credit, complete the on-line credit request process through My Transcript at www.diahome.org. 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 on Wednesday, October 31, 2007.

Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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

- Discuss the evolving Canadian regulatory environment
- Recognize the requirements of the Canadian regulatory authority
- Describe the future of drug development science
- Identify current challenges around long-term drug safety

TRAVEL AND HOTEL The Meeting will take place at the Ottawa Congress Centre, 55 promenade du Colonel By Drive, Ottawa, Ontario K1N 9J2 – adjacent to the Westin Ottawa Hotel. Telephone +1-613 563-1986 or +1-800-450-0077. The most convenient airport is Ottawa International Airport and attendees should make airline reservations as early as possible to ensure availability. The Westin Ottawa Hotel is holding a block of rooms at the reduced rate below until October 4, 2007, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $199 Canadian **Double $199 Canadian**

Please contact the Westin Ottawa Hotel by telephone at +1-800-WESTIN-1 or +1-613-560-7000 and mention the DIA meeting. The hotel is located at 11 Colonel By Drive, Ottawa, Ontario, Canada K1N 9H4.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! ***All 4 individuals must register and prepay at the same time – no exceptions.*** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

- **To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.**

Sunday, October 28, 2007 (Pre-meeting Event Only)

11:00 AM-1:00 PM **Tutorial Registration**

12:00-5:00 PM **Exhibitor Set-up and Registration**

1:30-5:00 PM **Tutorials**

Tutorial #1: Preparing a Complete Quality Overall Summary (QOS) and Quality Module

INSTRUCTORS: Arvin Naperstkow, MSc, Manager, Generic Drugs Quality Division, Health Canada

Gary Condran, Manager, New Drugs Quality Division, Health Canada

This tutorial is geared for those who are involved in completing a Quality Overall Summary and Quality Module. Experts in this arena will go through section by section of the summary reviewing the Health Canada requirements and what you need to know to facilitate the process of obtaining submission outcome in a timely manner. Examples will be discussed to highlight the requirements and avoid commonly made errors/omissions. There will be opportunities for interaction with the instructors, ask questions and clarify submission related issues

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

- Identify the information required to complete the quality portions of submissions
- Apply Health Canada requirements to a Quality Overall Summary and Quality Module
- Discuss commonly made errors/omissions

Tutorial Target Audience: This tutorial will benefit the following personnel:

- Regulatory Affairs
- Policy
- Drug Safety
- Manufacturing
- Quality Assurance

Tutorial #2: Practical Aspects of eCTD Preparation – From Efficient Content Development to the Compliant eCTD Lifecycle

INSTRUCTOR: Ted Hanebach, Director, Regulatory Standards, CanReg, Inc.

This tutorial provides a systematic, technical overview of the tools, best practices and processes required to prepare an eCTD submission for Health Canada. It will discuss the creation of a new eCTD submission and reuse of submissions previously filed with FDA and EU. Working in small groups, through case studies and interactive exercises, participants will learn the most current requirements for the preparation of a compliant eCTD submission, and the importance of managing of the submission content throughout the eCTD lifecycle.

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

- Describe a process-based approach to compilation submissions in the eCTD format
- Describe the best practices in the preparation of eCTD ready template-based documents
- Discuss eCTD project management and cross-functional document tracking
- Discuss region-specific document mapping
- Discuss the nuts and bolts of an electronic submission
- Describe what is entailed in building a compliant e-submission
- Discuss the submission life-cycle concerns and the best practices to manage submissions over the product's life
- Build a sample e-CTD submission

Tutorial Target Audience: This tutorial is designed for anyone involved in implementing the eCTD process, or involved in managing regulatory submissions, especially Submission/Project Managers, Regulatory Affairs, Regulatory Operations and IT staff.

4:00-6:00 PM **Meeting Registration**

Monday, October 29, 2007

7:30-8:30 AM **Registration and Continental Breakfast**

8:30-10:00 AM **OPENING PLENARY SESSION**

Welcome and Opening Remarks

Rav Kumar, PhD, Vice President, Regulatory and Development Operations, GlaxoSmithKline, Canada

KEYNOTE ADDRESS

The Opportunities/Challenges and Future Directions of the Pharmaceutical Industry

Philip Blake, President and CEO, Bayer, Inc. Canada
Chairman of the Board, Rx&D

During his 25-year career at Bayer, Blake has held leadership positions in Germany, the United Kingdom, Japan, and the United States, where he has focused on global strategic product marketing, business development, clinical planning, product developments, and sales management. He also has led an international action team in the strategic development and implementation of a new global and regional organizational structure and, most recently, stewarded the successful integration of a major Canadian pharmaceuticals company into Bayer's pharmaceuticals business in Canada.

Blake is currently the Chairman of the Board of Canada's Research-Based Pharmaceutical Companies, Rx&D, the national association representing more than 22,000 employees working for over 50 pharmaceuticals companies across Canada. During his one-year team, Blake will focus on improving patient access to innovative new treatments and partnering with governments to make affordable healthcare for Canadians a priority.

Blake attended Bristol University and Oxford University Business School in the United Kingdom, with extended business training at INSEAD Fontainbleu in Paris, France and the Wharton Business School in Philadelphia, Pennsylvania, United States.

Healthcare – 5-year Vision

Steven Fletcher
Parliamentary Secretary of Health

10:00-10:30 AM **Refreshment Break in the Exhibit Hall (Hall opens at 9:30 AM)**

10:30-12:00 PM **Progressive Licensing Framework: A New Regulatory Paradigm**

Session Chair:
Supriya Sharma, MD, MPH, FRCPC
Director General, Therapeutic Products Directorate, Health Canada

Overview of the Progressive Licensing Project
David K. Lee
Director, Office of Patent Medicines Liaison, Therapeutic Products Directorate, Health Canada

Establishing the Benefits and Risks of Therapeutic Agents: A Health Canada Perspective
Robyn Lim, PhD
Scientific Advisor, Progressive Licensing Project, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada

Panel Discussion
Supriya Sharma
David K. Lee
Robyn Lim
Sandra Wainwright

12:00-1:30 PM **Luncheon in the Exhibit Hall**

1:30-3:00 PM **PARALLEL TRACKS**

Track 1

Regulatory Affairs/ Clinical Trials

TRACK CO-CHAIRS
Anne Tomalin
President
CanReg, Inc. Canada

Adam Gibson
Associate Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

The Special Access Programme

Health Canada's Special Access Programme (SAP) provides limited access to products that cannot otherwise be sold or distributed in Canada to practitioners treating patients with a serious or life-threatening condition, when conventional therapies have failed, are unsuitable, unavailable or offer limited options. This session will explore the perspectives of the three primary stakeholders in the operations of the SAP (government, industry and physicians) as well as provide updates on the multiple initiatives that are presently underway within Health Canada with respect to the SAP.

Session Chair
John Patrick Stewart, MD
Acting Director, Office of Clinical Trials, Therapeutic Products Directorate
Health Canada

continued

Track 2

Safety/ Pharmacovigilance

TRACK CO-CHAIRS
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate
Health Canada

David Krakovsky, BScPhm, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline Inc.

New Approaches to Risk Management in the Pharmaceutical Industry

The objective of risk management is to ensure that the benefits of a medicine outweigh its risks to an individual patient and for the target population. Knowledge of a product's safety may change over time so it is extremely important to ensure earlier and better planning of pharmacovigilance activities. This session will discuss approaches to benefit/risk management taken by the pharmaceutical industry, review experiences and discuss current and future challenges of planning and implementation.

Session Chair
David Krakovsky, BScPhM, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline, Inc. Canada

continued

Track 3

Science and Technology

TRACK CO-CHAIRS
Yogesh Dandiker, PhD, MBA
Vice President, Product Development
Solid Dose Products
Apotex, Inc.

Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

Pharmacogenomics in Canada

Pharmacogenetics as well as Pharmacogenomics have been used in the past, either during drug development or when adverse reactions to drugs appeared. The regulatory use of these sciences was neither well-developed nor utilized to their full potential as tools to advance the sciences of Pharmacology and Therapeutics as well as Drug Development. Pharmacogenomics has become recognized for its potential to favor a more rapid and rational route for the development of new therapeutics that are better tailored to the needs of each individual patient. It is intended that this will provide the current views on Pharmacogenomics in Canada. It is also intended to incorporate into this session some new approaches to clinical trial design and statistical evaluation of studies that could increase confidence in the relatively small population samples that might result when designing clinical trials where PGx are a prominent consideration.

Session Chair
Agnes V. Klein, MD
Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics
Biologics and Genetic Therapies Directorate
Health Canada

continued

Track 1 *continued*

Regulatory Affairs/ Clinical Trials

Speakers

Update of Health Canada Activities for the Special Access Programme
Joanne Garrah
Special Access Officer, Therapeutic Products Directorate, Health Canada

The Special Access Programme: A Perspective from Industry
Gretchen Toolan
Director, Regulatory Affairs
Celgene Corporation

Physician Perspective: Challenges and Considerations When Making Requests through the Special Access Programme
Daniel Keene, MD, MA, FRCPC
Staff Neurologist\Associate Professor
Children's Hospital of Eastern Ontario (CHEO)

Track 2 *continued*

Safety/ Pharmacovigilance

Speakers

Risk Management Plan Development and Implementation
Karen Naim, MSc, PhD
Director, Benefit Risk Scientist
Johnson & Johnson Pharmaceutical Research and Development

Pharmacovigilance Planning
Fabio Lievano, MD
Senior Director, Clinical Risk Management and Safety Surveillance
Merck & Co., Inc

Where is Drug Safety Going?
Barton Cobert, MD, FACP, FACG, FFPM
Vice President, Global Regulatory Initiatives and Pharmacovigilance
Medidata Solutions Worldwide

Track 3 *continued*

Science and Technology

Speakers

Pharmacogenomics in Canada
Agnes V. Klein, MD
Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate
Health Canada

Status of the Science
Michael S. Phillips, PhD
Director, Pharmacogenomics Centre

Canadian Approach to the Regulations
Kwasi Nyarko, PhD
Unit Manager, Special Projects, Biologics and Genetic Therapies Directorate
Health Canada

Industry Viewpoint
Steven Lewitzky
Senior Principal Biostatistician
Novartis, US

3:00-3:30 PM **Refreshment Break in the Exhibit Hall**

3:30-5:00 PM **PARALLEL TRACKS *continued***

Track 1

Regulatory Affairs/ Clinical Trials

TRACK CO-CHAIRS
Anne Tomalin
President
CanReg, Inc. Canada

Adam Gibson
Associate Director, Office of Clinical Trials
Therapeutic Products Directorate, Health Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate, Health Canada

Challenges in Clinical Trials

There are numerous obstacles to the conducting an effective clinical trial, in Canada and abroad. This session will focus on three key challenges: Harmonization of clinical trial agreements for academic research sites, recruitment and retention of ethnic groups in clinical trials, and adaptive clinical trial designs. Initiatives, solutions and information on these topics will be covered.

Session Chair
Adam Gibson
Associate Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

Speakers
Eva Miller, PhD
Logistics and Implementation of Adaptive Designs for Clinical Trials
Head of Biostatistics
Almac Clinical Technologies

continued

Track 2

Safety/ Pharmacovigilance

TRACK CO-CHAIRS
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate, Health Canada

David Krakovsky, BScPhm, PharmD
Director, Medical Safety, Information and Governance, GlaxoSmithKline Inc.

Integrating Patient and Consumer Voices in Evidence-based Decisions about Risk

Input from the general public on drug safety related issues is an area of interest for many regulators around the world. Health Canada is developing a methodology to improve the way it currently integrates public input into its decision making process. This tool will be presented, as the approach taken in the US regarding integration of public input.

Session Chair
Erin Lepine
Manager, Office of Consumer and Public Involvement
Health Canada

Speakers
Introduction and Overview of Policy on Public Input
Erin Lepine
Manager, Office of Consumer and Public Involvement, Health Canada

continued

Track 3

Science and Technology

TRACK CO-CHAIRS
Yogesh Dandiker, PhD, MBA
Vice President, Product Development
Solid Dose Products
Apotex, Inc.

Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate, Health Canada

Documentation for Audit/Inspection

The demands for documentation for audit and inspection purposes have increased in all areas of the product lifecycle.

This session will focus on various approaches and methods that may be considered to improve an organization's operations to meet these demands.

Session Chair
Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate
Health Canada

Speakers
Knowledge Transfer and EDC – What Really Needs to Happen
John Simpson
Director of Product Strategy
TrialStat

continued

Track 1 *continued*

Regulatory Affairs/ Clinical Trials

Harmonization of Clinical Trial Agreements
Michelle Moldofsky
Policy & Legal Advisor, St. Michael's Hospital

Recruiting and Retention Strategies and Solutions for Ethnic Groups into Clinical Trials
Rayonne Caesar-Chavannes
President/Senior Research Consultant, ReSolve Research Solutions, Inc.

Track 2 *continued*

Safety/ Pharmacovigilance

FDA: OSHI: Similarities and Differences, Canada and US Models
Richard Klein
Public Health Specialist, Office of Special Health Issues, FDA

Patient Perspective
Dianna Schreuer
Patient Representative

Perspective of Industry: Transparency and Openness in Regulatory Processes
Bernard M. Prigent, MD, MBA
Vice President & Medical Director, Medical Division Pfizer Canada Inc.

Development of Supporting Methodologies to Incorporate Public Input Evidence into Decisions
Mavis Jones, PhD
Dalhousie University Researcher and recipient of CIHR Fellowship

Track 3 *continued*

Science and Technology

Options for Creation of a Good Laboratory Practice (GLP) Monitoring Authority in Canada for Health Products and Food Additives
David Clapin, PhD, MPA, DABT
Branch Science Advisor, Health Products and Food Branch, Health Canada

Patterns of Consolidation in Enterprise Content Management
Ken Lownie
Vice President and Chief Operations Officer Glemser Technologies Corporation

5:00-6:00 PM **Networking Reception in Exhibit Hall**

6:30-9:00 PM **Networking Dinner:** Westin Ottawa Hotel 4th Floor Ontario Room

US$ 55 – *Reservations must be made in advance.*

GUEST SPEAKER:

Changing Role of Canadian Pharmacists in Optimal Use of Medicines

Jeff Poston, PhD, Executive Director, Canadian Pharmacists Association

Dr. Jeff Poston was appointed CPhA's Executive Director in June 1999, following a successful tenure as Director of Research and Practice Development. A hallmark of Dr. Poston's career has been a commitment to innovation and pioneering innovative approaches to developing the role of the pharmacist.

Dr. Poston obtained his bachelor of pharmacy degree and a PhD in pharmacy from the University of Wales in Britain.

ABOUT OUR PROGRAM CHAIRS

Rav Kumar, B Pharm (Hons), PhD, MRPharmS

Dr. Rav Kumar leads GSK's Canadian R&D organization of over 250 scientists and staff involved in drug development, clinical trials and regulatory affairs. The Canadian Pharmaceutical R&D team develops new drugs, including diabetes, HIV, anti-malarial and cardiovascular medicines for worldwide markets and also collaborates with Canadian Universities to increase R&D activity in the pharmaceutical sciences.

Dr. Kumar is a pharmacy graduate with a PhD in pharmaceutical sciences from the University of Bath, United Kingdom for research into controlled delivery of drugs such as insulin. He has more than 20 years of global drug development experience having worked for start-up, CRO and multi national pharmaceutical companies in the UK, France and North America.

Dr. Kumar is President-Elect of the Canadian Society of Pharmaceutical Scientists and vice-chair of the Regulatory Affairs Committee of Rx&D. He has co-chaired the 2006 and 2007 Canadian DIA meetings and sits on the DIA Advisory Council of North America. He was a member of the University of Toronto Advancement Board for the new Pharmacy building and Board Governor at Hillfield Strathallan College in Hamilton.

Supriya Sharma,MD, MPH, FRCPC

Dr. Supriya Sharma assumed the duties of Acting Director General, Therapeutic Products Directorate (TPD) effective March 1, 2007. Prior to taking on this role, Dr. Sharma served as Associate Director General, TPD, since November 28, 2005.

Dr. Supriya Sharma joined Health Canada in February 2002 as Director of the Marketed Biologics and Biotechnology Products Division of the Marketed Health Products Directorate just before their transition from a Bureau to a Directorate on April 1, 2002. She also took on the additional role of A/Associate Director General from August 2004 to March 2005. Following that, she worked in the Health Policy Branch as a Senior Policy Advisor on the National Pharmaceuticals Strategy.

Trained as a Pediatrician in Calgary and Australia, prior to joining Health Canada Dr. Sharma worked in Hematology Research in thalassemia and sickle cell disease in a number of multi-centre international clinical trials, including one in Sri Lanka in collaboration with Oxford University. She completed a Masters of Public Health in International Health from the Harvard School of Public Health in 2001, and went on to work on a research project for the Kennedy School of Government on implementing strategies relating to the reduction of medical errors and patient safety in large scale health organizations.

Tuesday, October 30, 2007

8:00-9:00 AM **Registration and Continental Breakfast**

9:00-10:30 AM **PARALLEL TRACKS**

TRACK 1

Regulatory Affairs/ Clinical Trials

TRACK CO-CHAIRS
Anne Tomalin
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Health Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD) AND ITS USE BY INDUSTRY AND HEALTH CANADA

The implementation of eCTD by both industry and Health Canada is progressing. Challenges and opportunities exist for all stakeholders and this session will explore the different views surrounding the preparation, management and use of eCTD drug submissions.

Session Chair
Anne Tomalin
President, CanReg, Inc., Canada

Speakers

eCTD FROM AN INDUSTRY PERSPECTIVE-PREPARATION AND LIFECYCLE MANAGEMENT
Maria Boulanger
Manager, Regulatory Operations,
GlaxoSmithKline, Canada

ACCEPTANCE OF eCTD IN CANADA SUMMARY
Mei Ke
e-Review Project Lead, BIO,B&GTD
Health Canada

REVIEWING AN eCTD DRUG SUBMISSION: PERSPECTIVE OF A HEALTH CANADA ASSESSMENT OFFICER
Bob Kapitany, PhD
Asesser,
Health Canada

TRACK 2

Safety/ Pharmacovigilance

TRACK CO-CHAIRS
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate
Health Canada

David Krakovsky, BScPhm, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline Inc.

NAME-RELATED DRUG SAFETY ISSUES

The selection and approval of the brand name for a new medicine is extremely important to minimize potential safety issues. Most pharmaceutical companies begin their internal selection processes years in advance of submitting names to the regulatory agencies. It is essential that companies and regulators ensure that the brand name approved eliminates any possibility of medication errors and safety issues due to "sound-alike/look-alike names."

Session Chair
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate, Health Canada

Speakers

ASSESSING THE 'SAFETY' OF A BRAND NAME
Lili Loorand-Stiver, RPh
Managing Director, Canadian Regulatory Affairs
Drug Safety Institute

BRAND NAME DEVELOPMENT AND INDUSTRY PERSPECTIVE
Thomas Ruth
Director, Trademark Development, PGP Worldwide Commercial Development
Pfizer Inc

HEALTH CANADA PERSPECTIVE
Marilyn Schwartz
Director, Submission and Information Policy Division, Therapeutic Products Directorte, Health Canada

TRACK 3

Science and Technology

TRACK CO-CHAIRS
Yogesh Dandiker, PhD, MBA
Vice President, Product Development
Solid Dose Products
Apotex, Inc.

Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

FATE OF PHARMACEUTICALS IN THE ENVIRONMENT AND CANADIAN POLICY DIRECTIONS

Pharmaceuticals and personal care product compounds have been detected in wastewater treatment plant effluents and surface waters at levels of concern. Ecological impacts and impacts on wildlife (notably fish) have been observed *in vitro*. One of the current challenges is to properly interpret the data in terms of risk to ecological and human health. Following a consultation held in March 2006, Health Canada and Environment Canada committed to develop appropriate Environmental Assessment Regulations (EARs) for new substances under the Canadian Environmental Protection Act (CEPA). The existing requirements under the New Substance Notification Regulations (NSNR) are under revision to take into account the most recent environmental findings, such as the appropriateness of current trigger quantities for an EA, the appropriateness of ecotoxicological tests required and the suitability of existing fate and effects models.

Session Chair
Alan Viau, PhD
Associate Director Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Canada

Speakers

PHARMACEUTICALS IN THE ENVIRONMENT (PIE): OVERVIEW OF OCCURRENCE AND CURRENT CHALLENGES
Nathalie Ross, PhD
Sr. Regulatory Affairs Associate, CanReg, Inc.

CANADIAN POLICY DIRECTIONS
Alison McLaughlin
Environmental Impact Initiative, Policy, Planning and International Affairs Directorate, Health Canada

PHARMACEUTICALS AND THE ENVIRONMENT, WHAT IS THE PHARMACEUTICAL INDUSTRY DOING?
David Taylor
Global Director of Environment & Sustainability
AstraZeneca plc

10:30-11:00 AM **Refreshment Break in the Exhibit Hall**

11:00-12:30 PM PARALLEL TRACKS *continued*

TRACK 1

Regulatory Affairs/ Clinical Trials

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Health Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

RESEARCH ETHICS BOARDS (REBS) IN CANADIAN CLINICAL TRIALS IN CANADA AND ABROAD

REBs are an essential component of clinical trials. Their role, responsibilities and composition have been discussed at length in many jurisdictions around the world. This session will outline current Health Canada and Canadian REB perspectives as well as those in the United Kingdom.

Session Chair

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials, Therapeutic Products Directorate, Health Canada

Speakers

FORMALIZING THE PROCESSES OF REBS IN UK
Jonathan Bell
CEO, Infonetica Ltd

ACCREDITATION AND OTHER HEALTH CANADA INITIATIVES WITH RESPECT TO REBS
Peter Monette, PhD
Senior Policy Advisor, Ethics, Health Policy Branch, Health Canada

REB – PERSPECTIVE
Jack Corman
President
Institutional Review Board Services

TRACK 2

Safety/ Pharmacovigilance

TRACK CO-CHAIRS
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate
Health Canada

David Krakovsky, BScPhm, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline Inc.

PREDICTING DRUG SAFETY USING PHARMACOLOGY AND PHARMACOGENOMICS

Significant advances in pharmacology and pharmacogenomics can enhance the effective management of benefit and risk throughout the lifecycle of a medicine. Earlier identification of a potential safety issue during the development of a drug can lead to improved monitoring of safety and if necessary earlier termination of compounds. Pharmacogenomics can play a significant role in selecting potential targets to treat diseases and also help identify groups of patients in which a medicine would be most effective with least risk.

Session Chair

David Krakovsky, BScPhM, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline, Inc. Canada

Speakers

HEALTH CANADA PERSPECTIVE
Christine Nestruck, MSc, PhD
Clinical Reviewer, Clinical Trials Group 1
Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

ACADEMIA PERSPECTIVE
Michael Rieder, MD, PhD, FRCPC, FAAP, FRCP (Glascow)
CIHR-GSK Chair in Paediatric Clinical Pharmacology, Schulich School of Medicine and Dentistry, University of Western Ontario

INDUSTRY PERSPECTIVE
Nancy Yuen, Pharm D
Director, Global Clinical Safety and Pharmacovigilance
GlaxoSmithKline

TRACK 3

Science and Technology

TRACK CO-CHAIRS
Yogesh Dandiker, PhD, MBA
Vice President, Product Development
Solid Dose Products
Apotex, Inc.

Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

ICH Q8 – VIEW ON DESIGN SPACE

Products are expected to be developed which incorporate 'Quality by Design ' concepts that is the development of products within a 'Design Space'. This will lead to a thorough understanding of key product attributes which in turn will allow process changes to be made without prior approval. This session will focus on some of the experiences to date with this initiative both from an Industry and Health Canada perspective.

Session Chair

Yogesh Dandiker, PhD, MBA
Vice President, Product Development, Solid Dose Products
Apotex, Inc., Canada

Speakers

BUILDING A DESIGN SPACE
Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

QUALITY BY DESIGN AND PFIZER'S EXPERIENCE IN THE FDA PILOT PROGRAM
John Groskoph
Director GMC New Products Group
Pfizer, Inc.

12:30-1:30 PM Luncheon in the Exhibit Hall (Hall closes 1:30 PM)

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

1:30-3:00 PM PARALLEL TRACKS *continued*

Track 1

Regulatory Affairs/ Clinical Trials

TRACK CO-CHAIRS

Anne Tomalin
President
CanReg, Inc. Canada

Adam Gibson
Associate Director, Office of Clinical Trials,
Therapeutic Products Directorate
Health Canada

John Patrick Stewart, MD
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate
Health Canada

The Cost of Drug Access

Access to drugs in Canada is influenced by a number of factors including the cost of the product itself. This session will provide an overview of key processes and stakeholders that play a role in the relationship between drug access and costs.

Session Chair
Anne Tomalin
President
CanReg, Inc., Canada

Speakers

The Common Drug Review (CDR)
Mike Tierney, PhD
Vice-President, CDR, Canadian Agency for Drugs and Technologies in Health

The Patented Medicines Prices Review Board (PMPRB)
Barbara Ouellet
Executive Director, Patented Medicines Prices Review Board

Market Access and the cost of drugs in Canada – an industry perspective
Douglas Grant
Vice President Corporate Affairs
Bayer, Inc., Canada

Track 2

Safety/ Pharmacovigilance

TRACK CO-CHAIRS

Marc Berthiaume, MD, Director, Marketed Pharmaceuticals and Medical Devices Bureau
Marketed Health Products Directorate
Health Canada

David Krakovsky, BScPhm, PharmD
Director, Medical Safety, Information and Governance
GlaxoSmithKline Inc.

Use of Real World Safety and Effectiveness Data

The integration of real-world safety and effectiveness data in the evaluation and monitoring of marketed products is a currently underused tool to complement currently established sources of information. Generation of such data, its interpretation and its integration into the product life cycle will need to be further defined. This session will discuss the issue by identifying the current situation, and what types of approaches will need to be put in place to maximize the usefulness of real-world safety and effectiveness data.

Session Chair
Marc Berthiaume, MD
Director, Marketed Pharmaceuticals and Medical Services Bureau, Marketed Health Products Directorate, Health Canada

Speakers

Update on the National Pharmaceutical Strategy – Industry perspective
Judith Glennie, PharmD, MSc,FCSHP
Director, Post-marketing Effectiveness Research Government and Health Economics, Janssen-Ortho Inc

Strengthening the Evaluation of Real-world Sfety and Effectiveness of Health Products: Government Perspective
David F. Clapin, PhD, MPA, DABT
Branch Science Advisor, Health Products and Food Branch, Health Canada

Update on the National Pharmaceutical Strategy – Academia perspective
Muhammad Mamdani, PharmD, MA, MPH
Director, Applied Health Research Centre
St. Michaels Hospital, Toronto

Track 3

Science and Technology

TRACK CO-CHAIRS

Yogesh Dandiker, PhD, MBA
Vice President, Product Development
Solid Dose Products
Apotex, Inc.

Alan Viau, PhD
Associate Director, Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

ICH Q9 – Risk Management in Pharmaceutical Development and Production

ICH-Q9 articulates that manufacturing a drug necessarily entails some degree of risk. Product quality should be maintained throughout the product lifecycle. The discussion will be focused on the risk management aspects needed to make effective and consistent decisions by regulators and industry regarding the quality of drug substances and drug products.

Session Chair
Alan Viau, PhD
Associate Director Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Canada

Speakers

A Risk Based Approach to Regulatory Review
Alan Viau, PhD
Associate Director Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate, Health Canada

Balancing Risks and Benefits: down to a Science
Helen McRobbie
Institute of Population Health - Institute of Ottawa

3:00-3:30 PM Refreshment Break in Foyer Area

3:30-5:00 PM PANEL DISCUSSION

Challenges of Evaluating and Communicating the Benefit/Risk of Pharmaceuticals from Clinical Trials to Post-approval

Supriya Sharma, MD, MPH, FRCPC
Director General, Therapeutic Products Directorate
Health Canada

Vision of Drug Risk Management
Brett J. Skinner
Health, Pharmaceutical & Insurance Policy Research, Frazer Institute

Panel Members:
Brett Skinner
Marc Berthiaume
Supriya Sharma
David Krakovsky

5:00 PM Canadian Annual Meeting Adjourned

DIA'S 5th CANADIAN ANNUAL MEETING

Ottawa Congress Centre
Ottawa, Ontario, Canada

OCTOBER 28-30, 2007

HEALTH CANADA PARTICIPANTS

Marc Berthiaume
David Clapin
Gary Condran
Joanne Garrah
Adam Gibson
Stephanie Hardy
Mei Ke
Agnes Klein
David K. Lee
Erin Lepine
Robyn Lim
Peter Monette
Arvin Naperstkow
Christine Nestruck
John Patrick Stewart
Supriya Sharma
Alan Viau
Margaret Zimmerman

Three Parallel Tracks focusing on:

REGULATORY AFFAIRS/CLINICAL TRIALS
SAFETY/PHARMACOVIGILANCE
SCIENCE AND TECHNOLOGY

Two Tutorials

#1 Preparing a Complete Quality Overall Summary (QOS) and Quality Module

#2 Practical Aspects of eCTD Preparation – From Efficient Content Development to the Compliant eCTD Lifecycle

Register online or fax this page to +1-215-442-6199

CONTACT & EXHIBIT INFORMATION

Attendees may visit the exhibits during the meeting and during receptions (if applicable).

Meeting information: Contact Joanne Wallace at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.

Exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For exhibit space, please check the box below.

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TUTORIALS

#1 1:30-5:00 US $ 375 ❑ **#2** 1:30-5:00 US $ 375 ❑

NETWORKING DINNER MONDAY, OCTOBER 29, 6:30-9:00 PM
Westin Ottawa Hotel Reservations must be made in advance. Guest Speaker Jeff Poston, PhD, Canadian Pharmacists Association. US $ 55 ❑

CANCELLATION POLICY: On or before OCTOBER 22, 2007

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
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Tutorial = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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