Canadian Pharmacovigilance and Risk Management Strategies Conference

October 21-22 | Virtual

PROGRAM COMMITTEE

Marcia Bailey, BSN, MHS, RN
Senior Manager, Pharmacovigilance
Sierra Oncology, Canada

Rita Cassola, RPh
Executive Director PV
Certus PV Services Inc., Canada

Deborah Danoff, MD, FRCP
Medical Evaluator
Health Canada

Marc Poitras, PhD, MBA
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Sophie Sommerer, MS
Director
Health Canada

Bruce Valliant
Head of Pharmacovigilance and Medical Information, PharmaScience

Overview

Effective pharmacovigilance and risk management practices are critical to ensuring that health products available to Canadians are safe and that risks associated with use are balanced with benefits in a way that best meets the needs of patients. Today's safety and pharmacovigilance professionals must assess and manage risk for a broad range of new and traditional products, all within a changing landscape of global regulation.

DIA's *Canadian Pharmacovigilance and Risk Management Strategies Conference* is the premier place to hear the latest updates in pharmacovigilance, risk management, and drug safety from both a global and a tailored Canadian perspective.

In this year's program, biopharmaceutical and regulatory agency experts will engage with the audience on topics such as Health Canada and global regulatory updates, impact of the pandemic crisis on pharmacovigilance, regulatory flexibility, signal detection, GVP inspections of foreign MAHs, and foreign notifications. A special look at vigilance for vaccines and COVID-19 therapies will also be featured.

Who Should Attend?

Professionals involved in:

- Clinical Safety/Pharmacovigilance
- Clinical Research
- Project Management
- Quality Assurance and Control
- Regulatory Affairs and Operations

Schedule At-A-Glance

DAY ONE | WEDNESDAY, OCTOBER 21

10:25-10:30AM	**Welcome and Opening Remarks**
10:30-11:30AM	**Session 1:** Pharmacovigilance and Risk Management during the Pandemic: Perspective from the Regulators
11:30AM-12:30PM	Break
12:30-1:50PM	**Session 2:** Round Table with Inspector
1:50-2:30PM	Break
2:30-4:30PM	**Session 3:** Canada Vigilance

DAY TWO | THURSDAY, OCTOBER 22

10:00-11:30AM	**Session 4:** Challenges and Opportunities in the Implementation and Evaluation of Risk Minimization Measures
11:30-12:30PM	Break
12:30-1:15PM	**Session 5:** Notifying Health Canada of Foreign Actions
1:15-1:30PM	Break
1:30-2:45PM	**Session 6:** Signal Detection
2:45-3:00PM	Break
3:00-4:15PM	**Session 7:** Pharmacovigilance of Cannabis and Related Products

Learning Objectives

At the end of this session participants should be able to:

- Describe recent regulatory agency initiatives in Canada, Europe, and the US, to strengthen pharmacovigilance and risk management efforts within their respective regions
- Discuss recent updates to the Canada Vigilance database and perspectives of Health Canada and industry on opportunities and challenges that these changes pose
- Compare and contrast pharmacovigilance inspections by Health Canada, MHRA, and FDA, and discuss recent findings from Health Canada inspections
- Discuss Health Canada and industry perspectives on current pharmacovigilance risk management requirements and best practices in Canada

DAY ONE | WEDNESDAY, OCTOBER 21

10:25-10:30AM — **Welcome and Opening Remarks**

10:30-11:30AM — **Session 1:** Pharmacovigilance and Risk Management during the Pandemic: Perspective from the Regulators

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

The global pandemic has forced public health and regulatory authorities worldwide to adapt rapidly to deal with the evolving situation. In this session, representatives from regulatory agencies (EMA, FDA and Health Canada) will discuss how they have revised their pharmacovigilance and risk management practices while ensuring the safe use of therapeutic health products.

Speakers
Georgy Genov, MD, Head of Pharmacovigilance Office, Quality and Safety of Medicines Department, European Medicines Agency

Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology, CDER FDA

Kelly Robinson, MSc, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Health Canada

11:30AM-12:30PM — **Break**

12:30-1:50PM — **Session 2:** Round Table with Inspector

Session Chair
Rita Cassola, RPh, Executive Director PV, Certus PV Services Inc.

In this session, a representative from the Good Pharmacovigilance Practices (GVP) Inspection Program of Health Canada will discuss updates of the Program. The session will discuss:

- Inspection trends observed during fiscal year 2019-2020
- The addition of market authorization holders located outside of Canada within the scope of the Program
- The impact of COVID-19 on GVP inspections and other upcoming elements of the GVP Program Review

Updates on the Good Pharmacovigilance Practices (GVP) Inspection Program
Marc-André Giguère, B.Sc., Pharmacology, Senior Corporate Regulatory and Enforcement Advisor, Health Canada

1:50-2:30PM — **Break**

2:30-4:30PM — **Session 3:** Canada Vigilance

Session Co-Chairs
Marcia Bailey, RN, BSN, MHS, Senior Manager, Pharmacovigilance, Sierra Oncology

Deborah Danoff, MD, FRCP, Medical Evaluator, Health Canada

With many increasing health care and drug safety challenges, a good understanding of recent and evolving regulatory requirements and guidance will be important in maintaining patient safety in today's climate. In this session, strategies in safety data collection, mandatory reporting, and in managing duplicate reports will be discussed.

Canada Vigilance Database Duplicate Cases – Industry Challenges
Bernard Ogbiti, DrMED, Pharmacovigilance and Medical Information Associate II (HCP), Certus PV

Assuring Complete and Accurate Adverse Reaction Reporting-Moving from Good to Best
Gayatri Jayaraman, **PhD, MPH**, Director, Marketed Health Products Safety and Effectiveness, Information Bureau, Health Canada

ICH E19 Optimization of Safety Data Collection
Fannie St-Gelais, PhD, Senior Drug Reviewer, Health Canada

ICH E19 Guideline – An Industry Perspective
Heidi Levens, MSc, Head of Canada, Patient Safety, Bristol-Myers Squibb Company

DAY TWO | THURSDAY, OCTOBER 22

10:00-11:30AM

Session 4: Challenges and Opportunities in the Implementation and Evaluation of Risk Minimization Measures

Session Chair
Sophie Sommerer, MS, Director, Health Canada

Session Co-Chair
Bruce Valliant, Head of Pharmacovigilance and Medical Information, Pharmascience, Inc.

This session will focus on some of the challenges and opportunities in designing, implementing and evaluating the effectiveness of risk minimization measures in healthcare settings. The session will include a presentation from Health Canada about best practices in the design, implementation and evaluation of risk minimization measures. An industry presenter will discuss options for risk mitigation and the application of evaluation methods to assess their effectiveness. Both presentations will use real-world examples to highlight lessons learned.

Risk Management for the 21st Century: Current Status and Future Direction
Rania Mouchantaf, PhD, Associate Director, Health Canada

Real World Challenges with Evaluations
Janine Collins, MD, LLM, Executive Director Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

Panel Discussion
Meeting participants will have the opportunity to ask the presenters questions related to day to day issue associated with designing and implementing various risk mitigation measures and methods to evaluate the effectiveness.

11:30-12:30PM — **Break**

12:30-1:15PM

Session 5: Notifying Health Canada of Foreign Actions

Session Chair
Rita Cassola, RPh, Executive Director PV, Certus PV Services Inc.

This session will provide a high-level overview on the requirement to notify Health Canada of foreign actions, including the purpose of the regulation C.01.050, the corresponding guidance and the reporting form. Since the regulation came into force in November 2018, Health Canada has received a number of questions from the industry and will share the answers to these questions during this session.

Notification of Foreign Regulatory Actions – Compliance Questions and Answers
Bruce Wozny, MA, Senoir Policy Officer, Health Canada

Notification of Foreign Regulatory Actions – Compliance Questions and Answers
Eian Elliott, BSc, MBA, Senior Corporate Regulatory Compliance & Enforcement Advisor, Health Canada

1:15-1:30PM — **Break**

1:30-2:45PM

Session 6: Signal Detection

Session Chair
Bruce Valliant, Head of Pharmacovigilance and Medical Information, Pharmascience Inc.

Methods selected for detection of safety signals for a drug are dependent upon the safety profile of the drugs. The safety profile will also have a direct impact on how many reports of adverse drug reactions would be received over a given time period. The expectedness, quantity, seriousness and severity of such reports will all impact on the methods to be used in the signal detection process. As well, the capacity of a small pharmaceutical company to undertake a robust signal detection process may be somewhat limited as compared with that of a large multi-national corporation. Presentations will consider the effectiveness of various methodologies based on these scenarios and compare that with expectations of the regulatory authorities.

Health Canada Perspective on Selection of Signal Detection Process
Stéphane Bérard, Regional Regulatory Compliance and Enforcement Specialist, GVP Inspection Program, Health Canada

Speaker
Bruce Gordon, MSc, Senior Scientific Evaluator, Health Canada

Ruben M. Ayzin Rosoky, MD, PhD, MFPM, DPM, Senior Safety Physician, United BioSource Corporation

Panel Discussion
Meeting participants will have the opportunity to ask the presenters questions related to day to day issue associated with designing and implementing various risk mitigation measures and methods to evaluate the effectiveness.

2:45-3:00PM

Break

3:00-4:15PM

Session 7: Pharmacovigilance of Cannabis and related Products

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

Since the legalization of medical/recreational cannabis products, there has been a constant increase of adverse event cannabis related reporting to Health Canada. On June 30th, 2020, Health Canada issued its Guidance to Industry regarding Cannabis Adverse Reaction Reporting. In this session, representatives from Health Canada, and the Industry will discuss the specific aspects of Cannabis Pharmacovigilance focusing on the implementation of the new Guidance and will address questions/challenges stemming from the experience thus far in relation to the application of the Guidelines.

Speaker
Robert Pawinski, MEd, MHA, MSN, R&R Executive Consulting

Speaker
Stephanie Jack, MSc, Scientific Advisor, Health Canada

Speaker
Chanez Narimene Kebache, MBA, Director, Global Drug Safety & Pharmacovigilance, Canopy Growth Corporation