

# Pharmaceutical Compliance Congress **Canada**

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## Gain Proven Risk Management Strategies to Conquer the Unique Canadian Compliance Legal and Ethics Challenges

June 6-8, 2023 | Omni King Edward Hotel | Toronto, ON | **EVENT AGENDA** • DEDICATED PHARMA + MEDTECH TRACKS

### MEET THE 2023 ESTEEMED PROGRAM ADVISORY BOARD



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# ABOUT OUR EVENT

**PCC Canada** presents an exclusive opportunity to unite with industry peers across the healthcare landscape and stay on the pulse of the latest code considerations and regulatory updates that are impacting pharmaceutical and medical technology compliance. Join experts across the life sciences community, face-to-face or virtually, to drive innovation.



## ALL ACCESS EXPERIENCE Toronto, ON

Reunite with industry peers in-person! Enjoy networking, benchmarking and idea sharing face-to-face to enhance your Bio/pharma compliance and MedTech programs.

- 3 robust days of face-to-face content with industry trailblazers – Including an all new MedTech Track!
- In-depth, inclusive workshop focused on recent code updates that are shaping the healthcare landscape
- Open forum for benchmarking survey insights, Q&A and best practice sharing
- In-person networking with colleagues and industry counterparts
- All benefits included in the Virtual Experience



## VIRTUAL EXPERIENCE ConnectMe Virtual Platform

What's included in the Virtual Experience Pass?

- Live streaming during the in-person event
- Access to the ConnectMe virtual platform
- Recorded presentations\* from the in-person event, available for 12 months on our Streamly digital platform – One whole year of conference content!
- Attendee list with video chat, instant messaging and meeting request functionalities
- Access to the virtual exhibit hall and leading solution providers

\*pending speaker permissions

## WHO WILL I MEET?

You will benefit from attending this event if you work for a Bio/pharma or MedTech company and have responsibilities or involvement in the following areas:

- |                  |            |             |                 |                   |                                |
|------------------|------------|-------------|-----------------|-------------------|--------------------------------|
| ■ Compliance     | ■ Ethics   | ■ Integrity | ■ Legal/Counsel | ■ Risk Management | ■ Regulatory & Medical Affairs |
| ■ Investigations | ■ Training | ■ Oversight | ■ Monitoring    | ■ Patient Support | ■ Commercial Operations        |

... as well as members from industry leading law firms, consultants and technology providers



# EVENT AGENDA

\*Please note all times are listed in EDT

## Day One: Tuesday, June 6th, 2023

1:00 PM

CONFERENCE REGISTRATION

2:00-5:00 PM

\*There will be a  
networking and  
refreshment break  
3:00-3:30 PM

WORKSHOP:

DEEP DIVE INTO RECENT CODE UPDATES SHAPING THE HEALTHCARE COMPLIANCE LANDSCAPE



### Workshop Overview:

Take a deep dive into the codes related to IMC, MedTech Canada and the CGPA and review if/how they continuously evolve with the changing environment and international trends. Level set with colleagues and unearth appropriate measures that you can take to safeguard these new iterations.

### Key Questions to be Addressed:

- Familiarize yourself with IMC, MedTech and CGPA Codes
  - New Code for 2023 – Explore the MedTech Code of Conduct changes
- How do you navigate a principle-based Code designed to fit many complex scenarios and realities?
  - How to impact behavioral change within a commercial organization according to principle-based codes?
- What are the necessary steps that your company can take to ensure effective compliance, monitoring and oversight? Particularly in considerations of the online monitoring of Health Canada and PAAB

### WORKSHOP OUTLINE:

I. Overview Updates Pertaining to Each Group

II. Fireside Chat with Executives of the Leading Associations

III. Facilitated Benchmarking

### Workshop Leaders:

Lama Abi Khaled, Executive Director, Ethics, Legal & Regulatory, **Innovative Medicines Canada**

Danielle Lavalley, Head, Legal & Compliance, **Phillips Canada**

Stephan Ekmekjian, Health Care Compliance Officer, **Johnson & Johnson MedTech Canada**

Antoine Eloi, Vice President, Sales & Marketing, **DePuy Synthes Canada, Johnson & Johnson MedTech**

Elizabeth Gill, Vice President, Global Business Ethics and Compliance, and Compliance Officer U.S., **Apotex Inc.**

Declan Hamill, Vice President, Policy, Regulatory and Legal Affairs, **Innovative Medicines Canada**

5:00-6:00 PM

WELCOME RECEPTION

## A GREAT PLACE TO MEET YOUR MARKET!

Maximize your access to decision-makers and align your brand with the life sciences industry's premier thought-leaders and industry innovators. Informa Connect's custom sponsorship programs are designed to support your organization's overall business development and marketing initiatives through meaningful prospect and customer interactions, brand assertion campaigns and content-rich thought-leadership opportunities. For more information on how to position your company as a sponsor or exhibitor, contact **John Egan** at 908-310-7683 or email [john.egan@informa.com](mailto:john.egan@informa.com)

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## Day Two: Wednesday, June 7th, 2023

|                   |  |  |
|-------------------|--|--|
| 7:45-8:15 AM      | <b>CONTINENTAL BREAKFAST AND NETWORKING</b>  |  |
| 8:15-8:45 AM      | <b>Informa Connect Welcome and Co-Chair's Opening Remarks</b> <span>▶ LIVE STREAM</span> <p> <i>Callie Mertel, Conference Producer, Informa Connect</i><br/> <i>Anne Mayrand, Head, Legal Affairs &amp; Compliance, Organon Canada, Inc.</i><br/> <i>Rosy Sasso, President, PBECC – Privacy, Business Ethics &amp; Compliance Consulting</i> </p>  |  |
| 8:45-9:30 AM      | <b>LUMINARY PANEL: Top Compliance Challenges and Trends Facing Industry Leaders</b> <span>▶ LIVE STREAM</span> <p>           Deep dive into the topics and areas that are affecting the Canadian marketplace and keeping top compliance leaders up at night. Explore what is on their radar and why it should be on yours. Discuss key actions items and take aways that can have a real impact in instituting a culture of compliance from the top down.         </p> <p> <i>Moderator: Derek Frueh, Senior Director, Ethics and Compliance, Astellas Pharma Canada, Inc.</i><br/> <i>Panelists: Dan Clow, Director, Ethics and Compliance, GSK Canada</i><br/> <i>Daike Van de Putte, Chief Compliance Officer, General Counsel, Perspectrum Ltd</i><br/> <i>Litsa Kouroumalis, Director, Compliance and Ethics, Britsol Myers Squibb</i> </p>                                       |  |
| 9:30-10:00 AM     | <b>KEYNOTE ADDRESS: Patient Engagement: The Foundation for Improved Care</b> <span>▶ LIVE STREAM</span> <p>           Patients and caregivers are increasing in sophistication and involvement in their own healthcare in Canada and across the globe. Health care professional considerations for compliance and education needs are different than patient considerations. Patient insights lead supporting the path to innovation and improving all aspects of the patient care pathway.         </p> <p> <i>Ursula Mann, Principal and Chief Patient Officer, PatientVoicePartners</i> </p>  |  |
| 10:00-10:30 AM    | <b>NETWORKING AND REFRESHMENT BREAK</b>  |  |
| 10:30-11:15 AM    | <b>Fireside Chat with PAAB</b> <span>▶ LIVE STREAM</span> <p>           Sit down with PAAB during this intimate and interactive discussion to gain answers to the questions you need most. Discuss the new PAAB-Health Canada monitoring collaboration, AI, social media and more.         </p> <p> <i>Moderator: Annie Bourgault, President, Integrated Pharma Services</i><br/> <i>Panelist: Jennifer Carroll, Senior Reviewer, PAAB</i> </p>  |  |
| 11:15 AM-12:00 PM | <b>Social Media Risks – Practicalities and Understandings to Avoid Common Mistakes and Remain Compliant</b> <span>▶ LIVE STREAM</span> <p>           When it comes to social media, there is great room for opportunity but also grave room for danger. Benchmark with colleagues on apparent social media complexities, such as influencer marketing and off label promotion, as well as some of the hidden gray areas. Hear real life examples regarding which channels, and specific areas per platform, are important to monitor and how to avoid common mistakes to remain compliant.         </p> <p> <i>Moderator: Jean-Raphaël Champagne, Partner, Fasken</i><br/> <i>Panelists: Natalie Boucratie, Director, Legal Affairs, Gilead Sciences</i><br/> <i>Dara Jospe, Associate, Fasken</i><br/> <i>Ameen Owaisi, Senior Counsel, Johnson &amp; Johnson MedTech Canada</i> </p> |  |
| 12:00-12:30 PM    | <b>Digitizing the Life Sciences Sector</b> <span>▶ LIVE STREAM</span> <p>           The pace of digital transformation within the life sciences sector accelerated rapidly during the pandemic. This session will highlight recent digital developments and overall risk management. Topics will include digital therapeutic/support software, e-labelling, blockchain/smart contracts and generative artificial intelligence.         </p> <p> <i>Kristen Wall, Partner, Norton Rose Fulbright</i><br/> <i>Ywe Looper, Director, Legal Affairs, Boehringer Ingelheim Canada</i> </p>  |  |
| 12:30-1:30 PM     | <b>NETWORKING LUNCHEON</b>   |  |

## Afternoon Concurrent Tracks

1:30-5:00 PM

### TRACK 1: PHARMA

► LIVE STREAM

1:30-2:15 PM

#### What, Why and How – Compliance Considerations for Omni Channel Engagement

As the industry continues to explore channels beyond traditional face to face interaction, there has been a steady integration of both conventional and digital means of communication. This growing digital sophistication has resulted in increased HCP expectations for engagements to be more tailored and more engaging. Explore what exactly omni channel engagement means for compliance, why it is valuable to the different stakeholder groups and how your organization can achieve this model.

*Moderator:* Shurjeel Choudhri, Senior Vice President and Head, Medical & Scientific Affairs, **Bayer Inc.**

*Panelists:* Stefany Singh, Director, Omni Channel Engagement, **Takeda Canada**  
Alex Romanovschi, Vice President, Scientific Affairs Canada, **AstraZeneca Canada Inc.**  
Elena Domazetoska, Global Digital Engagement Catalyst Leader, **Roche**  
Muhammad Ali, Marketing Manager, **Boehringer Ingelheim Canada**

2:15-3:00 PM

#### Ethics and Compliance Update: International Organizations and Coalitions

- Understanding the role our international organizations (IFPMA) and Coalitions (APEC) play in building high- standard ethical business practices and facilitating a level playing field at a global level.
- The impact of international organizations and Coalitions on our domestic work in Ethics
- Find out more about the vital role Patients and Patient organizations play in our international community – Through the Business Ethics for APEC SMEs Initiative, patients and patient organizations serve a central role in the effective implementation of the APEC Kuala Lumpur Principles for Voluntary Codes of Business Ethics in the Medical Technology Sector and of the APEC Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector and serve as vital members of consensus framework agreements for ethical collaboration within many APEC economies
- Getting to know our Canadian Consensus Framework : Understanding how collective action initiatives convene diverse health stakeholders committed to heightening ethical collaboration together through consensus Frameworks

*Lama Abi Khaled, Executive Director, Ethics, Legal & Regulatory, Innovative Medicines Canada*  
*Russell Williams, Senior Vice President Mission, Diabetes Canada*

3:00-3:30 PM

### NETWORKING AND REFRESHMENT BREAK

3:30-4:15 PM

#### Enabling Innovation with SOPs and Policy Frameworks

A compliance framework provides an organization with a structured set of guidelines and standards in order to achieve and maintain compliance. Dive into policy framework, from beginning to end, and discover best tools and practices in creating, implementing and monitoring a policy framework that is holistic, innovative and prioritizes the end user experience.

*Moderator:* Rosy Sasso, Ethics, Compliance & Privacy Consultant, **Rosy Sasso Inc.**

*Panelists:* Andrea Macerollo, Head, Compliance Policy, Training and Communications, **Viatrix**  
John Wanyama, Country Head, Ethics, Risk & Compliance, **Novartis Pharmaceuticals Canada**  
Cara Laurello, North America Ethics & Compliance, **Moderna**

### TRACK 2: MEDTECH

#### Compliance Considerations for MedTech Capital Equipment Value Transfer (Rebates, Discounts, Service)

With fees and annual service costs, the capital acquisition of a medical device must be done in a way that is compliant and ethical. Learn best practices in compliant equipment acquisition and consider how to develop your financial model to be in alignment with the FCPA.

*Ameen Owaisi, Senior Counsel, Johnson & Johnson MedTech Canada*

#### Explore Changes within Procurement

As the procurement landscape within the medical device industry continues to evolve, there are many new compliance considerations that must be put into place. Benchmark with colleagues on best practices in responding to RFPs (requests for proposal), including discussion on value transfer in the form of rebate or discount.

*Linda Pichikian, Senior Market, Procurement Manager, Philips Electronics LLC*

#### Compliance Considerations for Services & Solutions Provided to HCPs and HCl's by Industry

Given the evolution from product to solution and services, take a closer look at the new compliance considerations that must not be factored.

- Dissect what constitutes fair market value, regarding these new compliance considerations
- Hear real life examples of the new tech solutions, such as remote patient management, and the ethics and compliance models that must now be incorporated

*Weronika Ciepulch-Dratwa, Health Care Compliance Officer, MedTechPoland & Baltics, Johnson & Johnson Poland*


## Afternoon Concurrent Tracks (Continued)

|              | <b>TRACK 1: PHARMA</b> <span>▶ LIVE STREAM</span>  | <b>TRACK 2: MEDTECH</b>  |
|--------------|--|--|
| 4:15-5:00 PM | <p><b>Understand the Importance of Soft Skills as a Compliance Leader</b></p> <p>When building your stature as a compliance leader, it takes more than just technical skills. Take a closer look at the impact of behavioral science in building not only a compliance program, but a compliance culture that engages your business.</p> <ul style="list-style-type: none"> <li>• Learn more about the specific soft skills that you can utilize to influence your organization without authority</li> <li>• Engage in discussion on leadership, negotiation, and confidence to help you better navigate tough conversations with colleagues and leadership</li> </ul> <p><i>Moderator:</i> Maria Daher Khouri, Head, Ethics and Business Integrity (EBI) Canada, <b>Sanofi</b></p> <p><i>Panelists:</i><br/>Chris MacDonald, Associate Professor, Director of Ted Rogers Leadership Centre, <b>Toronto Metropolitan University</b><br/>Kathy Brennan, Compliance Business Partner, <b>Roche Canada</b><br/>Rufina Ho, Compliance Officer, UK, Ireland &amp; Canada, <b>Biogen</b></p> | <p><b>Pricing, Challenges and Strategic Value Creation</b></p> <p>Delve into the intricate world of price vs. value, single transactions vs. volume/term commitments, and how to think about strategic value creation to meet stakeholder objectives, manage market pressures and ensuring fair market value. Explore common challenges such as institutional pricing, volume or term commitments, associated challenges and considerations for pricing and extracting value.</p> <p><i>Petter Hansson, General Manager, <b>Germiphene</b></i></p> |
| 5:00-6:00 PM | <b>NETWORKING RECEPTION</b>  |  |

## Day Three: Thursday, June 8th, 2023

|               |  |                            |
|---------------|--|----------------------------|
| 8:00-8:30 AM  | <b>CONTINENTAL BREAKFAST</b>   |                            |
| 8:30-8:45 AM  | <p><b>Conference Co-Chair's Review of Day Two</b></p> <p><i>Anne Mayrand, Head, Legal Affairs &amp; Compliance, <b>Organon Canada, Inc.</b></i><br/><i>Rosy Sasso, President, <b>PBECC – Privacy, Business Ethics &amp; Compliance Consulting</b></i></p>  | <span>▶ LIVE STREAM</span> |
| 8:45-9:30 AM  | <p><b>Preparing for Quebec's Law 25 (Part II)</b></p> <ul style="list-style-type: none"> <li>• Level-Setting on Law 25</li> <li>• Second round of obligations being enforced in 2023</li> <li>• Considerations and best practices to make for preparedness and compliance</li> <li>• Common questions asked and answered</li> </ul> <p><i>Cristina Aguirre, Licensed Paralegal &amp; Privacy Officer, <b>AstraZeneca</b></i></p>   | <span>▶ LIVE STREAM</span> |
| 9:30-10:00 AM | <p><b>Risk Management and the Economic Value of Copyright Licensing for Pharma</b></p> <p>In a world where sharing a published article or research study can be as easy as a mouse click, organizations struggle to manage their risks around copyright infringement while also enabling collaboration and knowledge sharing. Each publisher has its own restrictions on reuse, and risk managers face the challenge of complying with a wide variety of subscription terms and conditions. In addition, as more organizations cut back or eliminate their internal libraries, employees lack guidance on how to share and distribute digital content while remaining within the bounds of copyright laws. By strategic licensing of content – in addition to their traditional subscriptions – pharma organizations can reduce risk and administrative costs and collaborate strategically with others both within and outside the enterprise. Key takeaways include:</p> <ul style="list-style-type: none"> <li>• How licensing content can increase its value to the organization</li> <li>• Why protecting the organization from the risk of copyright infringement matters in the digital age</li> <li>• How copyright licenses benefit the enterprise in streamlined access and risk mitigation</li> </ul> <p><i>Roanie Levy, CEO and President, <b>Access Copyright</b></i></p> | <span>▶ LIVE STREAM</span> |



|  |   |  |
|--|---|--|
| 10:00-10:30 AM   | <b>NETWORKING AND REFRESHMENT BREAK</b>   |  |
| 10:30-11:15 AM   | <b>Deep Dive on Compliance Monitoring, Auditing and Investigations – Shifting the Focus from Output to Outcome</b> <span>▶ LIVE STREAM</span> <p>Though output metrics are undeniably important when it comes to monitoring and measuring a company's compliance program function, it is also undeniable that many compliance officers can easily fall into a rabbit hole of numbers, facts and stats. It is imperative to shift the mindset and become more focused on the <i>outcome</i> of these compliance processes, rather than the <i>output</i>. Discuss the importance of providing meaningful progress of the compliance program and the challenges associated with providing credible evidence.</p> <p><i>Ratika Ghandi, Head, Legal &amp; Compliance, Alcon Canada Inc</i><br/> <i>Olga Zinavenka, Senior Director, Compliance Investigations, Endo International plc</i><br/> <i>Stephan Ekmekjian, Health Care Compliance Officer, Johnson &amp; Johnson MedTech Canada</i></p>   |  |
| 11:15-11:45 AM   | <b>New Models for Patient Engagement – Building Relationships whilst Remaining Compliant</b> <span>▶ LIVE STREAM</span> <ul style="list-style-type: none"> <li>• Explore how to manage the new relationship with patients as stakeholders</li> <li>• Discuss best practices for managing compliance risk in PSPs and patient advocacy programs</li> <li>• Assess what should these relationships look like from a transparency perspective</li> <li>• Consider pre-ethic and compliance assessment in selection and hiring processes</li> </ul> <p><i>Cinda Serianni, Associate General Counsel, Gilead Sciences Canada Inc.</i><br/> <i>Kelly Gorman, Senior Director, Public Policy and Government Affairs, Arthritis Society Canada</i></p>  |  |
| 11:45 AM-1:00 PM   | <b>NETWORKING LUNCHEON</b>  |  |
| 1:00-1:45 PM<br> | <b>DEI SPOTLIGHT: Create a Culture of Inclusion through Health Equity and Business Continuity</b> <span>▶ LIVE STREAM</span> <p>Explore the topic of diversity, equity and inclusion in the workplace, and in the product life cycle, and discuss the key barriers that continue to exist today. Recognize the importance of environmental, social and governance practices in corporate responsibility. Join this discussion to identify key strategies and resources on how to incorporate social determinants of health equity into brand and commercial planning in a compliant manner.</p> <p><i>Moderator: Anne Mayrand, Head, Legal Affairs &amp; Compliance, Organon Canada, Inc</i><br/> <i>Panelists: Eugenia Blackmon, Executive Director, Legal &amp; OEC EEDI Strategist, AbbVie</i><br/> <i>Lindsay Kim Chung, Director, Global Compliance &amp; Ethics, Bristol Myers Squibb</i><br/> <i>Amy Yuda, Associate Director, Compliance, Covis Pharma</i><br/> <i>Joanie Lapalme, Intellectual Property Lawyer, Fasken</i></p> |  |
| 1:45-2:15 PM   | <b>Establish Compliant Partnerships Across Medical and Commercial Teams</b> <span>▶ LIVE STREAM</span> <ul style="list-style-type: none"> <li>• Navigate building an engaged and communicative relationship with your Thought Leader Liaisons (TLLs) and Medical Science Liaisons (MSLs) to ensure positive and productive interaction with Key Opinion Leaders (KOLs)</li> <li>• Differentiate between the TLL and MSL roles and relationships and ensure compliant organization between medical and commercial</li> <li>• Discover how to best optimize your relationships to gather key insights for your product development</li> </ul> <p><i>Randy Levitt, Director, Pharmacovigilance &amp; Medical Affairs, Paladin Labs</i><br/> <i>Josee Brisebois, Head of Medical Affairs, Incyte Biosciences Canada</i></p>   |  |
| 2:15-3:00 PM   | <b>ROUNDTABLE DISCUSSION: Bring your Own Challenge</b> <span>▶ LIVE STREAM</span> <p>Close out your conference experience by getting the answers to the questions you need most. Benchmark with colleagues on the daily challenges you face in your role and what you see as the biggest areas of concern moving forward.</p> <p><i>Weronika Ciepulch-Dratwa, Health Care Compliance Officer, MedTech &amp; Consumer, Poland &amp; Baltics, Johnson &amp; Johnson Poland</i><br/> <i>Mary Jo Climie, Ethics, Risk and Compliance Lead, Novartis</i></p>   |  |
| 3:00 PM  | <b>CLOSE OF CONFERENCE</b>  |  |

# REGISTRATION

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|--|---------------|
| Life Sciences Manufacturers              | \$2,399       |
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### EMAIL

[matt.hannon@informa.com](mailto:matt.hannon@informa.com)

## YOUR KEY POINTS OF CONTACT:



### Content Development:

Callie Mertel  
[callie.mertel@informa.com](mailto:callie.mertel@informa.com)  
**+1-860-328-0155**



### Registration & Teams:

George Barber  
[george.barber@informa.com](mailto:george.barber@informa.com)  
**+1-646-895-7430**



### Event Management:

Bridget Lacey  
[bridget.lacey@informa.com](mailto:bridget.lacey@informa.com)  
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