CANADA'S REGULATORY MEDTECH CONFERENCE 2021

PRESENTED BY Medtech Canada

Preliminary Virtual Conference Agenda

(Subject to Change)

June 2, 2021

Time	Session	Speakers
10:00 – 10:45	**Opening Remarks & What's New from Health Canada** Don't miss this unique opportunity to hear directly from David Boudreau, Director General of the Medical Devices Directorate who will share new developments in the medical devices program at Health Canada.	**David Boudreau**, Director General, Medical Devices Directorate, Health Canada
10:45 – 11:00	Break	
11:00 – 12:00	**Post-Market Surveillance amended Regulations effective in June** In this session, Health Canada will review the scope of post-market surveillance activities and requirements in Canada coming into effect on June 23, 2021.	**Emily Hollink**, Manager, Post-Market, Health Canada **Industry Speaker** TBA
12:00 – 12:30	Break	
12:30 – 1:15	**Clinical Trial Modernization** Learn about new developments in Clinical Trial Modernization. Health Canada will reflect on the current proposal and what you can expect from recent consultations.	**Marie-Pierre Desrosiers** & **Alana Hendry**, Health Canada
1:15 – 2:00	**Medical Device Investigational Testing Pilot** This session provides an overview and the key learnings from the Medical Device Investigational Testing Pilot. The medtech industry will share their experience with the pilot project and offer tips and suggestions for the future.	**Asma Syed**, A/National Manager & **Kevin Chin**, Compliance Specialist, Clinical Trial Compliance Program, Regulatory Operations and Enforcement Branch, Health Canada **Cathy Matthews** Regulatory Affairs Specialist, Edwards Lifesciences (Canada) Inc. **Additional Speakers** TBA

June 9, 2021

Time	Session	Speakers
10:00 – 11:15	**Opening Remarks & Updates on the European Union Medical Device Regulation (EU MDR)** Join us for this unique opportunity to hear from MedTech Europe, the Canadian medtech industry & Health Canada! This session will explore what Canadian manufacturers and importers need to know regarding the status of the Medical Device Regulation activities, key requirements, and potential international impact of EU MDR implementation.	**Diana Kanecka**, Strategies, Special Projects & International Affairs Senior Manager, MedTech Europe **Young Kim**, Director Regulatory Affairs, Johnson & Johnson Medical Companies **Kevin Day**, A/Executive Director, Bureau of Evaluation, Medical Devices Directorate, Health Canada

11:15 – 11:30	Break	
11:30 – 12:30	**Tips & Tricks for Health Canada Submissions** In this session, Health Canada will share best practices for minimizing issues with your device license application.	**Eliane George**, Acting Manager, Regulatory Screening Division, Medical Devices Directorate, Health Canada
12:30 – 1:00	Break	
1:00 – 2:00	**Ask Health Canada** Do you have questions about recent activities, trends, or upcoming initiatives? Hear from representatives from Health Canada in this "ask Health Canada" panel discussion.	Health Canada: **David Boudreau** **Sarah Chandler** **Saira David** **Weimin Zhao** **Colin Foster** **Frédéric Hamelin** **Emily Hollink** **Christine Leckie** **Tanya Ramsamy**

October 20, 2021

Time	Session
10:00 – 10:40	Opening Remarks & What's New from Health Canada
10:40 – 11:15	Challenges in Medical Device Research & Development
11:15 – 11:30	Break
11:30 – 12:30	Divisional Breakouts: • General & Restorative • In Vitro Diagnostic Devices • Digital Health • Musculoskeletal • Cardiovascular
12:30 – 1:00	Break
1:00 – 2:00	Post-Market Regulations Summary Reporting Requirements

October 21, 2021

Time	Session
10:00 – 11:05	Opening Remarks & Interim Order & Product Shortages – Health Canada Learnings
11:05 – 11:35	Upcoming Changes to Guidance Documents & Policies
11:35 – 11:45	Break
11:45 – 12:45	Implementation of Global Medical Device Nomenclature & Unique Device Identifier in Canada
12:45 – 1:00	Break
1:00 – 2:00	Ask Health Canada

On-Demand Sessions

China's Evolving Digital Health Regulatory Framework Cisema's experts present the regulatory framework in China for digital health products. The regulation is rapidly evolving as it tracks the fast-moving technology changes. Key digital health trends will be discussed including telehealth, internet hospitals and AI/ML products. How does risk class classification for the NMPA (former CFDA) work? Are there any fast-track regulatory pathways? What are the latest updates regarding digital health regulations? Cisema's experts will answer your questions and better equip you to access China's digital health market.
The Energy Reset Learn how to effectively manage stress and break through burnout!
More On-Demand Sessions To Be Announced

Don't Miss Out!

Click HERE for more info & registration