AGENDA (Subject to Change)

DATE: 10 JUNE 2025 **TIME: 9:00 AM - 6:00 PM**

CANADA'S REGULATORY & QUALITY MEDTECH CONFERENCE 2025

PRESENTED BY Medtech Canada

Schedule	Topic	Speakers
9:00-9:10 AM	Welcome & Opening Remarks	Mia Spiegelman & Olivier Bourbeau, Medtech Canada
9:10 - 9:40 AM	What's New - Medical Devices Directorate • Don't miss this unique opportunity to hear directly from the Director General of the Medical Devices Directorate (MDD) who will share new developments in the medical devices program at Health Canada.	Bruce Randal, Health Canada
9:40-10:25 AM	Regulatory Enrolment Process & eSTAR • Get the latest updates on Health Canada's progress with eSTAR, REP readiness, and industry challenges.	Sally Prawdzik, Health Canada & Kultar Singh, Medtronic
10:25 -10:55 AM	Break	
10:55-11:25 AM	International Medical Device Regulators Forum Update • Stay informed on the latest global regulatory developments with a summary of key discussions and outcomes from the March International Medical Device Regulators Forum (IMDRF)	Sally Prawdzik, Health Canada & Greg LeBlanc, Cook Medical
11:25-12:30 PM	Pre-Market Review Workshop • MDD's Bureau of Evaluation Management team will respond to questions on how to submit the technical components of a Class III and Class IV medical device licence applications.	Dr. Deepak Sharma, Marc Lamoureux, Constance Campbell, Weimin Zhao, Kevin Day, Patrice Sarrazin, Health Canada
12:30-1:30 PM	Lunch Break	
1:30-2:30 PM	Pre-Market Screening Workshop • MDD's Bureau of Licensing Services Management team will share tips about how to submit successful medical device licence applications, and answer questions from attendees	Colin Foster, Health Canada
2:30-3:30 PM	Medical Device Single Audit Program (MDSAP) • This session will explore the latest developments in the Medical Device Single Audit Program (MDSAP) and its alignment with ISO standards.	Fred Hamelin, Health Canada Mia Spiegelman, Medtech Canada Zaher Kharboutly, DNV Sophia Epshtein Elbrus, TUVSUD
3:30-4:15 PM	Day 1 -Ask the Speakers • Wrap up the first day of the conference with an engaging Q&A session featuring our keynote and panel speakers. This interactive session offers attendees the opportunity to ask questions, gain deeper insights, and explore key topics discussed throughout the day. Don't miss this chance to connect directly with Health Canada and industry leaders! Sponsored by Cencora cencora Innomar Strategies	Session Sponsored by Cencora
4:00 PM	Closing Remarks	
4:15-6:00 PM	Networking Reception • Connect with friends and colleagues during the Networking Reception on June 10 from 4:30pm – 6:30pm. Appetizers will be served.	

AGENDA (Subject to Change)

DATE: 11 JUNE 2025 **TIME: 9:00 AM - 4:15 PM**

CANADA'S REGULATORY & QUALITY MEDTECH CONFERENCE 2025

PRESENTED BY Medtech Canada

Schedule	Topic	Speakers
8:45 - 8:50 AM	Welcome & Opening Remarks	Mia Spiegelman & Olivier Bourbeau, Medtech Canada
8:50 - 9:05 AM	What's New from the Regulatory Operations and Enforcement Branch • Get the latest updates on ROEB's new initiatives, current structure, and key developments shaping regulatory oversight.	Christine Leckie, Health Canada
9:05-9:30 AM	What's New from the Regulatory Operations and Enforcement Branch • 2025-26 Program Priorities: MDEL Regulatory Package Update	Erin Skuce & Matt Ryan, Health Canada
9:30-9:55 AM	Medical Device Establishment License Inspection Program • Gain a comprehensive understanding of the Medical Devices Inspection Program, including its risk-based inspection approach (SRP), foreign inspection strategy, and best practices for preparation. This session will also highlight common inspection observations, helping medical device companies navigate compliance requirements effectively.	Nasila Ali, Health Canada
9:55-10:10 AM	Ask the Morning Speakers • Join us for an interactive session where you can ask questions directly to the morning's speakers. This open forum allows attendees to dive deeper into the topics presented, clarify any points of interest, and engage in insightful discussions with industry experts.	
10:10-10:40 AM	Break	
10:40-11:10 AM	Medical Device Shortages • Explore the latest developments in medical device shortages, including insights from recent consultations, ongoing initiatives, and industry perspectives.	Dheeman Vaydia, (TBC) IQVIA & Mia Spiegelman, Medtech Canada
11:10-11:45 AM	Post Market Surveilance • This session will provide an overview of the Medical Devices Compliance Verification Program, covering key aspects such as triaging complaints and recalls, compliance verification tools, and regulatory expectations.	Ladan Rabieymotemaen, Health Canada
11:45-12:25 PM	Medical Device Establishment Licence Program • This session will provide a brief overview of MDEL applications, recent updates, and key changes.	Marie-Odile Gomis & Barbara Morgan, Health Canada
12:25-1:25 PM	Lunch Break	
1:25-2:15 PM	Servicing & Installation: An Industry Perspective • This session will explore key challenges and best practices in medical device servicing and installation from an industry perspective.	Michael Frosina, ConMed; Germaynne Gibson, Alcon & Adrian Jess, ConMed
2:15-2:55 PM	2024/2025 Summary: Medtech Canada working for it's Members • Join Medtech Canada for an overview of the ongoing and completed initiatives led by our various committees, highlighting how they support our members and strengthen the medtech ecosystem.	Mia Spiegelman, Amy Swanson, Rob Pankhurst & Olivier Bourbeau, Medtech Canada Sandra Leffler, Leffler Consulting
2:55-3:55 PM	Day 2 - Ask the Speakers Wrap up the second day of the conference with an engaging Q&A session featuring our keynote and panel speakers. This interactive session offers attendees the opportunity to ask questions, gain deeper insights, and explore key topics discussed throughout the day. Don't miss this chance to connect directly with Health Canada and industry leaders! • Sponsored by IQVIA Medtech IQVIA MEDTECH	Sponsored by IQVIA
3:55 - 4:00 PM	Closing Remarks	Mia Spiegelman & Olivier Bourbeau, Medtech Canada

AGENDA (Subject to Change)

DATE: 12 JUNE 2025 **TIME: 9:00 AM - 2:30 PM**

CANADA'S REGULATORY & QUALITY MEDTECH CONFERENCE 2025

PRESENTED BY Medtech Canada

Schedule	Topic	Speakers
8:45- 8:50 PM	Welcome & Opening Remarks	Mia Spiegelman & Olivier Bourbeau, Medtech Canada
8:50-9:20 AM	Environment & Climate Change Canada • Join Environment & Climate Change Canada (ECCC) for an update on plastics and PFAS regulations, including the evolving regulatory structure and what's on the horizon. This session will also provide a high-level look at how international agreements, such as the UN Plastics Treaty and the Stockholm Convention, influence Canadian policy and decision-making.	George Kendros, Environment & Climate Change Canada
9:20-10:20 AM	The Balancing Act: Environment & Patients • Join this panel discussion on balancing environmental concerns with access to healthcare products, focusing on the Plastics and PFAS registries and next steps.	Nicolas Pugliano, W.L Gore, Lisa Schellenberg, Solventum & George Kendros, Environment & Climate Change Canada
10:20-10:50 AM	Break	
10:50-11:20 AM	Public Release of Clinical Information • This session will provide an update on the Public Release of Clinical Information project, including its progress and key considerations.	Marcin Boruk, Health Canada La-Toya Salmon, Abbott
11:20-11:40 AM	MDSAP/ISO 13485: What's Next for Quality Management Systems • Gain valuable insights into the future of ISO 13485, including updates based on the latest systematic review outcomes that could impact your compliance strategy and global market access.	Scott Sardeson, St. Cloud State University
11:40-12:25 PM	International Regulations & WHO • Explore the role of the World Health Organization (WHO) in shaping international regulatory standards, including MDSAP recognition and UK MHRA alignment.	Tatjana Sachse, Sidley Stephen Lee, Association of British HealthTech Industries (ABHI)
12:25-12:55 PM	Guidance on Wireless Equipment Certification for Manufacturers • Join representatives from Innovation, Science and Economic Development Canada (ISED) for an overview of the wireless equipment certification process. This session will provide manufacturers with key guidance, regulatory updates, and best practices to ensure compliance when bringing wireless-enabled medical devices to market in Canada.	Stephan Meyer & Nicolas Desmarais, ISED
12:55-1:00 PM	Closing Remarks	Mia Spiegelman & Olivier Bourbeau, Medtech Canada
1:00-2:00 PM	**Lunch and Networking Break** • Wrap up your day with a light lunch following the closing session. Whether you're sticking around to connect with fellow attendees or heading straight to the airport, we've got you covered—grab-and-go options will be available for those with travel booked. The room will remain open for networking and casual conversation until 2:30pm	