AGENDA (Subject to Change)

CANADA'S REGULATORY & QUALITY MEDTECH CONFERENCE 2025

PRESENTED BY Medtech Canada

Important Notice: 2025 Regulatory & Quality Medtech Conference Date Change

Due to the calling of a federal election, Medtech Canada has rescheduled the 2025 Regulatory & Quality Medtech Conference to June 10–12, 2025. This adjustment ensures full participation from Health Canada officials, allowing for the most relevant regulatory updates and meaningful engagement post-election.

We appreciate your understanding and remain committed to delivering a high-value experience. For any questions, please contact Karan Mehta at kmehta@medtechcanada.org

Stay tuned for more details—we look forward to seeing you in June 2025!

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

CANADA'S REGULATORY & QUALITY MEDTECH CONFERENCE 2025

PRESENTED BY Medtech Canada

Schedule	Topic
9:00-9:10 AM	Welcome & Opening Remarks
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.
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.
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)
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.
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
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.
3:30-3:50	Break
3:50-4:25 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
4:25 -4:30 PM	Closing Remarks
4:30-6:00 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
8:45 - 8:50 AM	Welcome & Opening Remarks
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.
9:05-9:30 AM	What's New from the Regulatory Operations and Enforcement Branch • 2025-26 Program Priorities: MDEL Regulatory Package Update
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.
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
10:40-11:25 AM	Medical Device Shortages • Explore the latest developments in medical device shortages, including insights from recent consultations, ongoing initiatives, and industry perspectives.
11:25-11:55 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.
11:55-12:35 PM	Medical Device Establishment Licence Program • This session will provide a brief overview of MDEL applications, recent updates, and key changes.
12:35-1:35 PM	Lunch Break
1:35-2:25 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.
2:25-2:55 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.
2:55-3:10 PM	Break
3:10-4:10 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
4:10-4:15 PM	Closing Remarks

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
9:00-9:05 AM	Welcome & Opening Remarks
9:05-9:35 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.
9:35-10:35 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.
10:35-11:05 AM	Break
11:05-11:35 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.
11:35-12:35 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.
12:35-1:35 PM	Lunch Break
1:35-2:25 PM	Day 3 - Ask the Speakers Wrap up 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!
2:25-2:30 PM	Closing Remarks