# CAPRA 2025 Medical Device & Combination Product Symposium

CAPRA will host the Medical Device and Combination Product event in collaboration with Health Canada, the FDA, and industry leaders to support our members.

This excellent event will start with an update on new developments in MDD from a policy and operations perspective by the Director General of MDD. We will also discuss the MLMD guidance and its impact on the industry, followed by various updates on MD guidance, common submission deficiencies, combination product and Medical Device classifications, and the regulation of Drug Delivery Systems to help you navigate submission strategies. Attendees will learn how AI can enhance your regulatory intelligence. We will also cover what to expect in the areas of combination products and the Medical Device Single Audit Program (MDSAP). Additionally, participants will gain insights into regulatory expectations and best practices for maintaining compliance from the Medical Devices Compliance Program, ROEB.

This event will deepen your professional knowledge through practical regulatory insights delivered via in-depth panel discussions with our outstanding speakers.

CAPRA ACPR

Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

**December 3, 2025**
**Westin Airport Hotel**
**950 Dixon Road**
**Toronto, ON, Canada**

## Agenda

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| **7:00 - 8:00 am** | **Registration and Breakfast** | |
| | **8:00 - 8:05 am** | **Welcoming Remarks** |
| | **8:05- 8:30 am** | **Opening Remarks, followed by Q&A**<br><br>The Director General of the Medical Devices Directorate will present MDD's organizational structure, recent performance metrics, and what's new in MDD from a policy and operations perspective.<br>○ Bruce Randall, Director General, Medical Devices Directorate, Health Canada. |
| | **8:30 - 9:00 am** | **Overview of the MLMD guidance and its impact on the industry, followed by Q&A**<br><br>During this session, the Manager of MDD's Digital Health Division will discuss the guidance provided in the MLMD guidance document, including the introduction of the concept of predetermined change control plans (PCCPs).<br>○ Marc Lamoureux, Manager, Digital Health Division, Bureau of Evaluation, Medical Devices Directorate (Virtual) |
| | **9:00 - 10:20 am** | **Medical Device Guidance Update, followed by Q&A**<br>• This section will discuss changes made to the guidance document on how to interpret **"Significant changes**" (20 mins)<br>○ Marc Lamoureux, Manager, Digital Health Division, Bureau of Evaluation, Medical Devices Directorate (Virtual)<br><br>• This presentation provides an overview of Health Canada's regulatory activities under the Regulatory Operations and Enforcement Branch. Hear about the various drivers behind the regulatory amendments and proposed changes to the **Medical Device Establishment Licensing Framework (Phase I & II).** (20 mins)<br>○ Matthew Ryan, Manager, Office of Regulatory and Strategic Activities, ROEB<br><br>• Sharing the impacts of agile licensing for medical device manufacturers as outlined in the guidance on **Agile licensing** for medical devices (20 mins)<br>○ Sally Prawdzik, Director, Bureau of Policy and International Programs, Medical Devices Directorate (Virtual)<br><br>• Discussion on the updates to the guidance on **Management of Applications for Medical Device Licences,** including the revised reconsideration process and the new additional information request option. (20 mins)<br>○ Sally Prawdzik, Director, Bureau of Policy and International Programs, Medical Devices Directorate (Virtual) |

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| | **10:20 -10:35 am** | **Question and Answer Period** |
| **10:35 – 11:00 am** | **Coffee Break (25 mins)** | |
| | **11:00 – 11:45 am** | **Common Medical Device submission deficiencies, followed by Q&A**<br><br>MDD's Director of the Bureau of Licensing Services will discuss a few common challenges with license applications, as well as tips and tricks to facilitate the application process, including the meeting request framework<br>○ Colin Foster, Director, Bureau of Licensing Services, Medical Devices Directorate, Health Canada |
| | **11:45 – noon** | **Medical device submissions deficiencies from the industry Perspective, followed by Q&A**<br>Medtech Canada has been working alongside Health Canada to provide industry signals for areas of concern and improvement. Mia will discuss a bit of the historical collaboration, areas of success, and ongoing engagement.<br>○ Mia Spiegelman, VP, Regulatory, Quality and Environmental Affairs, Medtech Canada |
| | **Noon – 12:15 pm** | **How can the industry navigate regulatory operations for medical devices and combination products using artificial intelligence, followed by Q&A**<br>AI will not replace RA specialists. Instead, AI will improve regulatory intelligence by helping RA teams to predict regulatory outcomes, handle data, automate processes, and support decision-making, thereby enabling the development of more combination medical device products.<br><br>○ Tanima Ghosh, Senior Executive, QMB-Qualiverse |
| | **12:15 – 12:30 am** | **Question and Answer Period** |
| **12:30 – 1:30 pm** | **Lunch Break** | |
| | **1:30 – 1:50 pm** | **Medical Device Classification and Combination Product, followed by Q&A**<br>This session will discuss how Health Canada classifies combination products<br>○ Colin Foster, Director of the Bureau of Licensing Services, Medical Devices Directorate, Health Canada. |
| | **1:50 – 2:10 pm** | **Regulation of Drug Delivery Systems from the Industry Perspective, followed by Q&A**<br>This presentation will focus on the nuances of how drug delivery systems are regulated by Health Canada, for example, the impact of how it is co-packaged and the intended use of individual components.<br><br>○ Mary Speagle, Senior Director, Regulatory Affairs, Innomar Strategies Inc. |

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| | **2:10 – 2:30 pm** | **Overview of the Combination Product from the FDA's perspective, followed by Q&A**<br>Overview of the submission process and jurisdiction<br>O TBD, Office of Combination Products, FDA |
| | **2:30 – 2:40 pm** | **Question and Answer Period** |
| | **2:40 – 3:05 pm** | **Combination Products and MDSAP – what to expect, followed by Q&A**<br>This session will offer an overview of MDSAP certification activities for combination products and highlight some of the key differences compared to conventional medical devices and IVDs.<br>○ Fred Hamelin, Manager, Quality Systems Section, Bureau of Planning and Operations, Medical Devices Directorate, Health Canada |
| | **3:05 -3:20 pm** | **Industry Perspective on the Medical Device Single Audit Program (MDSAP), followed by Q&A**<br>The role of industry as a participant in MDSAP is evolving. As the system becomes more mature, collecting and providing insights on areas of improvement and enhancement are key to continued adoption and success within international communities and jurisdictions. Mia will discuss various industry-led collaborations taking place both directly and indirectly in support of MDSAP.<br>○ Mia Spiegelman, VP, Regulatory, Quality and Environmental Affairs, Medtech Canada |
| | **3:20 -3:30 pm** | **PM Break** |
| | **3:30 – 3:50 pm** | **Overview of Medical Devices Compliance Program from a Compliance and Enforcement Perspective, followed by Q&A**<br>Gain a comprehensive understanding of the current structure, new initiatives, and key priorities of the Medical Devices Compliance Program. The session will offer an overview of the Medical Devices Establishment Licence Inspection and the Medical Devices Compliance Verification Programs, emphasizing the risk-based inspection approach, essential aspects of triaging complaints and recalls, and common findings from inspection activities. Participants will also receive insights into regulatory expectations and best practices to support compliance.<br>○ Erin Skuce, Director, Medical Devices Compliance Program, ROEB, Health Canada. |
| | **3:50 – 4:00 pm** | **Question and Answer Period** |
| **4:00 - 4:30 pm**<br>(30 mins) | **Panel Discussion for all Topics and Closing Remarks** | |

**Registration, Fees and Hotel Information:**

1. CAPRA member: $610 + HST in-person or $550 + HST online access
2. Non-member: $720 + HST or $640 + HST online access
3. Students: $368* + HST for in-person or online access
   *Limited spaces are available; proof of full-time registration in a Regulatory Programme is necessary.
4. Sponsorship and Vendor booth:

| Sponsorship Level | Benefits | Cost |
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| Platinum | 1. Company logo* and hyperlink to the company on all event media broadcasts and the CAPRA event webpage.<br>2. Promotion of the company's logo before and during the event.<br>3. One page of digital collateral to be sent to all attendees by the event host.<br>4. Two attendees | $2480 + HST |
| Gold | 1. Company logo* and company hyperlink on all event Media broadcasts and the CAPRA event webpage<br>2. Two attendees | $2080 + HST |
| Vendor | 1. Two attendees | $1792 + HST |
| | 2. One attendee | $1162 + HST |

*Logo to be provided in as high a resolution as possible in any of the following file types: jpg, png, .ai, pdf, .eps

**Registration Procedure:**

**The registration runs from September 02, 2025, to November 19, 2025.** Participants may be substituted, but no refunds will be issued.

**Westin Airport Hotel Reservation Information:**

Special room rates of $249 per night (plus applicable taxes and fees) for the CAPRA Symposium are subject to availability. **Make your reservation before November 11, 2025, via the link: Book your group rate for CAPRA Meeting** or **call 1-866-837-5184** for individual reservations. Guests making such reservations must identify as members of the CAPRA group — complimentary wireless high-speed internet.

HST Registration No. 85475 8349RT0001

**Disclaimer**

CAPRA reserves the right to modify the conference details, including but not limited to the speakers' identities, topics, locations, and timing, without prior notice. If the meeting is cancelled for any reason outside of CAPRA's control, CAPRA will not be responsible for any costs or losses incurred.