CAPRA 2026 Symposium
Harnessing the evolving regulatory technology landscape



This regulatory technology event highlights exciting discussions on the future of the regulatory landscape, exploring international regulatory modernization and its potential impact on Canada, as well as Canadian-focused regulatory modernization through collaboration and innovation.

We are pleased to welcome Kelly Robson, Director General at Health Canada, to open the event, which will cover a range of key initiatives.

Many of our leading industry experts, along with speakers from Health Canada, will help attendees explore the latest ICH topics, trusted regulatory areas, advanced technological solutions, and the evolving regulatory landscape. We will also hear about Health Canada's AI journey, how to achieve real-time exchange and review using FHIR, APIs, and AI, and how global AI regulations influence the use of AI in regulatory decision-making across the life sciences and healthcare sectors, including the impacts of different AI model types. These topics aim to foster dialogue and understanding between Health Canada and companies in a rapidly changing regulatory environment.

We encourage you not to miss this rare opportunity and to share this agenda with your regulatory affairs and regulatory operations teams and your R&D colleagues.

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December 1, 2026
Westin Airport Hotel
950 Dixon Road
Toronto, ON, Canada

Symposium Agenda

7:00 - 8:00 am	**Registration and Breakfast**	
	8:00 - 8:05 am	**Welcoming Remarks**
	8:05 – 8:35 am	**Opening Remarks and Overview, followed by Q&A.** Kelly will provide an update on key Health Canada initiatives aimed at strengthening international regulatory collaboration and efficiency. The update will cover progress on regulatory reliance and work-sharing among global regulators, including developments related to the ACCESS Consortium and Project Orbis, efforts to modernize regulatory processes, and recent activities and priorities within the International Council for Harmonization (ICH). a. Reliance & Work-sharing amongst regulators b. Modernization of regulatory exchange & interactions c. ACCESS / Orbis d. ICH Update • Kelly Robinson, Director General, Health Canada.
	8:35 – 10:05 am	**ICH M4Q R2, M16, and M11 Overview, followed by Q&A.** Each ICH sub-topic will cover: What is it? What is happening now? What is expected "tomorrow," and what are the implications for R.A. teams in Canada? • Industry speaker: Mark Gray, Senior Adviser, Submission Strategy, LORENZ. • Industry speaker: Laurent Lefebvre, Head, RA Data & Technology. • Industry speaker: Ron Fitzmartin, Principal Consultant, Decision Analytics, LLC.
	10:05 – 10:30 am	**From Documents to Dynamic Data: How FHIR is reshaping Regulatory Affairs, followed by Q&A.** This session looks at the transition from static, document-based regulatory submissions to a connected, real-time data environment. It highlights how FHIR standards for labelling, CMC, response to questions, and real-time submissions via API enable interoperable exchange of structured regulatory information, supporting faster interactions, greater transparency, and more efficient regulatory lifecycles. • Industry speaker: Craig Anderson, Business Product Director, Johnson & Johnson Innovative Medicine.
	10:30 – 10:50 am	**Q&A for the above topics**
	10:50 – 11:20 am	**Coffee Break/Vendor booths**
	11:20 – 11:45 am	**AI in Regulatory Decision-Making: Global Policies, Model Types, and Emerging Trends, followed by Q&A.** Overview of how global AI regulations are influencing the use of AI in regulatory decision-making across life sciences and healthcare, the impact of different AI model types, and emerging trends in AI initiatives aimed at accelerating regulatory review processes. • Industry speaker: Lorelle Leonienco, PMP, Executive Lead – Government & Regulatory Intelligence, LORENZ Life Sciences Group

	11:45 – 12:15 pm	**eCTD 4.0: Global Implementation and Impact on Canadian Landscape, followed by Q&A.** eCTD 4.0 is already implemented in Japan, and the FDA and the EMA have strong implementation timelines. This presentation covers eCTD 4.0 principles and the impact of global implementation on the Canadian submissions lifecycle, including forward compatibility and eCTD efficiencies. • Industry speaker: Khaled Yahiaoui, Associate Director, Regulatory Affairs Operations at Merck Canada.
	12:15 – 12:35 pm	**Q&A for the above topics**
	12:35 – 1:40 pm	**Lunch Break/Vendor booths**
	1:40 – 1:55 pm	**Health Canada eCTD 4.0 Update, followed by Q&A.** Health Canada will present the current status of eCTD 4.0 implementation and upcoming plans. The plan includes updates to the Implementation Guide and related validation documents, along with proposed dates for a pilot and full implementation. Health Canada Speakers • Joseph Mikhael, Manager of Digital Regulatory Operations in Health Canada's Health Products and Food Branch. • Irena Pastorekova, Supervisor of Regulatory Enablement Services division in Health Canada's Health Products and Food Branch.
	1:55 – 2:15 pm	**Artificial Intelligence in Regulatory Operations: Health Canada's Journey, Use Cases, and Lessons Learned, followed by Q&A.** This presentation will provide an overview of Health Canada's use of Artificial Intelligence (AI) to support regulatory operations and digital modernization efforts. It will highlight how AI is being leveraged to improve productivity, enhance information management, support regulatory review processes, and reduce administrative burden, while maintaining appropriate governance, privacy, security, and human oversight. The session will also share key lessons learned, current use cases, and future opportunities for responsible AI adoption within the regulatory environment. Health Canada Speakers: • Tim MacDonald, Project Lead for the Enablement of Artificial Intelligence in Health Canada's Health Products and Food Branch (HPFB). • Seema Verma-Pharasi, Executive Director with Health Canada's Health Products and Food Branch.
	2:15 – 2:35 pm	**XML Product Monographs: Health Canada Perspectives on Implementation, Lessons Learned, and Next Steps, followed by Q&A.** This presentation will provide Health Canada's perspective on XML implementation activities, including progress to date, key lessons learned, and common validation

		issues and errors observed during onboarding and use. It will also outline Health Canada's planned next steps to support continued implementation and adoption. The presentation will conclude with a question-and-answer period. Health Canada Speakers: • Michael Wood, Senior Regulatory Information Officer, Business Informatics Division, Health Products and Food Branch, Health Canada. • Tracy E Brown, Senior Project Manager, Business Informatics Division, Health Products and Food Branch, Health Canada
	2:35 – 2:55 pm	**XML Product Monographs: An Industry Perspective on Mandatory Implementation and Transition Challenges, followed by Q&A.** Building on Health Canada's Notice issued on November 18, 2024, this presentation offers an industry perspective on the mandatory implementation of XML Product Monographs (PMs) for New Drug Submissions. It will highlight key successes, practical lessons learned, and recommendations from early implementation, while also discussing the challenges of transitioning existing PMs. The session will further explore readiness considerations for continued voluntary use of XML PMs across other submission types and the path toward broader implementation. • Industry Speaker: Nadine Mukri, Manager, Operations, Regulatory Affairs, Bristol Myers Squibb.
	2:55 – 3:15 pm	**Q&A for the above topics**
	3:15 – 3:40 pm	**PM Break/Vendor Booths**
	3:40 – 4:05 pm	**Health Canada to provide an update on the e-PMI initiative, followed by Q&A.** Health Canada is streamlining prescription drug labelling to reduce the administrative and regulatory burden on industry. This presentation will provide updates on key labelling initiatives, including the Plain Language Labelling Guidance Document, XML-PM, and paper package insert waivers. It will also describe Health Canada's risk-based approach to paper package insert inclusion decisions, including framework development, implementation experience, and harmonization across regulatory directorates to enhance consistency, transparency, and stakeholder responsiveness. Health Canada Speakers: • Veronica Yip, Manager of the Labelling Division in PDD. • Amanda Starr, Clinical Scientific Evaluator in the Metabolic and Musculoskeletal Drugs Division of the PDD.
		Proposed path forward for electronic Product Information (ePI) in Canada, followed by Q&A. Proposed path forward for electronic Product Information (ePI) in Canada,

	4:05 – 4:30 pm	followed by Q&A. A coalition of 10 stakeholders across the pharmaceutical supply chain is working to advance e-labelling for human prescription drugs — replacing the limits of paper package inserts with something patients can actually use. This session presents a ready-to-run pilot: a QR code and short link on the pharmacy print-out patients already receive, resolving directly to Health Canada's approved Patient Medication Information — no app, no new system, nothing for Health Canada to build. Attendees will see how the pilot could work end to end, what it measures, how data governance and bilingual access are built in, and how digital health companies could chart the path forward for e-labelling in Canada. Industry Speakers: • Andrée-Anne Chevalier, CEO of Vigilance Santé. • Michaël Cardinal, Co-Founder & CEO of AppGuide.
	4:30 – 4:55 pm	**Trusted Regulatory Spaces (TRS) and the evolution of collaboration, followed by Q&A.** Trusted Regulatory Spaces: The Future of Regulatory Exchange, Interaction, and Collaboration. A high-level overview of some of the technology solutions transforming how companies and agencies work together, from ACCESS and PRISM to Cloud-Based submissions. Industry speaker: Charles Mathis, Regulatory Solutions Architect, LORENZ Life Sciences Group.
	4:55 – 5:25 pm	**Panel Discussion for all topics**
	5:25 – 5:30 pm	**Closing Remarks**