2026 CAPRA Symposium

Building high-quality submissions - a collaborative event with Health Canada



Join CAPRA and Health Canada for an engaging symposium focused on building high-quality regulatory submissions that support more efficient reviews and timely access to medicines in Canada. Through updates from Health Canada review programs and perspectives from generic, biologic, biosimilar, and branded pharmaceutical stakeholders, attendees will gain practical insight into common submission challenges, recurring deficiencies, backlog-reduction initiatives, and opportunities to improve predictability, consistency, and collaboration across the submission lifecycle.

The program is designed to be highly interactive, with roundtable discussions facilitated by Health Canada and informed by pre-shared questions and attendee input. Participants will have the opportunity to exchange ideas, raise concerns, explore practical solutions, and leave with clearer expectations for stronger submissions. Whether you work in regulatory affairs, quality, compliance, or submission strategy, this event offers a valuable forum to connect with peers and regulators while contributing to shared improvements in Canada's regulatory review process.

We encourage you to attend this event in person to participate in the roundtable and to share it with your colleagues across R&D, RA, and quality groups to gain insights, exchange ideas, and improve submission success.

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December 2, 2026
Westin Airport Hotel
950 Dixon Road
Toronto, ON, Canada

7:00 - 8:00 am	**Registration and Breakfast**	
	8:00 - 8:05 am	**Welcoming Remarks**
	8:05 – 8:35 am	**Opening Remarks, followed by Q&A.** Set the tone for the rest of the day by explaining why this event is important to both Health Canada and sponsors. • Health Canada Speaker: Kelly Robinson, Director General and Senior Executive Director, Health Canada.
	8:35 – 9:05 am	**Health Canada's Generic Drug Review Program: Backlog Reduction and Current Initiatives, followed by a Q&A.** This session will update the Bureau of Pharmaceutical Sciences on efforts to reduce the generic drug submission backlog and improve the efficiency of Health Canada's generic drug review program. The presentation will include workload and backlog data, progress on key action items, and updates on current initiatives aimed at enhancing review efficiency, predictability, and timely access to generic medicines in Canada. • Health Canada speaker: Dr. Tanya Ramsamy, Interim Director, Bureau of Pharmaceutical Sciences
	9:05 – 9:35 am	**PDD Reviewers' perspectives on building high-quality submissions, followed by Q&A.** This session will provide key observations identified by reviewers during assessment of drug review submissions, highlighting recurring strengths and challenges, with practical insights to support more effective and efficient submissions Health Canada Speakers: • Dr. Amanda Starr, Clinical Evaluator, Pharmaceutical Drugs Directorate. • Dr. Christiane Grise-Bard, Associate Director of the Bureau of Pharmaceutical Sciences.
	9:35 - 10:05 am	**BRDD Reviewer perspectives on the Quality and Clinical considerations that contribute to high-quality submissions, followed by Q&A.** Strong, complete, and comprehensive submissions are critical to timely, efficient review. These presentations will highlight best practices for the Quality and Clinical information included in a drug submission. Discussions will cover considerations for structuring the information, how best to present supporting information, and how to make the most of available resources (e.g., pre-submission meetings, General Note to Reviewer, Foreign Review Information). Health Canada Speakers: • Rachel Hanna, Quality Evaluator, Biological and Radiopharmaceutical Drugs Directorate, Health Canada • Mitchell Baldwin, Clinical Evaluator, Biological and Radiopharmaceutical Drugs Directorate, Health Canada
	10:05 -10:35 am	**Q&A for the above topics**
10:35 - 11:05 am	**AM Break/Vendor booths**	

	11:05 – 11:35 am	**Industry perspectives: Common issues observed during review of NDSs, ANDSs and Establishment Licensing Applications** We will discuss common issues observed in recent submissions to Health Canada. The presentation will cover New Drug Submissions, Abbreviated New Drug Submissions, and Establishment Licensing Applications. It will review common deficiencies and trends identified in these submissions, including New Drug Submissions (NDSs), Abbreviated New Drug Submissions (ANDSs), and Establishment Licence Applications (ELAs). Industry speakers: • Betty Cory, President of Regxia • Lori de Munnik, Vice President of Regxia
	11:35 – 11:55 am	**Generic industry perspectives on submission quality, followed by Q&A.** The current state of generic review challenges is changing regulatory filing strategies. CGPA will share member reflections on these challenges and lessons learned to improve the review experience. Priority solutions will be proposed for Health Canada to improve communication and help industry meet expectations. • Industry Speaker: Kristin Willemsen, Vice President, Scientific and Regulatory Affairs at Canadian Generic Pharmaceutical Association.
	11:55 – 12:15 pm	**Q&A for the above topics**
12:15 – 1:30 pm	**Lunch Break/Vendor Booths**	
	1:30 – 2:30 pm	**Roundtable discussion to share key submission challenges, concerns, and solutions, followed by sharing key points from each table. Health Canada will facilitate the discussions.** These roundtable exercises are based on pre-shared questions from HC and those submitted by attendees. HC will collect and retain these Q&As after the event.
	2:30 – 2:55 pm	**Health Canada's Innovator Drug Review Program: Managing Workload in a Changing Regulatory Environment, followed by a Q&A.** This session will provide an update on Health Canada's efforts to manage increasing workload pressures and strengthen the sustainability of the human drug review program. The presentation will highlight key lessons learned from recent backlog management initiatives, progress on actions taken in response to stakeholder feedback, and efficiencies implemented to improve transparency, predictability, and review performance. It will also provide an overview of future modernization efforts, including international collaboration, reliance, and sustainable workload management approaches. • Health Canada speaker: Elana Cherry, Director of the Centre for Blood, Blood Products and Biotherapeutics.
	2:55 – 3:15 pm	**Consistency of Submission Quality from the Industry's Perspective for Biologics, followed by Q&A.** This presentation probes the definition of a high-quality submission from the perspective of a global biopharma organization, what sets Biologic submissions apart with Health Canada, and the importance of alignment within Health

		Canada as well as with major international Health Authorities. The symbiotic relationship between regulatory modernization initiatives and building quality submissions at scale will be explored to anticipate opportunities for simplification and improve the consistency of submission quality. • Industry Speaker: Amy Tsung, CMC group manager, GSK.
	3:15 – 3:30 pm	**Q&A for the above topics**
3:30 – 3:50 pm	**PM Break/Vendor Booths**	
	3:50 – 4:10 pm	**Biosimilars industry perspectives on Canadian submissions, followed by Q&A.** Perspectives from Biosimilars Canada members on review challenges and solutions, and how science-based changes to Health Canada's submission framework will support future biosimilar developments for Canadians. • Industry Speaker: Sukhvir Hundal, Head of Regulatory Affairs, Biocon Biologics Canada and Co-Chair, Biosimilars Canada Science Committee
	4:10 – 4:30 pm	**Branded Pharmaceuticals' perspectives on Canadian submissions: Issues and Resolutions, followed by Q&A.** Common issues observed in recent New Drug Submissions to Health Canada will be discussed. This presentation will review common deficiencies and trends identified. • Industry Speaker: Denise David, VP Scientific Affairs, Kye Pharmaceuticals
	4:30 – 4:50 pm	**Health Product Compliance Directorate- Strategic Outlook and Program Updates, followed by Q&A.** This presentation will update attendees on the Health Product Compliance Directorate's key priorities, regulatory and operational developments, modernization initiatives, and emerging issues shaping the compliance landscape. The session will also highlight areas of focus and anticipated developments relevant to regulated parties and stakeholders Health Canada Speaker: • Melissa Sutherland, Director, Health Product Inspection and Licensing Division, Health Canada • Toufic Zayoun, Manager, Health Canada within the Regulatory Operations and Enforcement Branch (ROEB), specifically in the Health Product Compliance Directorate (HPCD)
	4:50 – 5:00 pm	**Q&A for the above topics**
5:00 – 5:25 pm	**Panel Discussion for all Topics**	
5:25 - 5:30 pm	**Closing Remarks**	