

CAPRA 2025 Biologics and Biosimilar Symposium



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation



CAPRA will host this Biologics and Biosimilar event with Health Canada and Industry leaders. This collaborative event represents a valuable opportunity to acquire insights and regulatory knowledge that will assist in addressing the challenges posed by the increasing complexity of scientific developments.

By attending, you will gain practical regulatory insights through in-person panel discussions with all speakers, enhancing your professional knowledge and skills.

We encourage you to share this news with your colleagues.

**March 28, 2025,
Westin Airport Hotel
950 Dixon Road
Toronto, ON, Canada**

Symposium Agenda

7:15 - 8:25 am	Registration and Breakfast	
	8:25 - 8:30 am	Welcoming Remarks
	8:30 - 8:45 am	Opening Remarks <ul style="list-style-type: none"> Sophie Sommerer, Director General, BRDD, Health Canada.
	8:45 - 9:30 am	Preparation of the Quality Information for Drug Submissions in the CTD Format: Biotherapeutic and Blood Products, followed by Q&A <p>The three CTD Guidance documents applicable to Conventional biotherapeutic products, Biotechnological/biological (Biotech) products, and Blood products have been merged into one document as they shared more than 95% of the content. The revised guidance document was posted in April 2024. An overview of the major changes will be provided during this session.</p> <ul style="list-style-type: none"> Hugo Hamel, Associate Director, CBBB, BRDD, Health Canada
	9:30 - 10:15 am	Update on ICH M4Q (R2), followed by Q&A <p>The CTD guidance document M4Q(R1) has been revised for the first time since 2001. It provides a harmonized structure and format for presenting CMC (Chemistry, Manufacturing, and Controls) information in a registration dossier. This session will present an overview of the revised guidance document.</p> <ul style="list-style-type: none"> Hugo Hamel, Associate Director, CBBB, BRDD, Health Canada, Health Canada
	10:15 -10:25 am	Question and Answer Period
10:25 - 10:45 am	Coffee Break	
	10:45 – 11:20 am	Biosimilar Guidance Update, followed by Q&A <p>Health Canada’s Biologic and Radiopharmaceutical Drug Directorate (BRDD) has undertaken a review of its guidance document on Information and Submission Requirements for Biosimilar Biologic Drugs (Biosimilars guidance), which was last updated in 2016. A section-by-section review of the current guidance is being conducted, with the objective of proposing amendments to update the Biosimilars guidance. These amendments are intended to ensure the Biosimilars guidance reflects the current state of regulatory science and lessons learned nationally and internationally since its last revision in 2016. Health Canada will provide an update on this initiative and planned stakeholder consultations regarding these proposed amendments to the Biosimilars guidance.</p> <ul style="list-style-type: none"> Denis Arsenault, Manager, Centre for Policy, Pediatrics and International Collaboration, Health Canada

	11:20 – 12:15 pm	<p>Discussing the 15-day Clarifax timelines for submitting samples with Health Canada followed by Q&A</p> <p>From an industry perspective, consistency sample requests for biologics based on Health Canada’s 15 calendar-day Clarifax timelines can be challenging to manage without advanced notice of the timing or samples required. This has resulted in review clock stops until all samples can be delivered to Health Canada. Health Canada will also provide an overview of how the tests are selected for consistency testing.</p> <ul style="list-style-type: none"> • Dr. Chris Ablenas, Senior Evaluator, CBBB, BRDD, Health Canada • Amy Tsung, Head, Regulatory Affairs, CMC, Sanofi Canada
	12:15 – 12:30 pm	Question and Answer Period
12:30 – 1:30 pm	Lunch Break	
	1:30 – 2:00 pm	<p>Agile Licensing of Drugs and Medical Devices regulations, followed by Q&A</p> <p>In December 2022, Health Canada published a regulatory outlining new targeted provisions and regulatory amendments to the Food and Drug Regulations (FDR) and Medical Devices Regulations (MDR) for stakeholder consultation. Building upon regulatory agilities piloted during the pandemic, the proposed regulatory amendments would, among other things, enable the use of terms and conditions, require risk management plans for higher-risk human drugs, and modernize Division 4 (biologic drugs) of Part C of the FDR. An update regarding this regulatory proposal will be provided at the meeting.</p> <ul style="list-style-type: none"> • Fiona Frappier, Manager, Centre for Policy, Pediatrics and International Collaboration, Health Canada
	2:00 – 2:20 pm	<p>Strengthening Canada’s biomanufacturing capacity and life sciences sector through regulatory modernization, followed by Q&A</p> <p>Canada’s ambition in the Biomanufacturing and Life Sciences Strategy of a modern and agile regulatory system is increasingly important not only for the treatments and therapeutics coming from global companies but also for the advancement of Canadian-based biotechnology companies. The presentation will highlight how this ambitious regulatory reform will position Canada as a global leader in biotechnology, driving economic growth, fostering innovation, and improving healthcare outcomes for all Canadians.</p> <ul style="list-style-type: none"> • Ron Boch, Vice President, Biotechnology and Industry Affairs, BIOTECanada

	2:20 – 2:50 pm	<p>Update on ATP, followed by Q&A</p> <p>Some therapeutic products are so unique or complex that they need a different regulatory approach. An advanced therapeutic product (ATP) is a drug or a medical device, or any combination that is so unique, complex and distinct that it faces a significant barrier under the existing regulations. The ATP framework provides the ability to authorize ATPs in a flexible and risk-based manner. Health Canada will provide an update regarding the implementation of the framework and current ATP candidates, report on the outcome of the public consultation of the draft guidance document, and share lessons learned on establishing regulatory sandboxes.</p> <ul style="list-style-type: none"> Johanne Veenstra, Senior Regulatory Policy and Risk Management Advisor, Office of Advanced Therapeutic Products, Health Canada
	2:50 – 3:10 pm	<p>From Foundations to Frontiers: The Evolving Landscape of Biologics Regulation, followed by Q&A</p> <p>Biologics continue gaining prominence as vital components of modern medicine, encompassing established therapies and cutting-edge innovations. This presentation will explore the evolving regulatory environment surrounding biologics, offering insights from an industry perspective. Additionally, the critical role of regulatory affairs professionals in navigating regulatory paradigms and advancing these life-changing therapies will be discussed.</p> <ul style="list-style-type: none"> Jennifer Wilhelm, Director, Regulatory Affairs at Merck Canada
	3:10 - 3:20 pm	Question and Answer Period
	3:20 – 3:50 pm	<p>Strategies to Overcome Development and Regulatory Challenges for Small and Medium Companies, followed by Q&A</p> <p>Small- and medium-sized enterprises (SMEs) often struggle to define “suitable” development paths and regulatory strategies for their products. This session will discuss approaches for development and regulatory strategies that make sense for SMEs.</p> <ul style="list-style-type: none"> Yatika Kohli, Chief Compliance and Strategy Officer, NoNO Inc.
3:50 – 4:00 pm	PM Break	
4:00 - 4:25 pm	Panel Discussion and Q&A for all Topics	
4:25 - 4:30 pm	Closing Remarks	

Registration, Fees and Hotel Information:

1. CAPRA member: \$580 + HST in-person or \$510 + HST online access.
2. Non-member: \$685 + HST or \$585 + HST online access
3. Students: \$350* + 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
Platinum	<ul style="list-style-type: none">✓ Company logo* and company hyperlink on all event Media broadcasts and the CAPRA event webpage✓ Promotion of the Company logo before and during the event✓ One page of digital collateral material to be sent to all attendees by the event host✓ Two attendees	\$2355 + HST
Gold	<ul style="list-style-type: none">✓ Company logo* and company hyperlink on all event Media broadcasts and the CAPRA event webpage✓ Two attendees	\$1975 + HST
Vendor	✓ Two attendees	\$1705 + HST
	✓ One attendee	\$1105 + 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:

Registration will be accepted at www.capra.ca/meetings.html. Credit card payment is available online through registration. Please use the name and address on the payment site that matches the card.

If you wish to pay by cheque, payment must be received by February 7, 2025. Please mail the cheque, with a list of registrants and company names, to:

CAPRA/ACPR
M108 -8901 Airport Rd, Brampton ON L6T 5T2
Email: administrator@capra.ca

Please Note: Registration deadline is March 19, 2025. Participants may be substituted, but no refunds will be issued.

Westin Airport Hotel Reservation Information:

Special Room rates of \$239/night (plus applicable tax and fees) for the CAPRA Symposium are subject to availability. Make your reservation **before March 6, 2025**, via the link: <https://book.passkey.com/e/50803163>.
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 amend the conference (including, but not limited to, the identity of speakers, topics, locations, and the timing of speakers) without your notice. If the meeting is cancelled for any reason not within CAPRA's control, CAPRA shall not be liable for any cost or loss otherwise incurred.