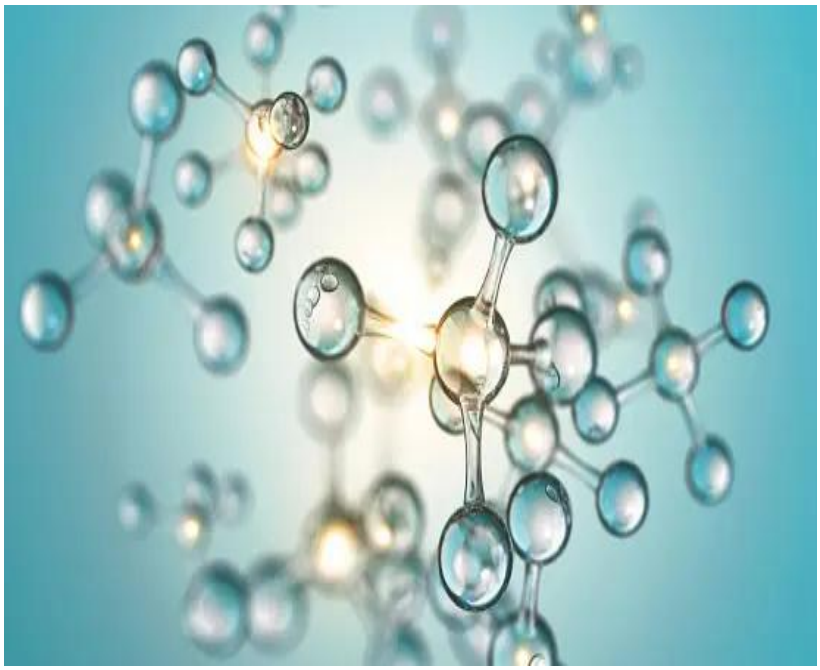
CAPRA 2025 Biologics and Biosimilar Symposium



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.

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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** • 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** 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. • Hugo Hamel, Associate Director, CBBB, BRDD, Health Canada
	9:30 - 10:15 am	**Update on ICH M4Q (R2), followed by Q&A** 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. • 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	**Canadian Biosimilars Landscape, followed by Q&A** The biosimilars market has been evolving rapidly in Canada in recent years. This presentation will review the current biosimilars landscape and highlight regulatory priorities that will help support a robust future pipeline of biosimilar medicines for Canadian patients. • Judy Cox, Vice President, Biosimilars Canada

	11:20 – 12:15 pm	**Discussing the 15-day Clarifax timelines for submitting samples with Health Canada, followed by Q&A** From an industry perspective, consistency in 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 the 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. • Dr. Chris Ablenas, Senior Evaluator, CBBB, BRDD, Health Canada • Amy Tsung, Head, Regulatory Affairs, CMC, Sanofi Canada • Ryan van Bendegem, Senior Manager for CMC, Regulatory Affairs at AstraZeneca Canada
	12:15 – 12:30 pm	**Question and Answer Period**
12:30 – 1:30 pm	**Lunch Break**	
	1:30 – 2:00 pm	**Agile Licensing of Drugs and Medical Devices regulations, followed by Q&A** 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. • Fiona Frappier, Manager, Centre for Policy, Pediatrics and International Collaboration, Health Canada
	2:00 – 2:20 pm	**Strengthening Canada's biomanufacturing capacity and life sciences sector through regulatory modernization, followed by Q&A** 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. • Ron Boch, Vice President, Biotechnology and Industry Affairs, BIOTECanada

	2:20 – 2:50 pm	**Update on ATP, followed by Q&A** 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. • Johanne Veenstra, Senior Regulatory Policy and Risk Management Advisor, Office of Advanced Therapeutic Products, Health Canada
	2:50 – 3:10 pm	**From Foundations to Frontiers: The Evolving Landscape of Biologics Regulation, followed by Q&A** 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. • Jennifer Wilhelm, Director, Regulatory Affairs at Merck Canada
	3:10 - 3:20 pm	**Question and Answer Period**
	3:20 – 3:50 pm	**Strategies to Overcome Development and Regulatory Challenges for Small and Medium Companies, followed by Q&A** 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. • 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**	

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We want to extend our heartfelt gratitude to the sponsors of the 2025 Biologics and Biosimilar Symposium. Your commitment not only helps us bring together the brightest minds in the pharmaceutical and regulatory fields but also ensures the continued success of these knowledge-sharing platforms. Together, we are driving innovation, fostering collaboration, and shaping the future of the industry.

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