

CAPRA 2024 Pharmaceutical Symposium



Canadian
Association of
Professionals
in Regulatory
Affairs

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professionnels en
réglementation



CAPRA will host this one-day pharmaceutical symposium with Health Canada and Industry leaders. This unparalleled collaborative event will provide a unique opportunity to hear from Health Canada and industry leaders to address the challenges posed by increasing workloads, globalization and the complexity of scientific issues.

You will also gain new regulatory insights through in-person panel discussions from all speakers. This event will be of interest to all Regulatory Affairs professionals. Please share this news with your regulatory colleagues and within your organization.

October 22, 2024
Westin Airport Hotel
950 Dixon Road
Toronto, ON, Canada

Symposium Agenda

7:15 - 8:25 am	Registration and Breakfast	
Setting the Stage	8:25 - 8:30 am	Welcoming Remarks
	8:30 - 8:45 am	Opening Remarks <ul style="list-style-type: none"> Karen Reynolds Director General, Pharmaceutical Drugs Directorate (PDD), Health Canada.
	8:45 - 9:00 am	Canadian Generic Pharmaceutical Association (CGPA) Overview To set the stage for supporting the generic industry's regulatory needs that are vital in supplying high-quality prescription medicines. <ul style="list-style-type: none"> Kristin Willemsen, Vice President, Scientific and Regulatory Affairs at Canadian Generic Pharmaceutical Association.
	9:00 - 9:15 am	Innovative Medicines Canada (IMC) Overview To set the stage for supporting the regulatory needs of the innovative industry, which plays an essential role in supplying high-quality prescription medicines. <ul style="list-style-type: none"> Lama Abi Khaled, Executive Director, Ethics, Legal and Regulatory, Innovative Medicines Canada.
	9:15 - 9:40 am	Updates from the Bureau of Pharmaceutical Sciences The Bureau of Pharmaceutical Sciences will provide updates on a variety of topics, including operational, policy, and regulatory initiatives, followed by a Q&A session. <ul style="list-style-type: none"> Chris Rose, Director, Bureau of Pharmaceutical Sciences, PDD, Health Canada.
	9:40 - 10:00 am	Question and Answer Period
10:00 – 10:30 am	Coffee Break and Visit Vendors	
Improving Submission Quality	10:30 -11:05 am	Negative Decision Analysis – Quality The Bureau of Pharmaceutical Sciences will present the results of the analysis and trending data covering the previous three years on negative decisions issued for both generic and innovator drugs. <ul style="list-style-type: none"> Susan Lum, Generic Drug Quality Division Manager, PDD, Health Canada.
	11:05 -11:25 am	Labelling Deficiencies Observed in Drug Submissions Labels and packages are the first point of interaction between a health product and a healthcare professional or patient. They communicate key information about the safe and effective use of health products and are important aids in product identification, selection and administration. This presentation will highlight common labelling deficiencies identified during the review of prescription pharmaceuticals drug labels and labelling best practices to support the objectives of the Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use), also known as the Plain Language Labelling Regulations, that were introduced with the intention of improving the safe use of drugs by making their labels easier to read and understand. <ul style="list-style-type: none"> Veronica Yip, Labelling Division Manager, Pharmaceutical Drugs Directorate (PDD), Health Canada.
	11:25-11:45 am	Question and Answer Period

11:45 – 1:00 pm	Lunch and Visit Vendors	
Global Issues	1:00 – 1:40 pm	<p>Comprehensive Drug Shortage Update</p> <p>Drug shortages have been an ongoing issue that has created difficulties for patients, healthcare systems and practitioners across the distribution channels. In response, Health Canada has been working with stakeholders such as federal, provincial, and territorial governments, health professionals, patients, and industry associations to share information and identify actions to prevent and mitigate drug shortages in Canada.</p> <p>Health Canada’s Health Product Shortage Directorate will provide a comprehensive update on the program and share a global perspective on drug shortages.</p> <p>We will also have an academic expert to explore the background of drug shortages in Canada, highlighting their global nature and the pressing need for proactive measures. The presentation will also emphasize the necessity of a systematic and transparent at-risk medicine list and discuss the ongoing development of a national list that comprehensively considers supply chain and clinical risk factors. This initiative aims to provide a first step and framework for identifying and mitigating vulnerabilities in medication availability, fostering a more resilient supply chain that can effectively navigate the complexities of drug shortages.</p> <ul style="list-style-type: none"> • Stephanie Di Trapani, Director of the Operations Division, Health Products Shortages Directorate, Health Canada. • Mina Tadrous, An Assistant Professor at the Leslie Dan Faculty of Pharmacy at the University of Toronto.
	1:40 – 3:00 pm	<p>Latest Nitrosamines Update</p> <p>In this session, you'll gain insights into Health Canada's latest perspectives on nitrosamines, including an overview of current requirements and strategies for risk mitigation and management. We'll also delve into industry viewpoints on navigating these standards globally and within Canada.</p> <ul style="list-style-type: none"> • Stephen Horne, Senior Scientific Evaluator/Nitrosamine Subject Matter Expert, Quality Risk Management and Operations Division, BPS, PDD, Health Canada. • Alisa Vespa, Senior Scientific Evaluator/Nitrosamine Safety Subject Matter Expert, Office of Risk Management Division, BMS, PDD, Health Canada. • Martin Ehlert, Vice President, Global API R&D, Apotex Inc.
	3:00 -3:40 pm	Question and Answer Period
3:40 – 4:00 pm	Break and Visit the Vendor	
4:00 – 4:30 pm	Panel Discussion and Q&A	
4:30 -4:35 pm	Closing Remarks	

Registration, Fees and Hotel Information:

1. CAPRA member: \$575 (includes HST) in-person or \$500 (includes HST) online access
2. Non-member: \$680 (includes HST) or \$580 (includes HST) online access
3. Students: \$320* (includes 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 	\$2350 + 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 	\$1970 + HST
Vendor	✓ Two attendees	\$1700 + HST
	✓ One attendee	\$1100 + 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 <https://capra.ca/en/meetings/capra-symposium2024-2024-10-22>. Credit card payment is available with online registration before the October 15, 2024 registration deadline. 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 **October 11, 2024**. 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 will be open till **October 17, 2024**. 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 September 23, 2024**, 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.