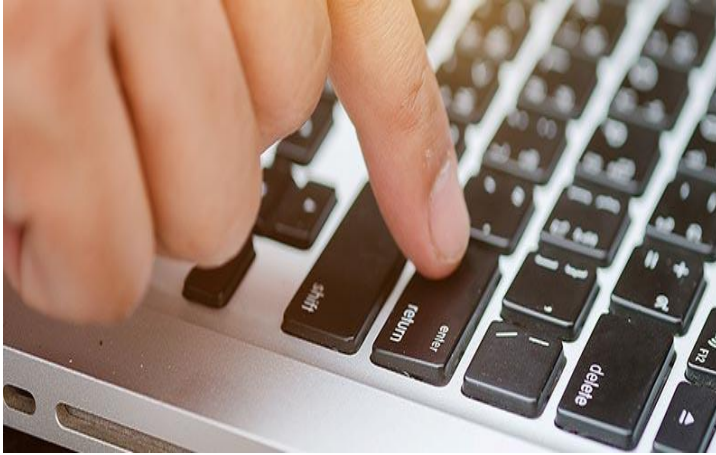


2023 CAPRA Symposium
Electronic Regulatory Landscape: Current Trends
and Upcoming Opportunities



The CAPRA Symposium Committee will host a one-day in-person event to share updates with our members on eCTD V4, eCTAs, XML PM, REP, and other key aspects of the electronic regulations.

Attendees will hear from Health Canada, Industry experts, and vendors' experiences throughout the event. This symposium will provide attendees opportunity understand the current regulations, learn about future requirements, and raise questions about the topics discussed.

This event will be of interest to:

- Regulatory Affairs professionals from pharmaceuticals/biologics medical devices, as well as veterinary drugs
- Clinical Research and Contract Research Organizations
- Clinical Data Management/Pharmacovigilance
- Research and Development

Please share the news of this event within your organization.



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CAPRA Symposium
June 01, 2023

Westin Toronto Airport Hotel
950 Dixon Road
Etobicoke, ON
M9W 5N4

Agenda: June 01, 2023

7:15 – 8:25 am	Registration + Breakfast
8:25 – 8:30 am	Welcoming Remarks
8:30 – 9:10 am	<p>Future of e-Regulatory Landscape and IT Modernization in Canada and Q&A <i>How will the Canadian e-Regulatory Landscape look in 2030?</i></p> <p>HC Speaker: Katerina Paschakis, Associate Director, Resource Management and Operations Directorate (RMOD)</p> <p>Industry Speaker: Khaled Yahiaoui, Associate Director, Regulatory Affairs - Operations at Merck Canada Inc.</p>
9:10 – 9:50 am	<p>eCTAs: A Go or A Not Go? and Q&A <i>eCTD CTAs – Pilot Experiences and Outcomes from HC and Challenges and Opportunities on LCM/REP/GESG from the industry step by step</i></p> <p>HC Speaker: Irena Pastorekova, Regulatory Affairs Manager at Health Canada</p> <p>Industry speaker: Jennifer Kutlesa, Regulatory Operations Manager at Bayer</p>
9:50 – 10:50 am	<p>Regulatory Enrolment Process (REP) and XML Application forms and Q&A <i>REP as Key for Future RIM Implementations, Regulatory Information Exchange Between Industry & HC, Application forms in XML format</i></p> <p>HC Speaker: Irena Pastorekova, Regulatory Affairs Manager at Health Canada</p> <p>Industry speaker: Mike Kurktschi, Senior Specialist, Regulatory Affairs – Operations, Merck Canada Inc.</p>
10:50 – 11:10 am	AM Break
11:10 – 12:05 pm	<p>eCTD V4.0 and Q&A Technical & Global Updates: Charles Mathis, Regulatory Solutions Architect, LORENZ Life Sciences Group</p> <p>eCTD 4.0: Challenges and Opportunities (Industry Readiness/Implementation Capabilities/Phases): Khaled Yahiaoui, Associate Director, Regulatory Affairs - Operations at Merck Canada Inc.</p> <p>Update on eCTD 4.0 Implementation in Canada: Irena Pastorekova, Regulatory Affairs Manager at Health Canada</p>
12:05 – 1:05 pm	Lunch
1:10 – 1:40 pm	<p>Product Monographs in the XML Format (XML PM) Update and Q&A HC Speaker: Tracy E. Brown, Project Manager, Business Informatics Division, RMOD, Health Canada</p>
1:40 – 2:15 pm	<p>The Journey of the XML PM Process: Opportunities and Challenges and Q&A Industry speaker: Anh Tran, Manager, Regulatory Submission Management Organization at Janssen Inc. Cynthia Martel, Senior French Labelling Specialist, Linguistic Services at Janssen Inc.</p>
2:15 – 2:40 pm	PM Break and Visiting Vendor Booths
2:40 – 3:15 pm	<p>Perspective on vendor XML experience and Q&A: Reed Tech Speaker: Gary Saner, Sr. Information Manager i4i Speaker: Amanpreet Kainth, Team Lead, Regulatory Affairs and Services</p>
3:15 – 3:40 pm	<p>Product Monographs in the XML Format Implementation experience and Q&A Industry Speaker: Maggy Mouradian, Manager, Regulatory Policy & Operations Boehringer Ingelheim (Canada) Ltd.</p>
3:40 – 4:00 pm	<p>Panel Discussion and Q&A: All Speakers to address questions or provide clarifications</p>
4:00 – 4:05 pm	Closing Remarks

Registration, Fees and Hotel Information:

1. CAPRA member: \$535 (includes HST) Or \$435(includes HST) for online access
2. Non-member: \$610 (includes HST) Or \$510 (includes HST) for online access
3. Students: \$300* (includes HST) for in person or online access
*A limited number of spaces are available for students. Proof of full-time registration in a Regulatory Programme is required.
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 symposium attendees by the event host ✓ Two attendees plus Booth 	\$2200 + 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 plus Booth 	\$1820 + HST
Vendor	✓ Two attendees plus Booth	\$1520 +HST
	✓ One attendee plus Booth	\$910 + 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 ONLINE ONLY at www.capra.ca/meetings.html. Credit card payment is available with online registration before the registration deadline of May 25, 2023. On the payment site, please use the name and address that match the card.

If you wish to pay by cheque, payment must be received by May 23, 2023. 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 from **March 6, 2023, to May 25, 2023**. Participants may be substituted, but no refunds will be issued.

Hotel Information:

Rooms are subject to availability – make your reservation before May 4, 2023, via the link below:

Book your group rate for Capra Symposium 2023 Or

Individual Reservations via Phone: 1-866-837-5184 by May 1, 2023, for a CAPRA rate of \$209.00/night (plus applicable tax and fees).

Guests making such reservations must identify themselves as members of the CAPRA group. Complimentary wireless high-speed internet.

HST Registration No. 85475 8349RT0001

Disclaimer

CAPRA reserves the right to make amendments to the conference (including but not limited to the identity of speakers, topics, locations, and the timing of speakers) without notice to you. If the conference is canceled for any reason whatsoever, such reason not within the control of CAPRA, CAPRA shall not be liable for any cost or loss otherwise incurred.

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