

2023 CAPRA Symposium
Understanding ICHQ12 Regulatory & Technical
Considerations to Manage Post Approval Changes



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation



The CAPRA Symposium Committee will host a virtual interactive session to provide an update on the implementation of ICH Q12 in Canada and the revisions made to the Post-NOC Changes guidance document to support the implementation.

Attendees will learn the objectives and the scope of the ICH Q12 guidelines and the impact and benefits of its implementation. This symposium will also share recent pilot program experiences on Established Conditions (ECs) and Post Approval Change Management Protocols (PACMPs) from both Health Canada and Industry.

This symposium will provide attendees with an opportunity to raise questions and concerns about this topic.

This event will be of interest to:

- Regulatory Affairs professionals from medical devices, pharmaceuticals/biologics,
- Pharmaceutical Scientists and QA personnel
- Research and Development Scientists
- Manufacturing & Technical Services SMEs

Please share the news of this event within your organization.

CAPRA Virtual Symposium
January 17, 2023

Symposium Agenda: January 17, 2023

8:00 – 8:15 am	Logging into Virtual Workshop
8:15 – 8:20 am	Welcoming Remarks
8:20 – 9:00 am	Understand the requirements and scope of the ICH Q12 guidance and Q&A HC speaker: Anthony Ridgway, ICHQ12 SME, and HC Implementation workgroup
9:00 – 9:40 am	Summary of Post-Notice of Compliance (NOC) Changes and Q&A HC speaker: Hugo Hamel, Associate Director, Biologic and Radiopharmaceutical Drugs Directorate
9:40 – 10:10 am	PLCM vs CPID and Q&A HC speaker: Hugo Hamel, Associate Director Biologic and Radiopharmaceutical Drugs Directorate, HC
10:10 – 10:20 am	Break
10:20 – 10:50 am	A case study from ISPE and Q&A Industry Speaker: Connie Langer, Global Regulatory CMC Director, Pfizer
10:50 – 11:25 am	Industry Perspective from the pilot program on PACMPs and Q&A Industry Speaker: Jennifer Wilhelm, Director, Regulatory Affairs, Merck Canada
11:25 – 12:05 am	Reviewers' perspective from the pilot program on ECs and PACMPs and Q&A HC Speaker: Hugo Hamel Associate Director, Biologic and Radiopharmaceutical Drugs Directorate
12:05 - 12:35 pm	Panel Discussion and Q&A: All Speakers to address questions or provide clarifications
12:35 – 12:40 pm	Closing Remarks

Registration & Fee

Session Fee:

1. CAPRA Member: \$475 (includes HST) for online access.
2. Non-member: \$550 (includes HST) for online access.
3. A limited number of spaces are available for students at \$250 (includes HST) for online access. Proof of full-time registration in a Regulatory Programme is required.
4. Sponsorship

Sponsorship Level	Benefits	Cost
Platinum	<ul style="list-style-type: none"> ✓ Large company logo* on new CAPRA Digital Platform homepage ✓ Logo and company hyperlink on all event Media broadcasts and the CAPRA event webpage ✓ One page of digital collateral material to be sent to all symposium attendees by the event host ✓ One complimentary event registration 	\$1250 + HST
Gold	<ul style="list-style-type: none"> ✓ Medium company logo* on new CAPRA Digital Platform homepage ✓ Logo and company hyperlink on all event Media broadcasts and the CAPRA event webpage 	\$950 + HST
Silver	<ul style="list-style-type: none"> ✓ Small company logo* on new CAPRA Digital Platform homepage ✓ Logo and company hyperlink on all event Media broadcasts and the CAPRA event webpage 	\$750 + HST

*logo to be provided in as high a resolution as possible in any of the following file types: jpg, png, .ai, pdf, .eps

HST Registration No. 85475 8349RT0001

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 January 11, 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 January 3, 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 **November 21, 2022 to January 11, 2023**. Participants may be substituted, but no refunds will be issued.

Disclaimer

CAPRA reserves the right to make amendments to the conference (including but not limited to the identity of speakers, topics, locations, 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.