

CAPRA ANNUAL EDUCATION DAY 2021

June 8 - 9, 2021

Virtual Webinar



CAPRA continues to stay committed to providing education to our members and staying connected.

The Education Day will take place virtually on June 8th and June 9th, 2021.

This is an opportunity to hear about hot topics of interest in regulatory affairs from Health Canada.

Topics will include the following:

- Pause the Clock
- Health Canada Implementation of ICH Q12: CMC Changes
- International Collaborative Review Activities: Updates on Access Consortium and Project Orbis
- Case Study: Industry Experience with Project ORBIS
- OTC Labelling: Canadian Drug Facts Table (CDFT)
- Covid-19-Future Regulatory Landscape
- Changes to the Filing of Post-NOC Submissions Following Cost Recovery 2020
- Regulatory Enrolment Process (REP)
- Strategies for Filing an Efficient Submissions

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PROGRAMME SCHEDULE

Tuesday, June 8, 2021:

9:00 am – 9:10 am

Day 1 Welcoming Remarks

9:10 am – 10:00 am

Pause the Clock

Speaker: Michèle Chadwick, Director, Office of Business Integration, Biologic and Radiopharmaceutical Drugs Directorate;

Speaker: Denis Arsenault, Manager, Policy Development, Office of Policy and International Collaboration, Biologic and Radiopharmaceutical Drugs Directorate; and Heather Cherry, Regulatory Affairs Project Manager, Regulatory Project Management Division, Therapeutic Products Directorate

Questions and Answers

10:00 am – 10:45 am

Health Canada Implementation of ICH Q12: CMC Changes

Speaker: Hugo Hamel, A/Manager, Radiopharmaceuticals and Monoclonal Antibodies (inflammation) Division, CERB, BRDD, HPFB

Questions and Answers

10:45 am – 11:00 am

Break

11:00 am – 12:15 pm

International Collaborative Review Activities: Updates on Access Consortium and Project Orbis

Speaker: Shajan Sivayogarajah, Policy and International Coordination Advisor, Office of Regulatory Intelligence and Risk Management, Biologic and Radiopharmaceutical Drugs Directorate;

Case Study: Industry Experience with Project ORBIS

Speaker: Mandy Go, Manager, Regulatory Affairs, AbbVie Corporation

Questions and Answers

12:15 pm – 1:00 pm

OTC Labelling: Canadian Drug Facts Table (CDFT)

Speaker: Taiwo Womiloju, Regulatory Affairs Specialist, Non-prescription Drugs Evaluation Division (NDED), Bureau of Product Review and Assessment, Natural and Non-prescription Health Products Directorate, Health Products and Food Branch

Questions and Answers

1:00 pm – 1:15 pm

Day 1 Closing Remarks

CAPRA Education Day Committee

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Wednesday, June 9, 2021:

9:00 am – 9:10 am

Day 2 Welcoming Remarks

9:10 am – 9:55 am

Covid-19 – Future Regulatory Landscape

Speaker: Fiona Frappier, Senior Policy Analyst in the Office of Policy and International Collaboration of the Biologic and Genetic Drugs Directorate

Questions and Answers

9:55 am – 10:40 am

Changes to Filing of Post-NOC Submissions Following Cost Recovery 2020

Speaker: Heather Cherry, Regulatory Affairs Project Manager, Regulatory Project Management Division, Therapeutic Products Directorate

Questions and Answers

10:40 am – 11:00 am

Break

11:00 am – 11:45 am

Regulatory Enrolment Process (REP)

Speaker: Sindy Fernando, Acting Manager, Health Products Food Branch;

Speaker: Irena Pastorekova, Regulatory Affairs Specialist, Office of Submissions and Intellectual Property, Health Products and Food Branch

Questions and Answers

11:45 am – 12:30 pm

Strategies for Filing an Efficient Submissions

Speaker: Joshua Nevelizer, Regulatory Project Manager

Therapeutic Products Directorate, Regulatory Project Management Unit-BCANS

Questions and Answers

12:30 pm – 12:45 pm

Day 2 Closing Remarks

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Registration Process & Fee

Registration Fee:

1. CAPRA Member: \$400 (includes HST) for online access.
2. Non-member: \$500 (includes HST) for online access.
3. CAPRA Students: \$100 (Includes HST) A limited number of spaces are available for students Proof of full-time registration in a Regulatory Programme is required at the time of booking.

Maximize Your Advertising Potential

Connect with our membership by becoming an Event Sponsor at our 2021 digital educational offerings. Digital sponsorship options include:

SPONSORSHIP LEVEL	BENEFITS	COST*
Premium Event Sponsorship	<ul style="list-style-type: none">✓ One page of digital marketing material to be sent to all conference delegates by the event host✓ One complimentary event registration✓ Company logo on sponsor slide during all breaks✓ Logo and hyperlink on all event Media and on the CAPRA event webpage	\$1,000
Event Sponsorship	<ul style="list-style-type: none">✓ Company logo on sponsor slide during all breaks✓ Logo and hyperlink on all event Media and on the CAPRA event webpage	\$500

*Plus, applicable taxes

HST Registration No. 85475 8349RT0001

Registration Procedure: Registration will be accepted [ONLINE ONLY](#). Credit card payment is available with on-line registration prior to the registration deadline of June 01, 2021. On the payment site, please use the name and address that matches the card.

If you wish to pay by cheque, payment must be received by June 01, 2021. Please mail the cheque, with the online registration Invoice and the event registration forms, to:

CAPRA
7111 Syntex Drive, 3rd Floor, #364
Mississauga, ON L5N 8C3
Tel: 289-290-4355

Please Note: Registration will be open from May 04, 2021 to June 01, 2021. Participants may be substituted, but no refunds will be issued after the deadline.

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