

CAPRA ANNUAL EDUCATION DAY 2021

June 8 - 9, 2021
Virtual Webinar



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

Speakers: Michèle Chadwick, Director, Office of Business Integration, Biologic and Radiopharmaceutical Drugs Directorate; Denis Arsenault, Manager, Policy Development, Office of Policy and International Collaboration, Biologic and Radiopharmaceutical Drugs Directorate; and Heather Cherry, Acting 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 Worksharing (ACCESS/ORBIS)

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

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

Questions and Answers

12:15 pm – 1:00 pm

OTC Labelling: Canadian Drug Facts

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, Acting 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)

Speakers: Sindy Fernando, Acting Manager, Health Products Food Branch; and 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

RPMD Tips for Effective Submissions from TPD

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

CAPRA Education Day Committee

DRAFT-subject to change

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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.

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SPONSORSHIP LEVEL	BENEFITS	COST*
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Event Sponsorship	✓ 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.

Disclaimer:

CAPRA reserves the right to make amendments to the conference (including but not limited to identity of speakers, topics, locations, timing of speakers) without notice to you. In the event that 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.