June 14 - 15, 2022 Virtual Webinar



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PROGRAMME SCHEDULE

Tuesday, June 14, 2022:

8:45 am – 9:00 am Day 1 Welcoming Remarks

9:00 am – 10:00 am Clinical Trial Modernization

Speaker: Larissa Lefebvre, Manager, Submission Management Division, Office of Clinical Trials, Therapeutic Products Directorate,

Health Products and Food Branch, Health Canada

Questions and Answers

10:00 am – 10:45 am Real World Evidence (RWE) Across the Product Life Cycle: An

Update

Speakers: Mary Speagle, Sr. Director Regulatory Affairs, TPIreg,

Innomar Strategies

Belinda Yap, Director, Health Economics & Outcomes Research,

Innomar Strategies

Questions and Answers

10:45 am – 11:00 am **Break**

11:00 am – 11:45 pm XML Product Monograph Updates

Speaker: Tracy Brown, Project Manager, Business Informatics Division, Health Products and Food Branch, Heath Canada

Questions and Answers

11:45 pm – 12:30 pm Strategies for Filing Efficient Submissions

Speaker: Mohammed Faisaluddin, Regulatory Project Manager, Regulatory Project Management Division, Therapeutic Products

Directorate, Health Products and Food Branch

Questions and Answers

12:30 pm – 12:45 pm **Day 1 Closing Remarks**

CAPRA Education Day Committee

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Wednesday, June 15, 2022:

8:45 am – 9:00 am Day 2 Welcoming Remarks

9:00 am - 10:00 am Post NOC Quality Guidance

Speaker: Hugo Hamel, Manager, Monoclonal Antibodies Division, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics,

Biologic and Radiopharmaceutical Drugs Directorate, Health

Products and Food Branch, Health Canada

Questions and Answers

10:00 am – 10:15 am **Break**

10:15 am – 10:45 am An Update by the Natural and Non-Prescription Health Products

Directorate (NNHPD)

Speakers: Jackie Cote, Senior Policy Analyst, Natural and Non-

Prescription Health Product Directorate

Matthew Bown, Senior Advisor, Consumer Health Product Modernisation, Natural and Non-Prescription Health Products

Directorate

Questions and Answers

10:45 am – 11:30 am Update on Common Quality Deficiencies Observed in Drug

Submissions

Speaker: Susan Lum Ph.D, Manager, Generic Drugs Quality Division #3, Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate. Health Products and Food Branch. Health Canada

Questions and Answers

11:30 am – 11:45 am **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.

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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 a 2-step process:

STEP 1: Event Registration form: Complete the <u>Registration form</u> on our brand-new event page. Make sure to add your First name, Last name and the Email address that you will use to log in the day of the event.

STEP 2: Payment: Click on the <u>Registration</u> button or scroll down to make a payment. NOTE: You must log into your CAPRA account to complete this activity.

Both steps must be completed to receive the link to the event. We will be sending you a link and password to access the virtual event in a separate email prior to the event.

Registration will be accepted <u>ONLINE ONLY</u>. Credit card payment is available with on-line registration prior to the registration deadline of June 10,2022. On the payment site, please use the name and address that matches the credit card.

Please Note: Registration will be open until June 10, 2022. 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.