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** *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* *Speaker: 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**

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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**