

Pricing: *Members:* \$500, *Non-Members:* \$600, *Students:* \$150 (must provide proof of current student enrollment prior to Education Day. The Education day will also be available as a Webinar.

For further information, please contact Krystyna Bienkiewicz at education_day@capra.ca.

If paying by cheque, you will need to print the confirmation and mail it to us with payment at: CAPRA, 2425 Matheson Blvd. E, 7th Floor, Suite 795, Mississauga, ON L4W 5K4

Please be advised the cheques should not be mailed less than a week prior to the meeting. Registrants for whom payment has not been received will be refused entry to the meeting.

THIS YEAR'S VENDORS INCLUDE:

- 1. Regulatory Affairs Professional Society (RAPS)**
- 2. Academy of Applied Pharmaceuticals (AAPS)**
- 3. Intrinsic Corporation**
- 4. TPIreg – A Division of Innomar**

**CAPRA
ACPR**



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation

CAPRA ANNUAL EDUCATION DAY

June 11th 2019

LOCATION:

Hilton Mississauga/Meadowvale

6750 Mississauga Rd, Mississauga,

ON L5N 5N3

Tel: (905) 821-1981

CAPRA|ACPR

Morning Session

- **7:30 am – 8:30 am**
Registration and Hot Breakfast
- **8:30 am – 8:40 am**
Welcoming Remarks
CAPRA Education Day Committee
- 8:40 am – 9:20 am
Role of Regulatory Affairs Globally
Keynote Speaker: Paul Brooks, Executive Director, RAPS
- 9:20 am – 10:00 am
Health Technology Assessments Aligned Reviews between Health Canada and Health Technology Assessment Organizations
Speaker: Kelly Robinson, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, Health Canada
- **10:00 am – 10:20 am**
Morning Break
- 10:20 am – 11:00 am
International Work Sharing
Speaker: Dr. Craig Simon, Associate Director Bureau of Metabolism, Oncology and Reproductive Sciences, TPD, HPFB, Health Canada
- 11:00 am – 11:40 am
Cost Recovery
Speaker: Maria Koulouris, Senior Policy Analyst, Strategic Planning and Accountability Division, HPFB, Health Canada
Speaker: Sylwia Knapczyk, Policy Analyst, Cost Recovery Team, HPFB, Health Canada

Lunch

- **11:40 am – 1:00 pm**
Lunch & Networking Break

Afternoon Session

- 1:00 pm – 1:40 pm
Update on Health Product Inspections and Licensing
Speaker: Julie Robert, Associate Director, Health Product Inspection and Licensing Division, ROEB, Health Canada
- 1:40 pm – 2:20 pm
Personalized Health Care – Cell and Gene Therapies
Speaker: Dr. Jian Wang, Division Manager Clinical Evaluation Division – Hematology/Oncology, Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics, BGTD, Health Canada
- **2:20 pm – 2:40 pm**
Afternoon Break
- 2:40 pm – 3:30 pm
Strategies for Filing Efficient Submissions
Speaker: Rachel Sampson (Licari), Regulatory Affairs Manager & Special Projects, Regulatory Project Management Division, TPD, Health Canada
Speaker: Lynda O'Reilly, Regulatory Project Manager, TPD, Health Canada
- 3:30 pm – 4:00 pm
Submissions Relying on Third Party Data (from a Regulatory Perspective)
Speaker: Rachel Sampson (Licari), Regulatory Affairs Manager & Special Projects, Regulatory Project Management Division, TPD, Health Canada
Speaker: Lynda O'Reilly, Regulatory Project Manager, TPD, Health Canada
- **4:00 pm – 4:15 pm**
Closing Remarks
CAPRA Education Day Committee