

CAPRA ANNUAL EDUCATION DAY

June 7th 2018

**CAPRA
ACPR**



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation

CAPRA|ACPR

Morning Session

- 7:30 am – 8:30 am
Registration and Hot Breakfast
- 8:30 am – 8:45 am
Welcoming Remarks
CAPRA Education Day Committee
- 8:45 am – 9:30 am
Overview of Cost Recovery for Drugs and Medical Devices
Speakers: Maria Koulouris, Senior Policy Analyst, Strategic Planning and Accountability Division, Health Canada

Naira Minto-Saeed, Director, Strategic Planning and Accountability Division, Health Canada
- 9:30 am – 10:15 am
Pharmacovigilance: Risk Minimization Measures & Evaluation of Their Impact
Speaker: Dr. Rania Mouchantaf, Marketed Pharmaceuticals and Medical Devices Bureau
- 10:15 am – 10:30 am
Morning Break
- 10:30 am – 11:15 am
Update on Health Canada's Quality Guidance Documents and Common Deficiencies Observed in Drug Submissions
Speaker: Dr Susan Lum, Manager, Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada
- 11:15 am – 12:00 pm
Regulation of Drugs for Rare Diseases
Speaker: Dr Fiona Frappier, Office of Policy and International Collaboration, Biologics and Generic Therapies Directorate, Health Canada

Lunch

- 12:00 pm – 1:00 pm
Lunch

THIS YEARS VENDORS INCLUDE:

AXSource Consulting Inc.
Network Partners
Therapeutic Products Inc.

LOCATION:

The Westin Bristol Place Hotel
Toronto Airport
950 Dixon Rd, Toronto, On M9W 5N4
Tel: (416) 675-9444

Pricing: Non- Members: \$550, Members: \$460, Students: \$150 (must provide proof of current student enrollment prior to Education Day)

For further information, please contact
Krystyna Bienkiewicz at
bienki@sympatico.ca or 905-220-1636

Afternoon Session

- 1:00 pm – 1:45 pm
Self-Care Products Framework Update
Speakers: Amanda Moir, Director, Consumer Health Products Modernization, Natural and Non-prescription Health Products Directorate, Health Products and Food Branch Health Canada / Government of Canada

Matthew Bown, Senior Policy Advisor, Natural and Non-prescription, Health Products Directorate, Health Products and Food Branch Health Canada / Government of Canada
- 1:45 pm – 2:30 pm
Plain Language Labelling Review of Non-Prescription Drugs
Speaker: Jason DiMuzio, MSc. Label Review Coordinator, Non-Prescription Drugs Evaluation Division (NDED), Natural and Non-Prescription Health Products Directorate, Health Canada
- 2:30 pm – 2:45 pm
Afternoon Break
- 2:45 pm – 3:30 pm
Overview of Regulatory Review of Drugs and Devices
Speaker: Michele Chadwick, Biologics and Generic Therapies Directorate
- 3:30 pm – 4:15 pm
Post-NOC Quality Guidance
Speaker: Hugo Hamel, Division Chief, Monoclonal Antibodies Division, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics (CERB), BGTD
- 4:15 pm – 4:30 pm
Closing Remarks
CAPRA Education Day Committee