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**CAPRA  
ACPR**



Canadian  
Association of  
Professionals  
in Regulatory  
Affairs

Association  
canadienne des  
professionnels en  
réglementation

# CAPRA ANNUAL EDUCATION DAY

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**June 7<sup>th</sup> 2018**

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**CAPRA|ACPR**

## Morning Session

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- 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

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- 12:00 pm – 1:00 pm  
**Lunch**

### THIS YEARS VENDORS INCLUDE:

**AXSource Consulting Inc.**  
**Network Partners**  
**Therapeutic Products Inc.**

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### 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](mailto:bienki@sympatico.ca) or 905-220-1636

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## Afternoon Session

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- 1:00 pm – 1:45 pm  
**Self-Care Products Framework Update**  
*Speaker: Tina Singal, 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  
**Health Canada's Regulatory Review of Drugs and Devices (R2D2)**  
*Speaker: Michèle Chadwick, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada*
- 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*