

**CAPRA
ACPR**



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation

Regulatory Review of Drugs & Devices R2D2 Workshop



CAPRA will host a two-day workshop to provide an update from Health Canada on the substantial regulatory reform initiatives underway. The proposed topics include: health care system needs concept, health technology assessment collaboration with CADTH, Special Access Programme (SAP) renewal, Public Release of Clinical Information (PRCI) regulations/ guidance, use of foreign reviews/decisions, real world evidence life cycle integration and stop the clock mechanisms. Further, there will be the option to attend a concurrent session on medical device projects related to building better access to digital health technologies, real world evidence life cycle integration and the provision of early scientific advice for medical devices.

The event format will include presentations followed by breakout sessions to address specific questions posed by Health Canada and plenary sessions to present the feedback received.

This event will be of interest to Regulatory Affairs and Market Access professionals. Please share the news of this event within your organization.

May 15 - 16, 2018

Shaw Centre, Ottawa

55 Colonel By Drive
Ottawa, Ontario K1N 9J2

WORKSHOP AGENDA

Day 1 May 15, 2018	
7:30 – 9:00 am	Registration and Breakfast
9:00 – 9:05 am	Welcoming Remarks CAPRA and Megan Bettle
9:05 – 9:35 am	Overview of R2D2 and Health Care System Needs concept – Improving access to and use of necessary drugs and devices Health Canada Speaker: Megan Bettle
9:35 – 10:15 am	Laying the Foundation for the Health Canada Review and HTA Assessment Alignment HC Speaker: Mandy Collier CADTH Speakers: Trevor Richter/Alexandra Chambers
10:15-10:30am	Break
10:30 – 11:00 am	Special Access Programme (SAP) Renewal Update Health Canada Speaker: Marilena Bassi
11:00 – 11:30 am	R2D2 – Industry Perspective Industry Speaker - TBD
11:30 - noon	Panel Discussion
Noon – 1:15 pm	Lunch
1:15 – 1:45 pm	Public Release of Clinical Information – Draft Guidance (PRCI) Health Canada Speaker: Marcin Boruk
2:00 – 3:15 pm	Public Release of Clinical Information (PRCI): [Consultation] Feedback session in break-out rooms.
3:15 – 3:30 pm	Break
3:30 – 4:00 pm	Plenary – Summary of Consultation on Draft PRCI Guidance Moderator: CAPRA
4:00 – 4:10 pm	Closing Remarks

Day 2
May 16, 2018

7:30 – 9:00 am	Registration and Breakfast	
9:00 - 9:10 am	Welcoming Remarks – Recap of Day 1 CAPRA	
	Concurrent Session #1 – Drugs [Main Room]	Concurrent Session #2 – Medical Devices [Break-out Room]
9:15 – 9:40 am	Developments in the Use of Foreign Reviews and Decisions in the Health Canada Review Process Health Canada Speaker: Léo Bouthillier	Building Better Access to Digital Health Technologies Health Canada Speakers: David Boudreau / Marc Lamoureux
9:40 – 10:05 am	Real World Evidence Lifecycle Integration Health Canada Speaker: Basanti Ghosh	Real World Evidence – Lifecycle Integration and New Regulatory Proposals Health Canada Speakers: Rebecca Bose / Melanie Adams
10:05 – 10:30am	Break	
10:30 – 11:00am	Stop the Clock Health Canada Speakers: Melissa Hunt / Stephanie Hardy	Real World Evidence for Medical Devices – Regulatory View Industry Speaker - TBC
11:00- 11:30 am	Stop the Clock – Industry Perspective Industry Speaker: TBC	Medical Device Advice Health Canada Speakers: David Boudreau / Colin Foster
11:45 – 1:00 pm	Lunch	
1:00 - 2:45 pm	Mechanism to Stop the Clock [Consultation] Feedback session in break-out rooms.	Medical Device Advice [Consultation] Feedback session
2:45 – 3:00 pm	Break	
3:00 – 3:45 pm	Plenary – Reports from Concurrent Session Consultations Moderator: CAPRA	
3:45- 4:00 pm	Closing Remarks Health Canada Speaker: Megan Bettle	

R2D2 Workshop Registration & Fee

Workshop Fee (*Includes continental breakfast, breaks and lunch*):

CAPRA Member: \$695 (includes HST)

Vendor – 1 person: \$1695 + HST

Non-member: \$745 (includes HST)

Vendor – 2 persons: \$2373 + HST

A limited number of spaces are available for students and Health Canada employees at a rate of \$200 (including HST). Proof of full-time registration in a Regulatory programme is required at the time of booking (HST Registration No. 85475 8349RT0001).

Registration Procedure:

Registration will be accepted **ON LINE ONLY** at www.capra.ca/meetings.html. **Credit card payment is available only with on-line registration prior to the registration deadline of April 27th, 2018.** On the payment site, please use the name and address that matches the card.

If you wish to pay by cheque, payment must be received by May 11, 2018. Please mail the cheque, with a list of registrants and company name, to:

CAPRA
2425 Matheson Boulevard East
7th Floor, Suite 795
Mississauga, Ontario L4W 5K4

Please Note: Registration will be open from **March 9, 2018 to April 27, 2018.** Participants may be substituted, but no refunds will be issued.

Hotel Information:

Suites are subject to availability and Ottawa hotels are already very booked – please ensure to make your reservation early!

- 1) Book with **Les Suites Hotel** before **April 13, 2018** for a CAPRA rate of \$219.00/night for a premiere one bedroom suite (plus applicable tax and fees). Complimentary wireless high-speed internet included. Parking is an additional \$23.00CAN/day (plus applicable tax) with unlimited in/out access.

Online reservation: [Group reservation link](#) (Password: 151230)

Reservations can also be made by contacting the hotel directly (quote group code 151230):

Reservations: (613) 232-2000/(800) 267-1989

By fax: (613) 232-1242

By email: reservations@les-suites.com

- 2) Book with **Novotel Ottawa** before **April 2, 2018** for a CAPRA rate of \$229.00/night (plus applicable taxes and fees). Complimentary high-speed internet included. Reservations can be made online at: <https://book.passkey.com/e/49616498> or contact the hotel directly by calling 1-855-677-3033 and quote booking code 599952 or ask for the CAPRA block to secure a room.

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.