

CAPRA
ACPR



Canadian
Association of
Professionals
in Regulatory
Affairs

Association
canadienne des
professionnels en
réglementation

R2D2 - Accelerated Pathway & New Device Guidances Workshop



This one-day consultation workshop is for Health Canada to provide an update and receive feedback on new initiatives.

Significant changes to the Priority Review Pathway under R2D2 called the *Accelerated Review Pathway* will be discussed including: expanded product eligibility criteria for accelerated review; creation of conditions that will promote price competition and creation of a single accelerated review pathway, merging priority review and NOC/c streams.

New device guidances, Cybersecurity and Software as a Device, will be discussed with respect to the mitigation and/or elimination of risk to patients due to cybersecurity vulnerabilities in medical devices. Specific topics will include: Health Canada's planned regulatory approach to medical device cybersecurity, relevant standards when designing, manufacturing and testing medical devices and license application changes.

This event will be of interest to:

- Regulatory Affairs professionals;
- Market Access professionals in relation to patient benefit;
- Medical device software subject matter experts.

Please share the news of this event within your organization.

February 14, 2019

The Westin, Toronto Airport

950 Dixon Road

Toronto, Ontario M9W 5N4

WORKSHOP AGENDA

7:30 – 9:00 am	Registration and Breakfast	
9:00 – 9:05 am	Welcoming Remarks	
9:05 – 9:50 am	Accelerated Pathway Guidance Health Canada Speaker: Megan Bettle, Director, Regulatory Review of Drugs and Devices, BGTD, HPFB	
9:50 – 10:30 am	Accelerated Pathway Guidance Industry Perspective Industry Speaker: Laura King, Head of Regulatory Affairs Novartis Pharmaceuticals Canada	
10:30 – 10:50am	Break	
	CONCURRENT WORKSHOP SESSIONS	
10:50 – 11:20 am	Accelerated Pathway Guidance Workshop based on proposal and key questions	Cyber Security Guidance Health Canada Speaker: Ian Glasgow, Senior Evaluator, Digital Health Division, Medical Devices Bureau (MDB), TPD, HPFB
11:20 – 12:00		Cyber Security - Breakout Workshop & Plenary Feedback
12:00 – 1:15 pm	Lunch	
1:15- 1:40 pm	Accelerated Pathway Guidance Plenary Feedback	Software as a Medical Device Guidance Health Canada Speaker: Colin Foster, Head, Regulatory and Scientific Information Section, MDB, TPD, HPFB
1:40- 2:20 pm		Software as a Device - Breakout Workshop & Plenary Feedback
2:20 – 2:30 pm	Break	
2:30 – 2:45 pm	Licensing of Medical Devices in Canada eLearning Training Health Canada Speaker: Colin Foster, Head, Regulatory and Scientific Information Section, Medical Devices Bureau, TPD, HPFB	
2:45 – 3:20 pm	Update on other Regulatory Review of Drug and Device Projects Health Canada Speaker: Megan Bettle, Director, Regulatory Review of Drugs and Devices, BGTD, HPFB	
3:20 – 3:50 pm	Panel discussion / Q&A	
3:50 - 4:00 pm	Closing Remarks	

R2D2 Workshop Registration & Fee

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

CAPRA Member: \$450 (includes HST)

Non-member: \$500 (includes HST)

A limited number of spaces are available for students at \$200. 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 **ONLINE ONLY** at www.capra.ca/meetings.html. **Credit card payment is available only with on-line registration prior to the registration deadline of Feb 7th, 2019.** 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 Feb 7, 2019. 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 **December 12, 2018 to Feb 7, 2019**. Participants may be substituted, but no refunds will be issued.

Hotel Information:

Suites are subject to availability– please ensure to make your reservation early!

- 1) Book with **Westin** before **Jan 25, 2019** for a CAPRA rate of \$179.00/night (plus applicable tax and fees). Complimentary wireless high-speed internet included. Parking is an additional \$10.00CAN/day (plus applicable tax).

Reservations can be made by contacting the hotel directly and stating they are part of CAPRA 1-866-837-5184.

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.