CAPRA ACPR

Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

# Electronic Regulatory Process Symposium 2017


*CAPRA will host a one day symposium to provide an update on the Electronic Regulatory Process activities from Health Canada and the Group on Electronic Regulatory Affairs (GERA).*

*Both Health Canada and Industry speakers will present their strategies, experiences and feedback on the Regulatory Enrolment Process (REP), Structured Product Monographs and eCTD Pilot for Clinical Trials project. You will also hear about the implementation considerations for eCTD V4 and introduction to IDMP standard and its application.*

*This event will be of interest to Regulatory Affairs professionals involved with Module 1 content, labelling and Regulatory Operations- all are encouraged to attend and share the news of this event within your organization.*

## *Dec 6, 2017*

**THE WESTIN TORONTO AIRPORT HOTEL**
**950 Dixon Rd.**
**Toronto, ON M9W 5N4**
**Canada**
**westintorontoairport.com**

# Topic Descriptions

**eCTD for Clinical Trials**
The pilot for clinical trial regulatory activities in electronic common technical document (eCTD) format began in October 2016. This presentation will provide background on this pilot, highlight key feedback from industry and describe next steps for this initiative.

**Regulatory Enrolment Process (REP)**
The Regulatory Enrolment Process (REP) is the set of activities which allows industry to provide information related to company, dossier, regulatory activity and regulatory transaction to Health Canada in advance of the regulatory review process. By using a collection of web-based templates to capture metadata in a structured XML format and introducing controlled vocabulary, Health Canada can receive the information via the Common Electronic Submission Gateway (CESG), partially populate internal systems ahead of time and automate certain procedures when a submission is received.

Both a Health Canada update and an Industry perspective will be provided on this initiative.

**Structured Product Monograph (PM)**
The objective of this project is to transition Product Monographs from Word and PDF to a structured format using the Structured Product Label (SPL) data standard; which is based on Extensible Markup Language (XML). This structured format will help ensure product information is easier to locate, presented in a consistent format and uses consistent terminology to facilitate search and retrieval

Both a Health Canada update and an Industry perspective will be provided on this initiative.

**Identification of Medicinal Products (IDMP)**
The IDMP is a set of ISO data standards that provide the means to uniquely identify medicinal products using (1) unique identifiers; (2) common data structures; and (3) common terminology. This presentation will provide an introduction to this standard and examples of its application.

**eCTD version 4: Overview and Implementation Considerations**
An overview of eCTD v4 and its use of the Health Level 7 (HL7) Regulated Product Submission (RPS) standard; key implementation considerations will be provided as well.

# Electronic Regulatory Process Symposium 2017 Agenda

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| 8:00 – 9:00 | **Registration and Hot Breakfast** |
| 9:00 – 9:10 | **Welcoming Remarks** |
| 9:10 – 10:10 | **Trends in Regulatory Informatics: HPFB IT Plan and Industry Perspective**<br>*Vikesh Srivastava – Associate Director, Business Informatics Division, Resource Management and Operations Directorate*<br>*Rocelyn Del Carmen – Co-Chairs of the Group on Electronic Regulatory Activities* |
| 10:10 – 10:30 | **Morning Break** |
| 10:30 – 11:00 | **Update on Ongoing Initiatives: eCTD Pilot for Clinical Trials**<br>*Irena Pastorekova – Regulatory Affairs Specialist, Office of Submissions and Intellectual Property, Therapeutic Products Directorate* |
| 11:00 – 11:30 | **Update on Ongoing Initiatives: Regulatory Enrolment Process (REP)**<br>*Vianney Caron – Senior Chemistry and Manufacturing Evaluator and Manager, Electronic Regulatory Activities, Therapeutic Products Directorate*<br>*Katerina Paschakis – Project Manager, Business Informatics Division, Resource Management and Operations Directorate* |
| 11:30 – 1:00 | **Lunch** |
| 1:00 – 1:30 | **Update on Ongoing Initiatives: Structured Product Monograph (SPM)**<br>*Craig Anderson – Business Analyst, Business Informatics Division, Resource Management and Operations Directorate* |
| 1:30 – 2:00 | **Industry Perspective: Regulatory Enrolment Process (REP) and Structured Product Monograph (SPM)**<br>*Khaled Yahiaoui – President, eCTD Now Inc.* |
| 2:00 – 2:30 | **Introduction to IDMP**<br>*Vikesh Srivastava – Associate Director, Business Informatics Division, Resource Management and Operations Directorate* |
| 2:30 – 2:45 | **Afternoon Break** |
| 2:45 – 3:15 | **eCTD v4: Overview and Implementation Considerations**<br>*Irena Pastorekova – Regulatory Affairs Specialist, Office of Submissions and Intellectual Property, Therapeutic Products Directorate*<br>*Craig Anderson – Business Analyst, Business Informatics Division, Resource Management and Operations Directorate* |
| 3:15 – 4:00 | **Panel Discussion and Closing Remarks** |

## Symposium Registration & Fee

**Symposium Fee** (*Includes continental breakfast, breaks and lunch)*

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| Members: | $376.11 + HST | Vendor – 1 person: | $730.10 + HST |
| Non-Members: | $398.23 + HST | Vendor – 2 persons: | $973.46 + HST |
| Students*: | $176.99 + HST | | |

*Proof of full-time registration in a Regulatory programme is required at the time of booking for student rate. (HST Registration No. 85475 8349RT0001).

### Registration Procedure:

Registration will be accepted **ON LINE ONLY** at https://capra.ca/en/meetings/register/?id=20.
**Credit card payment is available only with on-line registration prior to the registration deadline of November 24, 2017.** 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 November 30, 2017.** 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 until **November 24, 2017. After November 24th** participants may be substituted, but no refunds will be issued.

### Book Your Room for the Symposium at:

**Westin Toronto Airport Hotel**
**950 Dixon Road, Toronto, ON**

Book with the Westin Toronto Airport before **November 17, 2017** for a CAPRA rate of $169.00 (+ HST and hotel fees depending on room) **subject to availability**. Attendees may reserve by phone at: 1-866-837-5184, please identify yourself as part of CAPRA Symposium group. **Parking will be free for symposium attendees.**

Reservations must be guaranteed with a credit card or advanced deposit. Rates are subject to availability and only a limited number of rooms are available, so members are encouraged to book early to ensure they receive the discounted CAPRA room rate. All reservations MUST be made prior to the respective reservation deadlines by in order to be eligible for the discounted CAPRA room rates. After this date the discounted room rates will no longer be available and attendees will need to book at the prevailing market rate (should the hotel still have vacancy).

**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.

**Questions?** Please email**: symposium@capra.ca**.