

# 2021 CAPRA Labelling Symposium



Canadian  
Association of  
Professionals  
in Regulatory  
Affairs

Association  
canadienne des  
professionnels en  
réglementation



The CAPRA Symposium Committee will host two virtual interactive sessions to provide several labelling updates and best practices sessions from Health Canada.

Session one will focus on the XML Product Monograph (PM) project and provide a detailed overview of the new 2020 PM Master Template with best practices related to the conversion of the PM to the 2020 format. Session two will cover the Natural and Non-prescription Health Products Directorate (NNHPD) and What is New with NHPs. Best practices will be shared for submissions filed through the Administrative pathway.

This Symposium will also feature Industry perspectives and provide attendees with an opportunity to raise questions with Health Canada on these topics.

This event will be of interest to:

- Regulatory Affairs professionals from medical devices, pharmaceuticals/biologics, NHPs, as well as veterinary drugs
- Clinical Research and Contract Research Organizations
- Clinical Data Management/Pharmacovigilance
- Research and Development

Please share the news of this event within your organization.

***CAPRA Virtual Symposium  
Via Microsoft Teams  
December 7 & 8, 2021***

## Labelling Symposium Session 1: December 7, 2021

8:30 – 8:50 am	<b>Logging into Virtual Workshop Session # 1</b>
8:50 – 9:00 am	<b>Welcoming Remarks</b>
9:00 – 9:30 am	<b>Product Monographs in the XML Format (XML PM)</b> <b>Health Canada (HC) speaker:</b> Tracy E. Brown, Project Manager, Business Informatics Division, Resource Management and Operations Directorate, HC
9:30 – 10:30 am	<b>Product Monograph “Master” Template</b> <b>HC Speaker:</b> Lynda O'Reilly, Educator, Regulatory Project Management Division, Therapeutic Products Directorate (TPD), Health Products & Food Branch (HPFB)
10:30 – 10:40 am	<b>Break</b>
10:40 – 11:10 am	<b>Industry Perspective</b> <b>Speaker:</b> Khaled Yahiaoui, Associate Director - Regulatory Affairs, Operations, Merck Canada Inc.
11:10 – 11:40 am	<b>Software Developer Perspective</b> <b>Speakers from Infrastructures for Information Inc.:</b>  Jacqueline Bruner, Senior Director, Encoding Technology  Aman Kainth, Senior Team Lead, Regulatory Affairs
11:40 – 12:10	<b>Best Practices for Converting PM to 2020 Template from a Label Reviewer’s Perspective</b> <b>HC Speakers:</b> Sandra Alderdice, Supervisor, Labelling Division, TPD, HPFB  Taranum Singh, Supervisor, Labelling Division, TPD, HPFB
12:10 – 12:30 pm	<b>Panel Discussion and Q&amp;A:</b>  All Speakers to address questions or provide clarifications
12:30 – 12:35 pm	<b>Closing Remarks</b>

## Labelling Symposium Session 2: December 8, 2021

<b>8:30 – 8:50 am</b>	<b>Logging into Virtual Workshop Session 2:</b>
<b>8:50 – 9:00 am</b>	<b>Welcoming Remarks</b>
<b>9:00 – 9:45 am</b>	<p><b>NNHPD Update and Labelling (Drug Facts Table)</b>  <b>HC Speakers:</b>            Jason Di Muzio, Acting Manager, Non-prescription Drugs Evaluation Division (NDED), Bureau of Product Review and Assessment, Natural and Non-prescription Health Products Directorate, Health Products and Food Branch (HPFB)</p> <p>Rohini Gupta, Senior Regulatory Affairs Officer, NDED, Natural and Non-prescription Health Products Directorate, HPFB</p>
<b>9:45 – 10:15 am</b>	<p><b>What is New with NHPs</b>  <b>HC Speakers:</b>            Beatrice Lee, Manager, Bureau of Licensing Services and Systems, NNHPD</p> <p>Jaqueline Coté, Senior Policy Advisor, Bureau of Policy, Risk Management &amp; Stakeholders, NNHPD</p>
<b>10:15 – 10:30 am</b>	<b>Q&amp;A</b>
<b>10:30 – 10:40 am</b>	<b>Break</b>
<b>10:40 – 11:10 am</b>	<p><b>Best Practices to Address Screening Clarifications and/or Deficiencies for Submissions filed through the Administrative Pathway</b>  <b>HC Speakers:</b>            Marianne Giordano, Sr. Regulatory Officer, Administrative Services Unit, Labelling Division, Therapeutic Products Directorate, HPFB</p> <p>Kiyomi Leslie, Sr. Regulatory Specialist, Labelling Division, Therapeutic Products Directorate, HPFB</p>
<b>11:10 – 11:40 pm</b>	<b>Q&amp;A</b>
<b>11:40 – 11:45m</b>	<b>Closing Remarks</b>

## Premium Event Sponsorship



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