# 2021 CAPRA Labelling Symposium

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 conversion of the PM to the 2020 format. Session two will cover the new draft guidance, Electronic Media in Prescription Drug Labelling, plus updates from the Natural and Non-prescription Health Products Directorate (NNHPD). Best practices will be shared for submissions filed through the Administrative pathway.

This Symposium will also feature Industry perspectives and provide attendees 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 ACPR
Canadian Association of Professionals in Regulatory Affairs
Association canadienne des professionnels en réglementation

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

## Labelling Symposium Session 1: December 7, 2021

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| **8:30 – 8:50 am** | ***Logging into Virtual Workshop Session # 1*** |
| **8:50 – 9:00 am** | **Welcoming Remarks** |
| **9:00 – 9:30 am** | **Product Monographs in the XML Format (XML PM)**<br>**Health Canada (HC) speaker:** Tracy E. Brown, Project Manager, Business Informatics Division, Resource Management and Operations Directorate, HC |
| **9:30 – 10:30 am** | **Product Monograph "Master" Template**<br>**HC Speaker:** Lynda O'Reilly, Educator, Regulatory Project Management Division, Therapeutic Products Directorate (TPD), Health Products & Food Branch (HPFB) |
| **10:30 – 10:40 am** | **Break** |
| **10:40 – 11:10 am** | **Industry Perspective**<br>**Speaker:** Khaled Yahiaoui, Associate Director - Regulatory Affairs, Operations, Merck Canada Inc. |
| **11:10 – 11:40 am** | **Software Developer Perspective**<br>**Speakers from Infrastructures for Information Inc. (known as i4i):**<br>Jacqueline Bruner, Senior Director, Encoding Technology<br><br>Aman Kainth, Senior Team Lead, Regulatory Affairs |
| **11:40 – 12:10** | **Best Practices for Converting PM to 2020 Template from a Label Reviewer's Perspective**<br>**HC Speakers:**<br>Sandra Alderdice, Supervisor, Labelling Division, TPD, HPFB<br><br>Taranum Singh, Supervisor, Labelling Division, TPD, HPFB |
| **12:10 – 12:30 pm** | **Panel Discussion and Q&A:**<br><br>All Speakers to address questions or provide clarifications |
| **12:30 – 12:35 pm** | **Closing Remarks** |

## Labelling Symposium Session 2: December 8, 2021

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

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