IGDRP/Health Canada/CAPRA Symposium

Regulatory Collaboration and Emerging Issues in Generic Medicines - IGDRP and other Initiatives Responding to Today's Demands and Future Challenges

In collaboration with the International Generic Drug Regulators Programme (IGDRP) and Health Canada, CAPRA will host this one-day symposium. It will be an ideal opportunity to hear from key international regulators and industry representatives on drivers and the progress of the IGDRP activities and on other initiatives to address challenging and emerging issues facing regulators and the pharmaceutical industry.

The availability of quality medicines plays an increasingly important role in helping to address rising health care costs and in promoting access to essential medicines worldwide. The IGDRP was created to promote collaboration and convergence in generic drug regulatory programs in order to address the challenges posed by increasing workloads, globalisation and complexity of scientific issues.

This event will be of interest to all Regulatory Affairs professionals. Please share the news of this event with others in your organization, such as those from Product Development, Quality and QA, who would also benefit from attending.

Health Canada / Santé Canada

IGDRP International Generic Drug Regulators Programme

CAPRA ACPR Canadian Association of Professionals in Regulatory Affairs / Association canadienne des professionnels en réglementation

June 9, 2017

Fairmont Chateau Laurier
1 Rideau St,
Ottawa, Ontario
Canada

Symposium Agenda

8:00 - 8:45	**REGISTRATION**
9:00 - 9:20	**Welcoming** • Queenia Lee Director, Canadian Association of Professionals in Regulatory Affairs (CAPRA) **Opening Remarks** • Marion Law Director General, Therapeutic Products Directorate (TPD), Health Canada
9:20 - 10:00	***Session 1 - Setting the Stage*** **IGDRP Overview: What it is / What we are about** • Gary Condran Associate Director, Bureau of Pharmaceutical Sciences, TPD, Health Canada **Development and Licensing of Generic Medicines in a Global Environment: The Canadian Perspective** • Len Arsenault Chair, Scientific Affairs Committee, Canadian Generic Pharmaceutical Association (CGPA)
10:00 - 10:15	**COFFEE BREAK**
10:15 – 11:15	***Session 2 - IGDRP Priority Work Areas*** **Bioequivalence Working Group (BEWG)** • Craig Simon (Co-Chair, BEWG, IGDRP) Associate Director, Bureau of Pharmaceutical Sciences, TPD, Health Canada **Quality Working Group (QWG)** • Antony Fake (Co-Chair, QWG, IGDRP) Prequalification Team – Medicines, World Health Organization, Geneva, Switzerland **EU Information Sharing Initiatives** • Peter Bachmann Chair, CMDh, European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany
11:15 - 11:45	**Q&A PANEL - MORNING SESSION**
11:45 – 13:00	**LUNCH**
13:00 – 13:45	***Session 3 - Advancing Information and Work Sharing Initiatives*** **Australia/Canada/Singapore/Switzerland (ACSS) Consortium and the Generic Medicines Work Sharing Trial (GMWST)** • Christopher Crane Pharmaceutical Chemistry Section, Therapeutic Goods Administration (TGA), Australia **Participation in Regulatory Information Sharing Pilots - *An Industry Applicant's Experience*** • Michael Banks Senior Vice President, Regulatory Affairs Global Generics & OTC, Teva Pharmaceuticals

13:45 - 14:45	***Session 4 - Improving the Access to Medicines - Thinking Globally and Acting Locally*** **Health Canada: Improving Access to and Use of Necessary Therapeutic Products** • Michèle Chadwick Health Products and Food Branch, Health Canada **USFDA Update on GDUFA: The need for enhanced global collaboration for advancement of public health impact through generic medicines** • April Braddy Deputy Director, DBIII, Office of Generic Drugs, CDER, US Food and Drug Administration **Update of ANVISA´s Strategies for Generic Medicines** • Ana Carolina Moreira Marino Araujo Agência Nacional de Vigilância Sanitária (ANVISA), Brazil
14:45 - 15:00	**COFFEE BREAK**
15:00 – 16:00	***Session 5 - Quality Stream*** **Update on the European Directorate for the Quality of Medicines and HealthCare (EDQM) Activities – European Pharmacopoeia and CEP Procedure** • Hélène Bruguera Head, Certification of Substances Division, EDQM, Strasbourg, France **WHO's API Prequalification Programme and Common Deficiencies Observed in Master Files** • Antony Fake Prequalification Team – Medicines, World Health Organization, Geneva, Switzerland **Update on Health Canada's Quality Guidance Documents and Common Deficiencies Observed in Drug Submissions** • Alison Ingham Senior Scientific Advisor, Bureau of Pharmaceutical Sciences, TPD, Health Canada
16:00 – 16:25	**Q&A PANEL - AFTERNOON SESSION**
16:25 - 16:30	**Conclusions and Closing Remarks** • Bruce Randall Director, Bureau of Pharmaceutical Sciences, TPD, Health Canada
16:30	**END OF SYMPOSIUM**

Symposium Registration & Fee

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

Members: $376.11 + HST
Non-Members: $398.23 + 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://www.capra.ca/en/meetings/register/?id=11
Credit card payment is available only with on-line registration prior to the registration deadline of June 2nd. 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 June 5th, 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 **June 2nd, 2017. After June 2nd, 2017** participants may be substituted, but no refunds will be issued.

Book Your Room for the Symposium at:

Fairmont Chateau Laurier
1 Rideau St, Ottawa, ON

Book with Fairmont Chateau Laurier before **April 29, 2017** for a CAPRA rate of $289.00 - $369 (+ HST and hotel fees depending on room) **subject to availability**. Attendees may reserve by on line at https://aws.passkey.com/go/capramtg or by phone at: 1-800-441-1414, please identify yourself as part of CAPRA Symposium group.

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).

Parking: Hotel parking is provided at an additional fee.

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.