

DIA Annual Canadian Meeting

October 17-18, 2017 Ottawa Marriott Hotel | Ottawa, ON



Alliance for Safe Biologic Medicines

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ASBM is an organization composed of patients, physicians, pharmacists, manufacturers of innovator biologics and biosimilars, researchers, and others working together to ensure patient safety is at the forefront of the biosimilars policy discussion.





CAPRA

Canadian Association of Professionals in Regulatory Affairs

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Canada

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Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

The Canadian Association of Professionals in Regulatory Affairs (CAPRA) is a non-profit organization dedicated to providing its members with opportunities to enhance their professional development and maximize career opportunities. We foster learning, networking and professional excellence amongst our members. Founded in 1982, CAPRA's members represent the Canadian pharmaceutical, biologic, medical device, natural health product, and cosmetic sectors. CAPRA's goal is to build and strengthen relationships with governmental agencies, scientific experts and industry educators in order to create an affordable, professionally fulfilling and academically enriching environment for our members.



Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

CAPRA is Canada's leading society for Regulatory Professionals

We are a non-profit organization that serves the pharmaceutical, biologic, medical device, cosmetic and natural health product industries in Canada.











THERE ARE MANY BENEFITS OF AN ANNUAL CAPRA MEMBERSHIP!

- ✓ Educational forums offering professional development
- ✓ Symposia
- ✓ Quarterly news publication (The NOC)
- ✓ Membership email broadcasts

- ✓ Recorded webinars
- ✓ Early access to online job postings
- ✓ Advertising opportunities
- ✓ Bilingual website

WWW.CAPRA.CA



Educe Solutions Pvt. Ltd

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Email: <u>barryp@pharmedev.com</u>
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DRA Pharmedev Canada Inc. is the Canadian agent for Educe Solutions Pvt. Ltd, developer of e-CTD and other software for the Pharma industry (see website). Adapted to Canadian requirements, tested in Canada. Bilingual support desk IN Québec.



Mapi Group

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Canada

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Mapi Strategic Regulatory Services: Helping You Navigate through Regulatory Challenges

Mapi Group is the premier provider of regulatory strategy and commercialization services to health research and life science companies. Our full-service Strategic Regulatory Services team offers extensive experience as a globally established industry leader in regulatory, quality, safety, compliance, and commercialization services. Mapi's experts understand regional regulatory environments and offer essential in-depth functional expertise for designing and implementing best practices.

Developing an effective global regulatory strategy is essential for regulatory compliance; effective strategy design maximizes commercial opportunities for product developers and manufacturers and minimizes company risk. As the premier provider of health research, regulatory, quality, safety, compliance, and commercialization services to the life science industry, our experience and expertise can make things happen fast—and by providing regulatory assistance on routine work, our support lets you focus on your top priorities.



CMC

Medical Devices eCTD

Compliance & Quality ■

broad range of therapeutic areas. We provide unparalleled regulatory support for biologics, pharmaceuticals, NHPs, and medical devices. Our regulatory expertise is integrated into our wide range of services, ensuring compliance at every step of the development process.

www.mapigroup.com

Visit us at Table 6 for more information



Mapi

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ACUTA LLC Table 2

Contact: Michelle Gyzen Phone: +1.508.466.7799 info@acutallc.com www.acutallc.com

ACUTA is a provider of solutions and services to the Life Sciences and related industry. ACUTA offerings include a world class cloud based Regulatory Information Management System (RIMS), Regulatory Operations Outsourcing and Consulting Services.

Alliance for Safe Biologic Medicines Table 9

Contact: Michael Reilly Phone: +1.703.971.1700 michael@safebiologics.org www.safebiologics.org

The Alliance for Safe Biologic Medicines is an organization composed of patients, physicians, pharmacists, medical innovators, biosimilar manufacturers, researchers and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

CAPRA (Canadian Association of Professionals in Regulatory Affairs)

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Founded in 1982, the Canadian Association of Professionals in Regulatory Affairs (CAPRA) is a non-profit organization dedicated to providing its members with opportunities to enhance their professional development and regulatory expertise. We foster learning, networking and professional excellence of our members.

Certus PV Services Inc. Table 6

Contact: Agnes Jankowicz Phone: +1.905.306.3448 contact@certuspv.com www.certuspv.com

Certus PV provides a full suite of pre- and post-market pharmacovigilance (PV) and Medical Information (MI) services for drugs, biologics, radiopharmaceuticals, natural health products, medical devices and cosmetics. Our expert team provides you with the certainty that your PV and MI needs are addressed in a comprehensive and proficient manner.

Educe Solutions Pvt. Limited Table 12

Contact: Barry Poole Phone: +1.514.994.3721 barryp@pharmedev.com www.educesolutions.com

DRA Pharmedev Canada Inc. (1975) is the Canadian agent for Educe Solutions Pvt. Ltd., an experienced developer of e-CTD and other software for the pharma industry. For details see the Educe website. The software is adapted to Canadian requirements, successfully tested in Canada. A bilingual Canadian support desk is being established in Québec.

Table 1

Evidence Partners Inc.

Contact: Peter O'Blenis Phone: +1.844.622.8727 poblenis@evidencepartners.com www.evidencepartners.com

Evidence Partners is the creator of DistillerSR, the world's most widely used literature review software. DistillerSR is a a fully compliant, transparent, and audit-ready solution that automates many of the manual tasks involved in the preparation of pharmacovigilance literature reviews.

i4i Inc.

Table 10

Contact: Ruth Wylie Phone: +1.416.504.0141 rwylie@i4i.com www.i4i.com

i4i is a world leader in the development of structured content applications. i4i's innovative technology, regulatory and standards expertise enhance compliance through solutions that deliver intelligent content reuse, data identification, tracking and lifecycle management of key Corporate, Clinical, CMC, Safety and Labelling documents.

LORENZ Life Sciences Group

Table 7

Table 5

LORENZ Life Sciences Group has an array of RIM solutions geared towards industry, health authorities and academia which enable enforcing compliance globally. LORENZ's portfolio offers Product Registration/IDMP, Submission Assembly, Validation and Management, Publishing/eCTD, Regulatory Planning and Tracking products and related services.

Mapi Table 6

Contact: Stuart Wright Phone: +1.859.223.4334 webinquiry@mapigroup.com www.mapigroup.com

Mapi's global Strategic Regulatory Services Group has worked with hundreds of clients in 60+ countries. Mapi's team is your beginning to end solution to the successful navigation of your product's regulatory lifecycle. Mapi is the leading Patient-Centered Research company serving academia, life science researchers, and the pharmaceutical industry.

QCR Services Inc Table 4

Contact: Deborah Campbell Phone: +1.905.363.1182 x223 smcdonald@qualityandcompliance.com www.qualityandcompliance.com

Q&C is the largest full-service consultant and importer for Health Canada, US FDA and internationally regulated drugs, NHPs and medical devices. We offer Commercialization & Importing, Regulatory, Compliance and R&D services. Q&C is fully Health Canada and ISO licensed. Over 150000 copies of our pocket GMP booklets have been distributed worldwide.

Therapeutic Products Inc.

Table 3

Contact: Matthew French Phone: +1.905.690.4343 mfrench@tpireg.com www.tpireg.com

We are a boutique Canadian consulting firm offering regulatory and quality assurance services to the pharmaceutical and healthcare industry in North America. We provide strategic advice, and/or day-to-day or project specific resource support to complement your own capabilities.



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