


**MEDEC**

CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES  
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES  
DISPOSITIFS MÉDICAUX

# October 24th & 25th, 2007 MEDEC Legal & Regulatory Conference in Toronto



A not to be missed annual Legal & Regulatory learning and networking MEDEC event! Features speakers from Eucomed, FDA, Health Canada and industry experts presenting and discussing current and future scenarios as they apply to medical devices and emerging technologies in the different jurisdictions.

Special sessions focus on the potential effect of global harmonization, hot legal topics, medical device regulations, and workshops that provide the opportunity for information exchange with

presenters from the regulators side of the table as well as with peers in the industry.

## Who Should Attend?

- Regulatory Affairs Associates of all levels
- QA Managers/Associates
- Legal Counsel
- Marketing Directors, Marketing Associates & Product Managers
- Business Development Associates
- General Managers

For more information about event sponsorship opportunities, contact [sponsorship@medec.org](mailto:sponsorship@medec.org).

## REGISTRATION (Plus GST)

<b>MEDEC Members</b>	<b>\$899</b>
<b>Non-Members</b>	<b>\$1299</b>

## REGISTRATION INCLUDES

Speakers, Workshop, Breakfast, Lunch and Refreshments.

## DATE (2 day Conference)

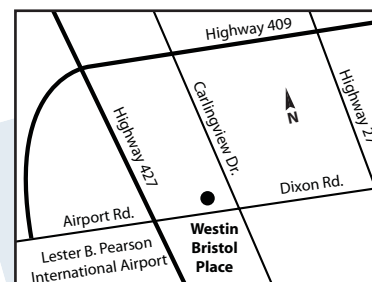
October 24-25, 2007

## LOCATION & ACCOMMODATION RATES

### Westin Bristol Place

950 Dixon Road  
Toronto, Ontario  
M9W 5N4 Canada  
Phone: (416) 675-9444

Special hotel room rate of \$179 available if booked by October 8th quoting "MEDEC".



To register online, go to:  
**[www.medec.org/events\\_and\\_programs](http://www.medec.org/events_and_programs)**



# MEDEC CONFERENCE AGENDA

## DAY 1 (October 24th)

### MEDEC Annual Regulatory and Legal Conference

October 24-25 at Westin Bristol Place, 950 Dixon Road, Toronto, Ontario

**7:45-8:25 Registration & Continental Breakfast**

**8:25-8:30 Welcome and Opening Remarks**

*Stephen Dibert* (MEDEC)

**8:30-9:30 Global Harmonization Round Table**

- Past and Present Goals
- Achievements and Challenges
- What the Future Holds

Presenter/Moderator: *Roland Rotter* (Health Canada)

Panel: *Tim Ulatowski* (FDA), *Dario Pirovano* (Eucomed), *Beth Staub* (Stryker USA), *Stephen Dibert* (MEDEC)

**9:30-9:40 Move to Breakout Sessions**

**9:40-12:30 Medical Devices Legal Hot Topics**

- Canadian Competition Law

Presenter: *Ian Nielsen-Jones*  
(Competition Bureau)

Panel: *Navin Joneja*  
(Blake, Cassels and Graydon),  
*Paul Crampton* (Osler Hoskin and Harcourt)

- Contracts Between Industry and Health Care Institutions

Presenter: *Karima Kanani* (Miller Thomson)

- MEDEC's Code of Conduct

Presenter: *Emily Larose*  
(Cassels, Brock & Blackwell)

**Medical Device Regulations 2007**

- Access to the Canadian Market Part 1  
Co-Presenters: *Anne Tomalin* (CanReg),  
*Dave McCarthy* (McCarthy Consultants)

- International Regulations

- USA status and trends

Presenter: *Tim Ulatowski* (FDA)

- EU status and trends

Presenter: *Dario Pirovano* (Eucomed)

- Japan Emerging Markets, e.g., China—  
status and trends

Presenter: *Ed Rozyński* (Stryker USA)

**12:30-1:30 Lunch**

**1:30-4:30 Medical Device Post-Market Issues**

- Medical vigilance and post-market surveillance

Presenter: *Barbara Harrison* (Health Canada)

**Workshop on Establishment Audits/Operational Compliance**

- Best practices for the internal process
- How to live by the regulations

Presenter: *Richard Kirchner* (Health Canada)

**Workshop on Canadian Competition Law**

Presenter: *Ian Nielsen-Jones*  
(Competition Bureau)

Facilitators: *Navin Joneja*  
(Blake, Cassels and Graydon),  
*Paul Crampton* (Osler Hoskin and Harcourt)



# MEDEC CONFERENCE AGENDA

## DAY 2 (October 25th)

### MEDEC Annual Regulatory and Legal Conference

October 24-25 at Westin Bristol Place, 950 Dixon Road, Toronto, Ontario

#### 8:00-8:05 **Welcome and Opening Remarks**

*Klaus Stitz*, Head of Regulatory Affairs (MEDEC)

#### 8:05-9:00 **Adapting Regulations to the Needs of Future Medical Devices Round Table**

- Medical Devices/Drug Combinations
- Medical Devices/Software combinations
- Emerging Technologies/Nanotechnologies
- Medical Devices from bioengineered materials

Presenter/Moderator: *Tim Ulatowski* (FDA)

Panel: *Roland Rotter* (Health Canada), *Dario Pirovano* (Eucomed),  
*Beth Staub* (Stryker USA), *Stephen Dibert* (MEDEC)

#### 9:00-10:30 **Clinical Trials for Medical Devices in Canada**

- Current status and where we are headed

Presenter: *Heather Van Dusen* (Health Canada)

#### 10:30-10:45 **Break**

#### 10:45-12:45 **Medical Devices Legal Hot Topics (cont'd)**

- Litigation in Canada vs. in the US

Co-presenters: *Gordon McKee* (Blake Cassels and Graydon),  
*Kathryn M. Frelick* (Miller Thomson)

- Selling on the internet and counterfeit products

Presenter: *Alan Aucoin*

(Blake Cassels and Graydon)

#### **Access to the Canadian Market Part 2**

- International Co-operations and mutual recognition
  - FDA multi-purpose audit
  - Australia MoU
- Trends in Quality Management Systems (Internationally and in Canada)

Presenter: *Egan Cobbold* (Health Canada)

#### 12:45-1:45 **Lunch**

#### 1:45-4:45 **Workshop/Case Studies on Smooth Sailing in Licensing**

- How to speed up your license application
- Most common causes for delayed licensing
- Examples for class II, III/IV IVDDs

Presenter: *John Helmky* (Health Canada)



# MEDEC CONFERENCE REGISTRATION FORM

## 2007 MEDEC ANNUAL LEGAL AND REGULATORY CONFERENCE

October 24-25 at Westin Bristol Place, 950 Dixon Road, Toronto, Ontario

To register, please complete this form and fax to: 416-620-1595.

☐ Mr. ☐ Mrs. ☐ Ms. ☐ Dr. ☐ M.D. ☐ Ph.D.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Organization/Company: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

(City) \_\_\_\_\_ (Province/State) \_\_\_\_\_ (Postal Code) \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

- ☐ I am a MEDEC member  
☐ I am not a MEDEC member  
☐ I will require a vegetarian meal

### REGISTRATION FEES FOR REGULATORY & LEGAL CONFERENCE

Two-Day Conference

6% G.S.T.

**TOTAL**

### MEMBERS

\$899.00

\$53.94

**\$952.94**

### NON-MEMBERS

\$1299.00

\$77.94

**\$1376.94**

### PAYMENT METHOD

☐ Please bill me ☐ Cheque enclosed (payable to MEDEC) ☐ VISA ☐ MASTERCARD

Card Number \_\_\_\_\_ Expiration Date (Month/Year) \_\_\_\_\_

Card Holder's Name \_\_\_\_\_ Signature \_\_\_\_\_

### CANCELLATION POLICY

Cancellations must be received in writing by Wednesday October 10<sup>th</sup>, 2007 to qualify for a refund. Substitutions are permitted. Failure to show will result in a full fee charge. Payment must be received prior to the start of the conference. Please note that registration fees are the same for those who choose to attend only one day. MEDEC GST registration Number: R123660573.

### ADDITIONAL INFORMATION

For further information, please contact Karen Hipson, Executive Assistant and Membership Coordinator (416) 620-1915 ext. 229 or by email at [medec@medec.org](mailto:medec@medec.org). For information about the conference location, visit [www.internationalcentre.com](http://www.internationalcentre.com) or call (905) 677-6131.



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405 The West Mall, Suite 900, Toronto, Ontario M9C 5J1  
T: (416) 620-1915 F: (416) 620-1595 Toll-Free: (866) 58-MEDEC  
E: [medec@medec.org](mailto:medec@medec.org) [www.medec.org](http://www.medec.org)