



# Asia-Pacific Economic Cooperation

## **APEC - Funded Medical Devices Regulatory Harmonization Delegation Visit to Canada and the United States August 8 - 18, 2010 • Ottawa, Canada; Boston, Massachusetts; and Washington D.C., USA**

Health Canada, the U.S. Food and Drug Administration (USFDA), the Global Harmonization Task Force (GHTF), the Pan American Health Association (PAHO), the Latin American Harmonization Working Party (LAHWP), the Asian Harmonization Working Party (AHWP), the U.S. Department of Commerce (USDOC), and the Advanced Medical Technology Association (AdvaMed) present the latest in the series of APEC-funded projects educating regulators on global harmonization of medical devices regulation. AdvaMed will coordinate with U.S. and Canada industry in organizing the industry portion of this delegation visit.

Participation in this delegation visit will help you as a regulator to better understand global medical device regulations and the emerging similarities between them. This delegation visit builds upon a similar APEC-funded September 2009 delegation visit of APEC Asia medical devices regulators to Australia. The focus of the August 2010 delegation visit will be training, laboratory visits, and training conducted by regulatory government and industry regulatory experts involved in GHTF, with a concentration on how two of the GHTF founding members (Health Canada and USFDA) implement their regulatory regime including auditing, quality system and surveillance. English – Spanish translation will be provided during all training activities and firm visits. While this August 2010 delegation visit to Canada and the United States is an APEC-funded project, with focus on Latin American APEC economies, all APEC economies are welcome to participate. APEC has also authorized the following non-APEC economies to participate - Argentina, Bolivia, Brazil, Colombia, Costa Rica, El Salvador, Honduras, Nicaragua, Panama, Uruguay, India, Laos, and Cambodia.

See the schedule of activities during the delegation visit listed on page two of this announcement. The trainers during this delegation visit will make presentations, participate in panel discussions, lead group discussions and present case studies. Due to space limitations we will need to limit the total delegation size to 30 regulators. While this will be essentially done on a first-come first-serve basis, we may need to limit the number of regulators per economy if more than 30 regulators register, so the registration deadline is important.

### ***Who should attend the Workshop?***

Representatives from:

- APEC member economies with established or developing medical regulatory systems
- Non APEC member economies with established or developing medical regulatory systems (APEC has authorized limited non-APEC Asia regulators participation from the following economies Argentina, Bolivia, Brazil, Colombia, Costa Rica, El Salvador, Honduras, Nicaragua, Panama, Uruguay, India, Laos, and Cambodia).

### ***Workshop's objectives:***

- Understanding GHTF recommendations on issues relating to regulation, auditing, quality systems and surveillance
- Practical training sessions achieved through a smaller instructor to student ratio, using case studies and interactive discussion between instructors and students
- Providing guidance on the role of regulators, industry, and distributors in regulatory harmonization and securing the integrity of the medical devices supply chain.

### ***Limited funds for subsidized travel:***

- See note at the end of this announcement.

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**AGENDA**

<b>Sunday, August 8</b> 6:30 pm - 8:30 pm	Informal Dinner at (to be determined) (No-host, optional for those attending at their own cost)
<b>Monday, August 9</b> 8:30 am - 9:00 am	Registration
9:00 am - 5:00 am	Training Program Conducted by Health Canada
7:30pm - 9:30 pm	Possible US DOC hosted dinner
<b>Tuesday, August 10</b> 9:00 am - 5:00 pm	Training Program Conducted by Health Canada
<b>Wednesday, August 11</b>	Travel from Ottawa to Boston and free time. (Recommended flight: UAL 8319, departing at 11:35 a.m., and arriving at Boston Logan Airport at 12:53 p.m. Alternate: UAL 8317 departs at 7:45, arrives at 9:03. <i>Delegation members must book their own travel reservations</i> )
<b>Thursday, August 12</b> 8:30 am - 5:00 pm	Industry Portion of the Training Program for Two Days to be Coordinated by AdvaMed in Boston
<b>Friday, August 13</b> 8:30 am - 5:00 pm	Training Program and Company Visits Coordinated by AdvaMed
<b>Saturday, August 14</b>	Travel from Boston to Washington DC and free time in Washington DC (Recommended flight: USAirways 1229, departing at 10:00 a.m. and arriving at Washington Reagan National Airport at 11:27 a.m. <i>Delegation members must book their own travel reservations</i> )
<b>Sunday, August 15</b>	Sightseeing in Washington, DC
<b>Monday, August 16</b> 9:00 am - 5:00 pm	Training Program Conducted by US Food and Drug Administration and hosted at the USDOC
<b>Tuesday, August 17</b> 9:00 am - 5:00 pm	Training Program Conducted by US Food and Drug Administration and hosted at the USDOC
6:30 pm - 8:30 pm	Reception/Dinner Hosted by Industry
<b>Wednesday, August 18</b> 8:30 am - 5:00 pm	Training Program Conducted by US Food and Drug Administration and hosted at the USDOC

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**REGISTRATION FORM**

To register for the delegation visit, please email or fax this registration form (two pages) to:

Gerry Zapiain  
US Department of Commerce, Office of Health and Consumer Goods  
Washington DC 20230, Room 1015

Tel: 1 202 482 2410  
Fax: 1 202 482 0975  
Email: Gerry.Zapiain@trade.gov

**A. Participant's Information**                      **Mr. \_\_\_ Mrs. \_\_\_ Ms. \_\_\_ Dr. \_\_\_ Prof. \_\_\_**

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_

Title/Position: \_\_\_\_\_

Organization/Country: \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

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

Email: \_\_\_\_\_

**B. Your confirmation on the following dinner arrangement is required.**

Dietary Requests: Vegetarian     Beef Free     Pork Free     None     Others  \_\_\_\_\_

I will attend the official hospitality dinner on August 11                      Yes     No

I will attend the industry hospitality dinner on August 13                      Yes     No

I will attend the industry hospitality dinner on August 17                      Yes     No

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**REGISTRATION FORM (continued)**

**REGISTRATION**

The last day for registration is June 15, 2010. The delegation size is limited to thirty participants, and attendees will be accepted on a space-available basis. All hotel rates quoted below are in Canadian or US dollars.

**HOTEL RESERVATIONS (to be added)**

- 1) Ottawa – The Lord Elgin Hotel. Address: 100 Elgin Street, Ottawa, Ontario ON, K1P 5K8. Tel: 613-235-3333. Rate: C\$149. Reference: Medical Devices Delegation Visit, reserved by Monique Chaîné of Health Canada. *The special room rates apply for reservations made by July 29. After this date, availability cannot be guaranteed and prevailing room rates will apply.*
- 2) Boston – The Taj Hotel. Address: 14 Arlington Street, Boston, Mass. 02116. Tel: 617-536-5700. Rate: US\$205. Reference: APEC Medical Devices Delegation Visit. *The special room rates apply for reservations made by July 12. After this date, availability cannot be guaranteed and prevailing room rates will apply.*
- 3) Washington DC – One Washington Circle Hotel. Address: One Washington Circle, NW, Washington, D.C. 20037; Tel: 202-872-1680. Rate: US\$170. Confirmation code: 557460. *Group rates confirmed for August 14 through August 19. The special room rates apply for reservations made by July 14. After this date, availability cannot be guaranteed and prevailing room rates will apply.*

Please note that bookings and special room rates have been arranged with the above hotels for the workshop attendees. Reservation deadlines apply. However, you are required to finalize your hotel reservation by contacting each of the hotels *directly* using the information provided below. You will be asked to provide your credit card details and quote the group booking reference codes by the respective hotel staff to secure your booking.

I will be staying at the Lord Elgin Hotel in Ottawa. I will check in on August \_\_\_\_, Checkout is August 11 and I agree to confirm my room booking directly with the hotel.

I will be staying at the Taj Hotel in Boston. Check in is August 11, check out is August 14, and I agree to confirm my room booking directly with the hotel.

I will be staying at the One Washington Circle Hotel in Washington, D.C. Check in is August 14 and I will be checking out on August \_\_\_\_. I agree to confirm my room booking directly with the hotel.

*After the group reservations expire on the dates for each hotel indicated above, it will be your own responsibility to find suitable arrangements for your stay in Ottawa, Boston, or Washington DC.*

**LIMITED FUNDS FOR SUBSIDIZED TRAVEL**

**Subsidized Travel Support for Latin American APEC Regulators** - There are limited funds available for travel support (the cost of round trip economy-class airfare, lodging, and *per diem* costs) for two medical devices regulators from the three Latin America APEC economies: Mexico, Peru, and Chile. If you are a government official from one of these three Latin American APEC economies and you wish to be considered for the travel support available, please send an e-mail to Gerry Zapiain at gerry.zapiain@trade.gov and Jeffrey Gren at jeffrey.gren@trade.gov. Please include your name, position, agency or ministry, and full contact information. We will need this e-mail submitted no later than **May 26, 2010**. You will be notified if you are selected for the travel support by **June 25, 2010**.

APEC has also authorized the following non-APEC Latin America economies to participate in this regulatory training program: Argentina, Bolivia, Brazil, Colombia, Cost Rica, El Salvador, Honduras, Nicaragua, Panama, and Uruguay. We are working with the Pan American Health Organization (PAHO) to coordinate Latin American non-APEC economy participation, which may include travel funding.

**Subsidized Travel Support for Asian APEC Regulators** – There are also limited APEC travel funds for regulators (6 – 7 delegates) from Asian APEC travel-eligible economies (China, Indonesia, Malaysia, Papua New Guinea, Philippines, Russia, Thailand and Vietnam). If you are a medical devices regulator from one of these Asia economies, please e-mail your interest to Gerry Zapiain and Jeffrey Gren at the above e-mail addresses. **Of course, all APEC Asia economies can self-fund participants.**