



**4th APEC-Funded Seminar on
Harmonization of Medical Device Regulation
*The Role of Regulators, Industry, and Distributors in Harmonization of Medical
Device Regulation in the Asia/Pacific Region***

**March 4 – 7, 2008
Kuala Lumpur, Malaysia
Sunway Lagoon Resort Hotel**

The Malaysian Ministry of Health, together with the Malaysian Medical Device Association, the Asian Harmonization Working Party, the U.S. FDA, and the U.S. Department of Commerce, presents the latest in the series of successful seminars educating regulators and industry professionals on harmonization of medical device regulation. Participation in the seminar will help you as a regulator, an industry regulatory professional, or a distributor of medical devices, better understand global medical device regulations and the emerging similarities between them. There will be significant business and private sector cooperation in the seminar. Major medical device industry associations in many APEC economies support the event, and representatives from several of these organizations serve on the seminar planning committee. Government and private sector regulatory experts from the medical device Global Harmonization Task Force (GHTF) Study Groups will serve as faculty, further broadening your educational progress.

The focus of the seminar will be GHTF Study Groups (involving SG1, SG2, SG3 and SG4), with a concentration on how GHTF founding member economies deal with regulatory, auditing, quality system and surveillance issues. Case studies will be used as a learning tool. For example, a case study may be developed on how to handle the problem of a medical device failure in the marketplace, and how regulators and industry work together to resolve the problem. Another focus of the seminar will be the roles of regulators, industry, and distributors to ensure a secure medical devices supply chain.

The seminar's trainers will make presentations, participate in panel discussions, lead group discussions and present case studies. A new feature of this training will build on the experience of regulators who have attended previous seminars. For some sessions, the seminar will be "two-tracked" with advanced courses for participants who have participated in past APEC-funded training seminars. This will provide an additional benefit to students attending the seminars, offering both an entry level and a more advanced curriculum.

Who should attend the Seminar?

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 regulators participation upon payment of a registration fee to offset seminar costs*)
- Regulatory affairs professionals of the medical devices industry, foreign and local
- Medical device distributors

Seminar'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

There are limited funds available for travel subsidies (to be applied to the cost of round trip economy-class airfare and lodging) for government representatives from the following APEC economies: China, Indonesia, Malaysia, Papua New Guinea, Philippines, Russia, Thailand and Viet Nam. If you are a government official from one of these economies and you wish to be considered for the travel subsidies available, please send an e-mail to Gerry Zapiain at Gerry.Zapiain@mail.doc.gov. Please include your name, position, agency or ministry, and a short narrative on why you and your economy would benefit from your participation in the APEC seminar. We will need this e-mail submitted no later than DATE. You will be notified if you are selected for the travel subsidy by DATE.

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AGENDA

Wednesday, March 5

- 8:00 – 12:00 Registration
12:00 – 1:00 Lunch
1:00 – 5:15 APEC Seminar Opening Plenary
- 1:00 – 1:10 Welcome and Program Overview – Jeffrey Gren, Project Overseer and Director, Office of Health and Consumer Goods, U.S. Department of Commerce
1:10 – 1:40 Welcome Remarks – (TBA: Malaysia Government Official, GHTF or AHWP representative).
1:40 – 2:10 Overview of the Global Harmonization Task Force (GHTF), Role of GHTF Study Groups, and Future GHTF Activities – Dr. Larry Kessler, GHTF Steering Committee Chair
2:10 – 3:00 Overview of **Study Group 2 and NCAR** – Jorge Garcia, Therapeutic Goods Administration
3:00 – 3:15 Coffee Break
3:15 – 5:15 Panel Discussion - **The role of regulators, industry, and distributors in global medical device regulatory harmonization and the integrity of the medical device supply chain**
- 5:15 – 5:30 **Group Picture**
6:30 – 8:00 Reception

Thursday, March 6

- 8:30 – 12:00 Group A: Introductory **Study Group 1** Training (Convergence of Regulatory Systems) -- Ginette Michaud, U.S. FDA; John Brennan, European Commission; Michael Gropp, Medtronic.
Group B: Intermediate **Study Group 1** Training
10:30 – 10:45 Coffee Break
10:45 – 12:00 **Study Group 1** Training continues
- 12:00 – 1:00 Lunch
1:00 – 5:00 **Study Group 5** Training (Clinical Safety and Performance) – Herb Lerner, U.S. FDA, Johan Brinch, Medical Industry Association of Australia
3:00 – 3:15 Coffee Break
3:15 – 5:00 **Study Group 5** Training continues
- 5:00 Day's training ends
- 7:00 – 10:00 Hospitality Dinner Event (funded by Malaysian Ministry of Health, venue TBD)

Friday, March 7

- 8:30 – 2:45 **Study Group 3** Training (Quality Systems) – Roland Rotter, Health Canada; Hideki Asai, Hitachi; Gunter Frey, GE Medical
10:30 – 10:45 Coffee Break
10:45 – 12:00 **Study Group 3** Training continues
12:00 – 1:00 Lunch
1:00 – 2:45 **Study Group 3** Training continues
- 2:45 – 3:00 Coffee Break
3:00 – 5:00 Summary of **Study Group 4** Tim Missios, Boston Scientific (Auditing)

**Not part of the APEC-funded training program*

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For Adm Secretariat Use Only

Reg No :
Date
Received:

REGISTRATION FORM

To register for the Seminar, please mail or fax this Registration Form (two pages) together with appropriate payment to:

NAME
Malaysian Medical Device Association
Address, Kuala Lumpur
Tel: xxx xxx xxx; Fax: xxx xxx xxx
Email: address@address.com

A. Participant's Information Mr. ___ Mrs. ___ Ms. ___ Dr. ___ Prof. ___

Last Name: _____ First Name: _____

Organization: _____ Title: _____

Tel: _____ Fax: _____

Address: _____

Email: _____ Dietary Requests: Vegetarian Beef Free Pork Free None

I will attend the welcome reception on March 4, 2008 Yes No

I will attend the hospitality dinner on March 6, 2008 Yes No

Accompanying Spouse to attend reception and dinner* Yes No

*Please add US\$50 for accompanying spouse and kindly provide his/her name: _____

B. Registration Fee Details (Please tick one)

Non-Government participants: US\$150.00 fee if paid *before* DATE

Non-Government participants: US\$200.00 fee if paid *after* DATE

Government officials: No registration fee

*Malaysian industry may pay in Ringgit.

C. Payment Methods Registration Form must be accompanied by full payment. (Tick where appropriate)

Telegraphic Transfers payable to:

Name of Account: xxxxx

Bank Name and Address: xxxxx

Account no: xxxxx; Routing: xxxxx; Swift no: xxxxx

Please note that telegraphic transfer charges, both outgoing and incoming, must be paid by sender. Attach a copy of the TT form to your Registration Form.

Bank Draft / Money Orders are payable to: Malaysian Medical Device Association. Please submit with Registration Form to: Malaysian Medical Device Association, c/o NAME

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Received:

REGISTRATION FORM (*continued*)

C. Payment Methods (*continued*)

Credit Card Visa MasterCard AMEX
Name on Credit Card _____ Expiry Date MM/YYYY _____
Credit Card Number _____ Validation Code*
Total Amount _____ Signature _____

*Card Validation Code: For Visa/MasterCard include the last 3 digits of the number printed on the back signature panel of your credit card. For AMEX cards, include the 4 digit number printed on the front of your card after the 15 digit card number.

REGISTRATION

Registration is on a first-come-first-serve basis. The last day for registration is DATE. There is a limited capacity for participants at the Seminar. Attendees will be admitted on a space-available basis.

All non-government participants must pay registration fees in advance. Registration will only be confirmed upon receipt of payment. The registration fee includes refreshments and lunch during the Seminar and receptions as well as handout materials.

CONFIRMATION

All registrations, once acknowledged, are considered confirmed. The cancellation clauses will apply for any cancellations received after registration with payment is duly acknowledged.

CANCELLATIONS AND TRANSFERS

If you are unable to attend, a substitute attendee is welcome at no extra charge. Please provide the name and the title of the substitute attendee on or before January 3, 2008. In the event of cancellation of registration with payment, 50% of the registration fee will be refunded if the cancellation notice is received on or before DATE (last day for registration). No refund will be made if the cancellation is received after DATE.

HOTEL RESERVATIONS

Hotel charges are at the participant's own account and reservations must be made directly with the hotel. To enjoy the special room rates at the Sunway Resort Hotel, complete the enclosed Hotel Booking Form and send direct to the hotel, fax +xxx xxx xxx, or email: address@address.com. The special room rates apply for reservations made by DATE. After this date, prevailing room rates will apply. For more information on the hotel, please visit www.sunway.com.my/hotel.

I will be staying at the Sunway Resort Hotel I will be staying at other hotel _____

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