



**Asia-Pacific
Economic Cooperation**



MEDEC

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

Agenda APEC Funded GHTF Latin America Regulatory Harmonization Training Program Toronto, Canada, May 14 - 16, 2009

Thursday, May 14th, 2009 – Toronto Westin Hotel

11:00am – 2:00pm	Registration Desk Opens
1:00pm – 3:30pm	APEC Funded GHTF Training Seminar Opening Plenary Pier 4 & 5, Westin Hotel
1:00pm – 1:10pm	Welcome and Program Overview - Jeffrey Gren, Project Overseer and Director, Office of Health and Consumer Goods, U.S. Department of Commerce, Manufacturing and Services
1:10pm – 1:40pm	Overview of the Global Harmonization Task Force (GHTF), Role of GHTF Study Groups, and Future GHTF Activities - Roland Rotter, GHTF Steering Committee Chair
1:40pm – 2:40pm	<p>Panel Discussion: “The role of regulators, industry, and distributors in global medical device regulatory harmonization and the integrity of the medical device supply chain”</p> <p>Moderator: Jeffrey Gren, Director, Office of Health and Consumer Goods, U.S. Department of Commerce</p> <p>Panel Members:</p> <p>Meghal Khakhar, Manager, Regulatory and Scientific Affairs , Baylis Medical, Canada Petra Kaars-Wiele, Director International Regulatory Affairs/Affiliate Compliance, Abbott Laboratories, Germany Miang Chadaporn Tanakasemsub, Regional Regulatory Affairs Director, Asia, Bausch & Lomb Ltd., Hong Kong</p>
2:40pm – 3:40pm	Special Session - Study Group 5 (Clinical Safety/Performance) Dr. Greg Leblanc , MEDEC and Cook Canada
6:00 pm	Buses depart Westin Hotel for Humber College (available only on May 14)

Friday, May 15th, 2009 – Humber College

7:30am – 9:00am	Registration Desk Open Main Floor, Guelph-Humber Building, Humber College	
7:00am – 8:00am	Breakfast for participants staying at Humber College Cafeteria, Student Residence, Humber College	
Breakout Sessions – Seminar attendees will be divided into two smaller groups (Group A and Group B) to facilitate discussion and interaction.		
	Group A	Group B
	GH111, Guelph-Humber Building, Humber College	GH117, Guelph-Humber Building, Humber College
8:30am – 10:15	Study Group 1 Training (Pre-market Evaluation) Ms. Maria Carballo , Health Canada Dr. Petra Kaars-Wiele , European Diagnostic Manufacturers Association (EDMA) and Abbott Mr. Michael C. Morton , AdvaMed and Medtronic Ms. Brenda Murphy , MEDEC and SciCan	Study Group 4 Training (Auditing) Mr. Armand Tsai , Health Canada Mr. Albert Li , Industrial Technology Research Institute (Chinese Taipei)
10:15am - 10:30am	Coffee Break	
	Group A	Group B
10:30am – 12:15pm	Study Group 1 Training (Pre-market Evaluation)	Study Group 4 Training (Auditing)

12:15pm – 1:15pm	Lunch	
	Group A	Group B
	GH111, Guelph-Humber Building, Humber College	GH117, Guelph-Humber Building, Humber College
1:15pm – 3:00pm	Study Group 2 Training (Post-market Surveillance/Vigilance) Dr. Ekkehard Stoesslein , BFARM, (Germany) Mr. Philippe Auclair , EUCOMED and Abbott Vascular	Study Group 3 Training (Quality Systems) Mr. Egan Cobbold , Health Canada Mr. Gunter Frey , National Electrical Manufacturers Association (NEMA) and Philips Healthcare
3:00pm – 3:15pm	Coffee Break	
	Group A	Group B
3:15pm – 5:00pm	Study Group 2 Training (Post-market Surveillance/Vigilance)	Study Group 3 Training (Quality Systems)
7:30pm – 10:30pm	Hospitality Dinner (Summary and Closing Remarks) 7th Semester, Building L-M, Humber College	
<u>Saturday May 16th, 2009 – Humber College</u>		
7:00am – 8:00am	Breakfast for participants staying at Humber College Cafeteria, Student Residence, Humber College	
	Group A	Group B
	GH111, Guelph-Humber Building, Humber College	GH117, Guelph-Humber Building, Humber College
8:30am – 10:15	Study Group 3 Training (Quality Systems)	Study Group 2 Training (Post-Market Surveillance/Vigilance)
10:15am - 10:30am	Coffee Break	
	Group A	Group B
10:30am – 12:15pm	Study Group 3 Training (Quality Systems)	Study Group 2 Training (Post-Market Surveillance/Vigilance)
12:15pm – 1:15pm	Lunch	
	Group A	Group B
	GH111, Guelph-Humber Building, Humber College	GH117, Guelph-Humber Building, Humber College
1:15pm – 3:00pm	Study Group 4 Training (Auditing)	Study Group 1 Training (Premarket Evaluation)
3:00pm – 3:15pm	Coffee Break	
	Group A	Group B
3:15pm – 5:00pm	Study Group 4 Training (Auditing)	Study Group 1 Training (Premarket Evaluation)
500pm	Training Seminar Concludes	

Humber College
Guelph-Humber Building
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From Humber College Boulevard use the driveway marked 'A'. This will get you closest to the Guelph-Humber Building where the APEC training is taking place.