Report on APEC-Funded Medical Device Delegation Visit Program to Australia, and Canada and the United States

Australia, September 21 – 25; Canada and United States, August 9 – 18, 2010

Life Sciences Innovation Forum
APEC Committee on Trade and Investment

December 2010

CTI 23/2009T

Prepared by
Jeffrey L. Gren
U.S. Department of Commerce, International Trade Administration
1401 Constitution Avenue, Suite 1015
Washington, DC 20230
USA

Produced for:
Asia Pacific Economic Cooperation Secretariat
35 Heng Mui Keng Terrace Singapore 119616
Tel: (65) 6891 9600 Fax: (65) 6891 9690
Email: info@apec.org Website: www.apec.org

APEC#210-CT-01.7

TABLE OF CONTENTS .

Report on APEC-Funded Delegation Visit Program to Australia and Canada and the United States

(CTI 23/2009T)

Introduction

This project included funding for separate delegation visits to 1) Australia and to 2) the United States and Canada. This is a *combined report* covering the Australia portion (referred to as the "Asia program") and the Canada and United States portion (referred to as the "Latin America program.") The Project Overseer has already submitted an evaluation report on the Asia program.

The United States requested APEC funding for two limited size delegations (originally estimated at 15 – 25 officials each) of medical device regulators from APEC economies with developing regulatory regimes to visit APEC economies with developed medical device regulatory regimes: one from Asia, to visit Australia, and the other from Latin America to visit Canada and the United States. Organizers planned separate delegation visits to keep the size of each delegation manageable. Also, because the Latin America delegation would require Spanish/English interpretation, the logistics would be simpler with separate delegations. In addition, having the Asia delegation travel to Australia and the Latin America delegation travel to the United States and Canada would help contain costs.[1]

The Asia program, held from September 21 – 25, 2009, was a five-day event with three days spent in training and educational workshops and meetings with Australia's Therapeutic Goods Administration (TGA) officials, and two days with industry representatives for company visits and training and educational workshops.[2]

The Latin America program, held from August 9 – 18, 2010, was a seven-day event, including two days of training organized by Health Canada, in Ottawa, followed by two days of industry training organized by AdvaMed,[3] in the Boston, Massachusetts area (a metropolitan region world renowned for their high concentration of advanced medical device technology manufacturers), with the remaining three days of training organized by the United States Food and Drug Administration (USFDA) in Washington, D.C. and Silver Spring, Maryland.

For recruitment and planning for both programs we worked closely with the Global Harmonization Task Force (GHTF) and the respective regional harmonization working party (the Asian Harmonization Working Party (AHWP) or the Latin American

[1] Although the Australia program was designed for Asian APEC member economies, and the Canada/United States program was intended for Latin American APEC member economies, both programs were open to all APEC members.
[2] The Asia delegation visited both Canberra and Sydney, Australia. Canberra is the seat of Australia's Therapeutic Goods Administration, and Sydney represents a medical devices industry cluster.
[3] AdvaMed, the Advanced Medical Technology Association, is the leading medical device manufacturer industry association in the United States.

Harmonization Working Party (LAHWP), as appropriate). In addition for the Latin America program we worked with the Pan-American Health Organization (PAHO).

Activities for both the Asia and the Latin America programs included:

- Capacity building training workshops conducted by government regulators (either Australia's TGA or Health Canada and USFDA, as appropriate) related to regulatory practices such as product approval, clinical trials, plant audits, quality management systems, good manufacturing practices and post market surveillance.
- Visits to government laboratories used for evaluation of medical devices.
- Capacity building training workshops conducted by industry representatives.
- Tours of medical device manufacturing facilities organized by industry to witness firsthand how medical device manufacturers comply with regulations and share relevant experiences core to this educational project.
- The capacity building workshops conducted by government and industry regulatory experts were also related to regulatory practices such as, product approval, clinical trials, plant audits, quality management systems, good manufacturing practices and post market surveillance.

Delegation members in both programs participated in regulatory briefings and medical device firm visits to further their understanding of the application of harmonized international standards and to witness their benefits. We expect that this unique "hands on" feature of this educational program to help further global acceptance of harmonized medical device regulations.

Regulatory harmonization contributes to trade liberalization and facilitation and achieving the Osaka Action Agenda by reducing trade barriers and enhancing healthcare system access to innovative new technologies. It can also help regional health care systems address the fiscal and socetal challenges of aging populations. Use of advanced medical technologies in APEC economies will also lead to better healthcare, improved outcomes from treatment, reduced disability, and improved quality of life at lower cost. These objectives are relevant to comparability, non-discrimination, transparency, and cooperation components of the Osaka Action Agenda as outlined in Paragraph 8. The project increased confidence in the supply chain and thus in trade and investment in APEC economies, consistent with the Bogor Goals.

Part 1: Asia Delegation Visit to Australia, September 21 – 25, 2009

A. *Summary:* The September 21 – 25, 2009 APEC funded Asia medical devices regulatory harmonization delegation visit to Australia was a great success. The educational program included five days of training, with the first three days organized and conducted by the Australia Therapeutic Goods Administration (TGA), and the final two days organized by the Medical Technology Association of Australia (MTAA).

B. *Attendance:* The delegation included twenty-two regulators from the following eleven APEC Asia economies - China, Chinese Taipei, Hong Kong, Singapore, Russia, Philippines, Indonesia, Papua New Guinea, Thailand, Vietnam and New Zealand.

C. *Program Outline:* The first three days of the regulatory training program (Monday, September 21 - Wednesday, September 23) were developed and organized by the TGA in Canberra. The TGA training focused on how Australia, as of the medical devices Global Harmonization Task Force (GHTF) five founding member economies, implements its medical devices regulatory regime.

The regulatory training program included the following topics - 1) pre-market evaluation and requirements for regulatory market authorization, 2) medical devices product classification and risk analysis, 3) post-market surveillance and project recalls and monitoring, 4) quality management systems, 5) manufacturing plant auditing, and 6) clinical evidence. The training also included a demonstration of how medical device firms use TGA's website to submit applications and to pay the required user fees. In addition, the delegation was provided a tour of TGA's laboratory that is used to test TGA regulated products.

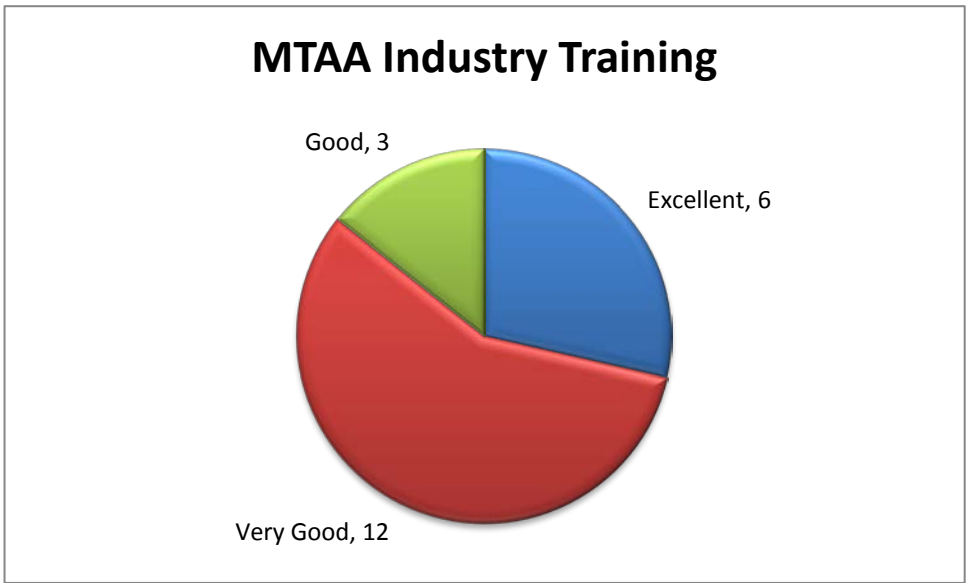
The next two days of the training program were organized by MTAA. On Thursday, September 24, the delegation attended workshops conducted by industry regulatory experts during the final day of MTAA's annual conference. Workshops included topics such as 1) conformity assessment, 2) supply chain management, 3) clinical date requirements, 4) global regulatory issues, 5) health technology assessments and 6) procurement of medical devices.

On Friday, September 25, the delegation visited three medical device firms in Sydney. The three companies, CathRx, a small company which has developed an innovative and unique electrophysiology catheter, Cochlear, a world leading company designing and manufacturing hearing implants and Device Technologies, a company importing and distributing products manufactured overseas, were selected to demonstrate how they operated in the Australian regulatory environment. The companies were representative of the different facets of the medical technology sector in this country.

Each company conducted guided tours of their facilities and discussed the various features of their products, their markets, and the different issues they faced in complying with the Australian regulatory requirements. The industry-organized portion of the delegation visit helped balance the delegation visit with both government regulator and industry points of view and provided the delegation with great insight concerning the global regulatory challenges faced by industry in key markets. A review of the evaluation forms completed by the delegation indicated that all aspects of the delegation visit were received very favorably.

The list of speakers and presentations for the Australia visit is attached.

D. *Evaluation*. The feedback from the Australia delegation visit was extremely positive, and almost all attendees submitted evaluation forms. Responses regarding the overall quality of the seminar are charted as follows:



E. *Next Steps:* Each attendee at the training seminar received hard copies of most presentations. The U.S. Department of Commerce, the Pan American Health Organization, Health Canada, the U.S. FDA, and the GHTF Steering Committee later focused on the 2010 Latin America Medical Device Delegation Visit Program to Canada and the United States.

F. *Conclusion:* Participants rated the APEC Asia regulatory training program as an overwhelming success. A significant number of regulators and industry representatives from APEC economies with developing regulatory systems attended and were very satisfied with the program based on evaluation forms. The trainers also did an excellent job and the slides developed of the seminar will serve as a future reference for regulators. The slides have been made available to regulators from APEC economies that did not attend the seminar.

The key to continued success is the involvement of APEC regulators and industry representatives in the Asian Harmonization Working Party and the Global Harmonization Task Force.

U.S. DOC, AHWP, and GHTF appreciate APEC's support for this project, which will have a positive impact on the global harmonization of medical device regulations, auditing procedures, and safety vigilance.

G. List of Speakers and Presentations for Asia Delegation Visit to Australia, September 21 – 25, 2009.

Flood, Michael: Office of Devices, Blood & Tissues Therapeutic Goods Administration: *"Global Harmonization Task Force Regulatory Model Overview," "TGA Implementation as a Model."*

Burgess, Gary: Director, Medical Device Application Section, Office of Devices, Blood and Tissues, Therapeutic Goods Administration: *"Medical Device Classification Risk Analysis."*

Janssen, Antje: Therapeutic Goods Administration. *"*IVD *Classification," "*IVD *Clinical Evidence Design Examination."*

Rankin, Jon: Senior Medical Advisor, Therapeutic Goods Administration. *"Medical Device Clinical Evidence."*

Jamieson, John: Conformity Assessment Branch, Therapeutic Goods Administration. *"Demonstrating Compliance with Essential Principles," "Bringing it all Together – Conformity Assessment"*

Milic, Dragana: Director, Medical Devices Audit Team, Therapeutic Goods Administration. *"Quality Management System – Introduction," "Vigilance & Quality Management System Postmarket Requirements."*

Carter, Pam: Market Vigilance and Monitoring Section, Therapeutic Goods Administration . *"Introduction to Medical Device Post Market Vigilance," "Incident Reporting & Global Harmonization Task Force Exchange."*

Garcia, Jorge: Manager, Medical Device Laboratory Program, Therapeutic Goods Administration. *"Introduction to Laboratory Sampling and Testing."*

Part 2: Latin America Delegation Visit to Canada and the United States, August 9 – 18, 2010

A. *Summary:* The August 9 – 18 2010 APEC-funded Latin America medical devices regulatory harmonization delegation visit to Canada and the United States was extremely successful. The agenda consisted of a seven-day program including two days of training organized by Health Canada, in Ottawa, followed by two days of industry training organized by AdvaMed, in the Boston, Massachusetts area (a metropolitan region world renowned for their high concentration of advanced medical device technology manufacturers), with the remaining three days of training organized by the United States Food and Drug Administration (USFDA) in Washington, D.C. and Silver Spring, Maryland.

B. *Attendance:* The delegation included twenty-seven regulators from fifteen economies. Seven were from the three Latin American APEC economies (Chile, Mexico, and Peru), and four were from other Latin American economies (Brazil and Costa Rica). The remaining sixteen were from Asian APEC economies (China; Hong Kong, China; Indonesia, the Republic of Korea; Malaysia; Papua New Guinea; Philippines; Russia; Singapore; , , and Thailand, ,).

C. *Program Outline:* The first two days of the regulatory training program (Monday, August 9 – Tuesday, August 10) were developed and organized by Health Canada in Ottawa. This portion of the training focused on how Canada, as one of the five GHTF member economies, implements its medical devices regulatory regime. The regulatory training program included the following topics among others – 1) an overview of the Canadian and GHTF regulatory models, 2) classification rules for *in vitro* diagnostic devices, 3) safety and effectiveness of medical devices, and requirements for Class III and IV medical devices, 4) quality management system requirements in the Canadian medical device regulation, and 5) requirements for medical device reporting and inspection.

   AdvaMed, organized the next two days of the training program which consisted of visits to medical device firms in the Boston, Massachusetts area (Thursday, August 12 – Friday, August 13). The industry organized portion of the program helped balance the delegation visit with both government regulator and industry points of view and provided the delegation with great insight concerning the global regulatory challenges faced by industry in key markets.

   On Thursday, August 12, the delegation first visited Boston Scientific, where the theme of the visit was quality systems in the global medical device distribution process. The delegation next arrived at DePuy, where the main topics were harmonization in submissions, clinical evidence, and reliance on ISO certificate of quality system audits.

On Friday, August 13, the delegation started the day with presentations from Becton Dickinson, where the focus was on global product development, manufacturing, quality management, and purchasing control. The delegation later visited Philips U.S. headquarters, where the topics for discussion centered around compliance with international testing standards.

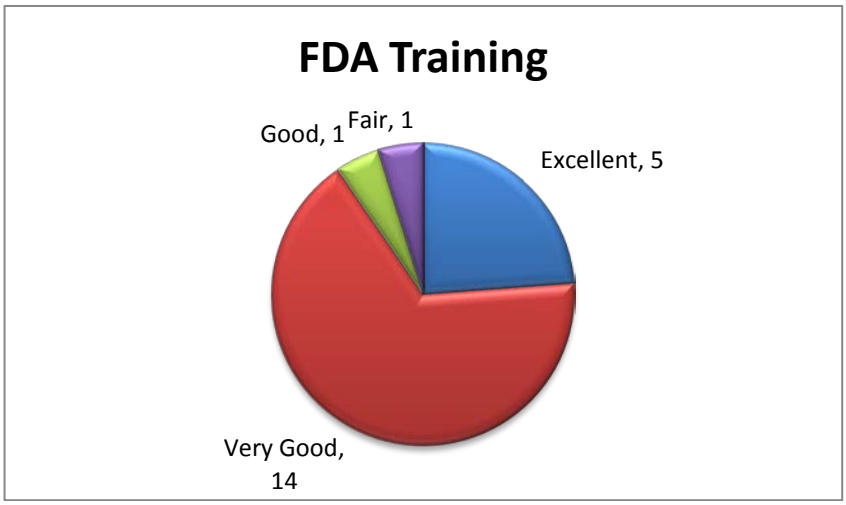
From Monday, August 16, through Wednesday, August 18, training was held by the FDA in Washington, D.C., and Silver Spring, Maryland. This portion of the training focused on the following topics: FDA's globalization priorities, its regulatory mandate and organizational structure, the Center for Devices and Radiological Health's (CDRH) premarket program and enforcement, comparisons to GHTF recommendations, FDA's use of ISO standards, the Summary Technical Document (STED) program, *in vitro* regulation, FDA's unique device identifier program, global medical device nomenclature, and FDA's quality management system. The FDA training concluded with a visit to the CDRH laboratories in Silver Spring, Maryland.

The list of speakers and presentations is attached

D. *Evaluation:* Feedback from the event was overwhelmingly positive. A breakout of the evaluation responses from the three locations follows:

Comments gathered from this phase of the training maintained that the best part was the overview of Health Canada's regulatory requirements and how they compare to GHTF recommendations. Several commentors would have preferred more details, practical cases and examples, and a tour of Health Canada.

Commentors noted that the overview of the quality-management-systems-based approach to medical device regulation and its impimpact on the industry was good during the firm visit portion of the training. However, several respondents would have preferred to participate in a plant tour as well to see a production line.



Respondents stated that they significantly improved their understanding of FDA's regulatory requirements for medical devices, that the trainers were knowledgeable, and that there was a good opportunity to network with FDA regulators. However, one respondent stated that "there should have been better time management."

E. *Next Steps:* Each attendee at the training seminar received hard copies of most presentations. The U.S. Department of Commerce, the Pan American Health Organization, Health Canada, the U.S. FDA, and the GHTF Steering Committee have evaluated feedback for use in potential future global medical device regulation training.

F. *Conclusion:* Participants and trainers viewed the APEC Latin America regulatory training program as an overwhelming success. A significant number of

regulators and industry representatives from APEC economies with developing regulatory systems attended and were very satisfied with the program based on evaluation forms. The trainers also did an excellent job and the slides developed of the seminar will serve as a future reference for regulators. The slides have been made available to regulators from APEC economies that did not attend the seminar.

The key to continued success is the involvement of APEC regulators and industry representatives in the Asian and Latin American Harmonization Working Parties and GHTF.

U.S. DOC, PAHO, U.S.FDA, Health Canada, and GHTF appreciate APEC's support for this project, which will have a positive impact on the global harmonization of medical device regulations, auditing procedures, and safety vigilance.

G. List of Speakers and Presentations for Latin America Delegation Visit to Canada and the United States, August 9 -- 18, 2010:

Black, Dennis: Director e-Commerce, Becton Dickinson Medical. *"Product Distribution and UDI."*

Campbell, Constance: Senior Scientific Evaluator General and Restorative Section. "*Health Canada's Requirements for Class III and IV Medical Devices."*

Cobbold, Egan, M.Sc.. *"Medical Devices Regulations: Quality Systems Requirements and The Canadian Assessment System (CMDCAS);" "SCC Accreditation and the CMDCAS Program Qualification Process"*

Crowley, Jay: Senior Advisor for Patient Safety, FDA. *"FDA's Unique Device Identification (UDI) and Global Medical Device Nomenclature (GMDN) Programs."*

Gill, Lillian, DPA: Senior Associate Director, Center For Devices and Radiological Health, FDA. *"Welcome to FDA's Medical Device Training for International Regulatory Authorities;" "Overview of FDA's Globalization Priorities;" "Overview of FDA/CDRH's Regulatory Mandate and Organizational Structure."*

Hardmon, Mark, Vice President, Corporate Regulatory Affairs and Compliance, Becton Dickinson. *"Brief Overview of : BD Global Product Development System (GPDS), Manufacturing Process, Quality Management, and Purchasing Control*." With Joe Spruill

Harris, Kathy, Manager, DePuy. *"GHTF Harmonization Efforts for Medical Device Life-Cycle Management."*

Harrison, Barbara, R.N., Bs. C. N.: Senior Medical Device Specialist. *"Health Canada's Requirements for Medical Device Reporting."*

Hossack, Brad: VP International RA, Boston Scientific. *"Managing Patient Safety in Medical Device Distribution Systems."*

Kalush, Francis, Ph.D.: Diagnostics and Personalized Medicine Network Leader, Office of Center Director/CHRH/FDA. *"Overview of FDA's Regulation of* In Vitro *Diagnostic Devices. Similarities and Differences with GHTF Regulations."*

Melkerson, Mark: Director, Division of Surgical, Orthopedic and Restorative Devices, Office of Device Evaluation, CDRH, FDA. *"Overview of CDRH's Premarket Program;" "FDA's use of ISO Standards in the Premarket Program;" "Status on the STED Initiatives;" "FDA Requirements for Clinical Trial Designs and Applications."*

Missios, Tim: Director, Regulatory Affairs, America and Asia-Pacific, Boston Scientific Corporation. *"Global Regulations: A Confusing Journey for Harmonization."*

Naples, Rick: Vice President, Corporate Regulatory Affairs and Compliance. *"The Value of* In Vitro *Diagnostics in Health Care."*

Rosecrans, Heather: Chief, Premarket Notification Section, Office of Device Evaluation, CDRH, FDA. *"FDA Requirements for Premarket Notification (510(k)) and Review."*

Shadeed, Nancy: Manager, Device Licensing Division, Medical Devices Bureau, Therapeutic Products Directorate, Health Canada. "*Medical Devices Regulations Overview;" "Canadian Rule-Based Classification System;" "Canadian Rule-Based Classification System (IVDD);" "Use of Essential Principles;" "Use of GHTF Documents in the License Application Process;" "Regulated Product Submission – Release 3 (RPS 3 Project) and its Link to the Summary Technical Document (STED).*

Song, Dongjiang, M.D., M.Sc.: Chair, Standards Recognition Committee. *"Recognition and Use of Standards."*

Spruill, Joe: Validation Manager, Corporate Quality Engineering, Becton Dickinson. *"Brief Overview of: BD Global Product Development System (GPDS), Manufacturing Process, Quality Management, and Purchasing Control*." With Mark Hardmon.

Torres, Melissa: Office of Compliance, Center for Devices and Radiological Health. "*Overview of the Quality System Regulation for Medical Devices"* with Patrick Weixel.

Ulatowski, Timothy A.: Director, Office of Compliance, Center for Devices and Radiological Health. *"Overview of CDRH's Enforcement Program;" "Overview of ISO Standards: How FDA Plans to Utilize ISO 13485."*

Weixel, Patrick: Office of Compliance, Center for Devices and Radiological Health. "*Overview of the Quality System Regulation for Medical Devices"* with Melissa Torres.

Yoder, Deb: FDA Expert on Global Device Adverse Event Reporting. *"Comparing FDA's Postmarket Device Adverse Event Reporting Requirements to GHTF Guidelines."*

Zirger, Brigitte: Bureau of Policy, Science, and International Programs, Therapeutic Products Directorate, Health Canada. "*An Overview of Health Products and Food Branch."*

Part 3: APEC Funding

Item	Budget	Rev. Budget	Paid	Balance
Translator fees	$12,000.00		$7,972.50	**$4,027.50**
Consultant	10,000.00		00.00	**10,000.00**
Consultant secy.	2,000.00		00.00	**2,000**
***Per diem* prtcpnt.**	50,885.00		57,167.05	**(6,282.05)**
Airfare prtcpnt.	52,766.00		44,609.95	**8,156.05**
Rept. publication	2,000.00		00.00	**2,000.00**
Transportation	5,000.00		5669.58	**(669.58)**
Photocopying	126.00		00.00	**126.00**
Communications	500.00		00.00	**500.00**
Hosting[4]	8,000.00		00.00	**8,000.00**
Component total	143,277.00		115,419.08	27,877.92
Project total	**143,277.00**		**115,419.08**	**27,877.92**

Both delegation visits included a portion of cost sharing. APEC did not require recordkeeping, but many costs were borne by the organizers, including meals, consultant fees, advance trips, administrative staff, personnel to attend the delegation visits, speaker fees, simultaneous interpretation in Ottawa, and other hospitality. Government and industry trainers provided significant time (preparation, travel and time at the seminar itself) which represents considerable value if computed based upon average salary levels.

[4] At the time of this writing, the amount for hosting claimed by Health Canada of $2,868.89 is in process for consideration.