Training Report

Medical Device Regulation Capacity Building Workshop

March 30 – 31, 2009 in Penang, Malaysia

COMPILED FOR
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The ASEAN-US Technical Assistance and Training Facility

SUBMITTED BY
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Government regulators and industry representatives came together 30-31 March 2009 in Penang, Malaysia to underscore ASEAN's clear goal of establishing an ASEAN-wide harmonized medical device regulatory regime. A work in progress, ASEAN is in the process of drafting and developing the ASEAN Medical Device Directive (AMDD). Once adopted, all member countries will be required to pass national laws with the same provisions. The AMDD lays out basic requirements for medical device safety and performance, the medical device classification system, and a Common Submission Dossier Template for medical devices (CSDT). An ASEAN-wide post-marketing alert system will also be developed.

While the AMDD focuses on product registration, the CSDT will focus on a common format for medical device application dossiers. This will mean that medical device firms will be able to prepare identical dossiers to submit in each ASEAN country. Currently, out of the 10 ASEAN countries, seven have laws or guidelines that govern medical devices; these countries are Singapore, Malaysia, Indonesia, Thailand, Vietnam, the Philippines and Myanmar. The other three countries—Brunei, Cambodia, and Laos—are working on developing laws or guidelines.

The ASEAN-US Technical Assistance and Training Facility ("the Facility"), together with the U.S. Department of Commerce (DOC) and the ASEAN Coordinating Committee on Standards and Quality (ACCSQ) co-organized the ASEAN-US Enhanced Partnership Medical Device Regulation Capacity Building Workshop to support these ongoing initiatives, and ensure that the new and revised regulatory regimes are developed in line with the Global Harmonization Task Force on Medical Devices (GHTF) guidelines.

The workshop was built around 4 main themes of: (1)-Building a Regulatory Infrastructure to Promote the Access and Use of Medical Technology; (2) - The Role of Conformity Assessment Bodies (CABs) and National Competent Authorities in Pre-Market Conformity Assessment, Post-Market Surveillance and Market Supervision; (3) - How to Grow a Medical Technology Sector at the National and Regional ASEAN Levels; and (4) - Wrap-Up, Conclusion and Future Activities: How GHTF Founding Member Regulators and Industry Representatives Can Help the ASEAN Economic Community Establish a Harmonized Medical Devices Regulatory Regime. The panel discussions highlighted a range of issues including the Basics of Establishing a Medical Devices Regulatory Regime; Case Studies on Establishing Flexible Medical Devices Regulatory Regimes; Promoting Public Confidence in the Role of Accredited Persons/CABs in Pre-Market Approval Process, Plant Auditing; Issues Facing ASEAN countries; How National Competent Authorities Can Have Confidence in the Work Products of CABs in Other Countries; and How multinational Medical Device Firms Make Foreign Investment Decisions;

The workshop was very well received and attended by 170 participants from both the public (regulators) and private sector (medical device industry representatives). An interesting note on participation is that close to two thirds of the participants were female. In addition to the Facility's speakers from the DOC, the Australian Therapeutic Goods Administration and an alumni of the U.S. Food and Drug Administration, there were 11 other speakers from the medical device industry based in ASEAN and non-ASEAN countries (US, EU and Australia).

Medical Device Workshop, 30-31 March 2009, Penang, Malaysia
Summary Evaluation

I. Representation	Score	%
• Regulators	14	22.6
• Industry	37	59.7
• Speakers	4	6.5
• Others	7	11.3
	62	100.0
II. Overall rating		
• Excellent	4	6.6
• Very Good	18	29.5
• Good	31	50.8
• Fair	8	13.1
• Poor	0	0.0
	61	100
III. Highest rated topics		
• **Panel Discussion -** Basics of Establishing a Medical Device Regulatory Regime	22	34.9
• **Panel Discussion /lectures:** Case Studies - Establishing Flexible Medical Devices Regulatory Regimes	22	34.9
• **Panel Discussion /lectures:** Conformity Assessment Bodies	12	19.0
• **Panel Discussion/case studies:** How to grow medical technology sector at national/regional level	7	11.1
	63	100.0
IV. Highest rated items		
• Case Studies/panel discussion	12	96.8
• Trainers ' Expertise and knowledge about topics presented	21	0.0
• Effective forum for interaction between industry and regulator	13	34.9
• Ability of regulator to meet medical device experts and clarify	6	34.9
• Good opportunities to network with regulator	7	19.0
• Good opportunity for regulator to share expertise	4	11.1
	63	100.0
V. Suggestion to improve seminar **Logistics & arrangement** • Smaller groups 10-15 pax • Poor/No handouts/small fonts • Ask for written questions from participants • Agenda too long and tight each day. • Need slower delivery in English due to poor command of language for some participants • Small group workshop for regulators only.		

• Gather topics of interest before event • Complete documentation in kit • Complete participants list • More interactive sessions • Agenda not clear • Have breakup sessions • **Participation** • Share and update regulatory framework from developed countries eg. Canada and Japan • Invite more local regulators/More sharing/presentations from ASEAN regulators • ASEAN regulators to be more actively involved in the exchange of ideas • Full attendance of ASEAN regulators and in panel discussions • Balanced topics for industry and regulators • More coordination among speakers and avoid overlapping topics. • **Agenda** • More specific topics than broad and superficial • More technical topics less trade issues • More training on combination products regulations • Progress of establishing medical device regulatory bodies in ASEAN • Local regulations compared to international standards • Latest regulatory requirement and how industry able to comply • Include industry perspectives on new regulations • Standardize product evaluation which allow for single country approval of product to be applicable to all • Status and progress of ASEAN in this project • What industry can do to better meet a more regulated environment? • More sharing of real experience on planning and implementation of MD regulations **Others** • No conclusion on follow-up actions • Provide more reference materials or websites • Focus on harmonization not difference • Topics which can reflect local industry/ASEAN region • SME presentations from ASEAN •		
VI. Future topics • ISO training or briefing • PMS • IVD topics • Combination products • Focus on ASEAN regulation especially on implementing regulations in local industry		

• Medical devices requirements of AMS. Procedures and protocols/audit that will be conducted by AMS. • Training on medical devices documentation, registration and other classifications (eg product classification, definition, regulatory updates and harmonization) • Harmonization of labelling requirements • Medical device technology • ASEAN countries position on baseline products, new technology such as stem cell, tissue cell etc. • Latest development in ACCSQ-MDPWG meeting • Briefing by individual AMS on guidelines to meet regulatory requirements • Flexibility on medical device regulatory regime • Monitoring and Listing of CABs • ASEAN regulatory framework • Role of stakeholders in medical device supply chain • How to combat counterfeit • Role of GHTF and AHWP in harmonization of regulatory and quality standards • GMDN Code • Product classification - GHTF and ASEAN • Sharing of experience with regulators from GHTF countries • How to establish flexible MD regime • CSDT and GMDS • ISO 13485 implementation • CSDT, clinical trials, conformity assessment, tests • How to develop local MD industry • CABs • Selection of criteria of CABs, governance of CABs and NBs regulators • How MDB collaborate with NPCB for combination devices with biologic/reengineered devices • Common guidelines to medical devices • SME technical requirement • ASEAN Regulatory process and changes • Technical Assistance to regulatory authorities especially the low income countries • Information on regulations in some EU countries/Japan		
VII. Additional Suggestions • Organize seminar periodically until GHTF is accepted by ASEAN • Invite Pharma/Biologic Regulators		
Total respondent - 64		

AGENDA

ASEAN-US ENHANCED PARTNERSHIP Devices Capacity Building Workshop

March 30 – 31, 2009, Penang, Malaysia

Monday, March 30

7:30 - 8:30 **Registration of Participants**

8:30 - 9:00 **Introductory Session**

- ***Speaker,*** ASEAN Secretariat
- ***Mr. Zamane Abdul Rahman, Director, Medical Device Bureau,*** Ministry of Health, Malaysia and Chair of ASEAN ACCSQ Medical Device Product Working Group - ASEAN Medical Device Harmonization Activities, Welcome Remarks
- ***Michael Flood,*** Australia Therapeutic Goods Administration (TGA), Representing GHTF, Welcome Remarks
- ***Jeffrey Gren,*** Director, Office of Health and Consumer Goods, U.S. Department of Commerce, Workshop Goals, Background and Summary of Workshop Agenda

Theme #1 - Building a Regulatory Infrastructure to Promote the Access and Use of Medical Technology

9:00 - 11:00 **Panel Discussion - Basics of Establishing a Medical Devices Regulatory Regime**

Moderator: ***Christine Nelson,*** Consultant/Trainer, Retired from U.S. FDA

Panelists:

Topics and Speakers:

1) ***Michael Gropp***, Medtronic, The legal definition of medical device (what products are subject to medical devices regulatory controls),
2) ***Michael Flood***, Australia TGA, Registration of manufacturers, importers and distributors (how do regulators know what medical devices are placed "listed" on the market?);
3) ***Miang Chadaporn Tanakasemsub,*** Bausch and Lomb, Effective Regulatory Post-market Surveillance;
4) ***Christine Nelson,*** Consultant/Trainer, Retired from U.S. FDA, Classification of medical devices based on risk; and
5) ***Tim Missios,*** Boston Scientific, Appropriate requirements for manufacturer's quality management system/good manufacturing practices (GMPs)

Question and Aswer Session

11:00 - 11:30 **Coffee Break**

11:30 - 1:00 **Panel Discussion: Case Studies - Establishing Flexible Medical Devices Regulatory Regimes**

Moderator: ***Jeffrey Gren,*** Director, Office of Health and Consumer Goods, U.S. Department of Commerce
Panelists:
1) ***Christine Nelson,*** Consultant/Trainer, Retired from U.S. FDA;
2) ***Michael Gropp,*** Medtronic;
3) **TBD,** Thailand
4) **TBD,** Malaysia; and
5) **TBD,** Singapore

Question and Aswer Session

1:00 - 2:00 **Lunch and Prayer**

2:00 - 2:30 ***Janet Trunzo,*** Executive Vice President Technology and Regulatory Affairs, AdvaMed – The Need for Flexible Medical Device Regulatory Regimes to Address the Changing Nature of Medical Devices

2:30 - 3:00 ***Michael Gropp,*** Vice President, Global Regulatory Stategy, Medtronic, Representing AdvaMed and Eucomed - Differences Between Pharmaceuticals and Medical Devices

3:00 - 3:30 **Coffee Break**

Theme #2 - The Role of Conformity Assessment Bodies (CABs) and National Competent Authorities in Pre-Market Conformity Assessment, Post-Market Surveillance and Market Supervision

3:30 - 4:00 ***Michael Flood,*** Australia TGA, *Roles of Notified Bodies and National Competent Authorities in the EU Regulatory Process*

4:00 - 5:30 **Panel Discussion:** Promoting Public Confidence in the Role of Accredited Persons/Conformity Assessment Bodies in the Pre-Market Approval Process, Plant Auditing, Post-Market Surveillance and Market Supervision - Lessons Learned
Moderator: ***Janet Trunzo,*** AdvaMed
Panelists:
1) ***Michael Flood,*** Australia TGA;
2) ***Christine Nelson,*** Consultant/Trainer, Retired from U.S. FDA;
3) ***Miang Chadaporn Tanakasemsub,*** Bausch and Lomb;
4) ASEAN Country Regulator; and
5) ***Manickam Palaniappan***, Underwriters Laboratories

Question and Aswer Session

7:45 - 10.30 **Hospitality Dinner**

<u>Tuesday, March 30</u>

Theme #2 (cont) - The Role of Conformity Assessment Bodies (CABs) and National Competent Authorities in Pre-Market Conformity Assessment, Post-Market Surveillance and Market Supervision

8:30 - 10:00 **Panel Discussion: Issues Facing ASEAN Countries in the Process of Establishing Medical Device Regulatory Regimes Using Conformity Assessment Bodies - Ensuring Quality and Performance**

Moderator: **Michael Flood,** Australia TGA

Panelists: 1) ***Alfred Kwek,*** Singapore Health Science Authority;
2) ***Manickam Palaniappan***, Underwriters Laboratories;
3) ***Christine Nelson,*** Former USFDA Regulator; and
4) ***Tim Missios,*** Boston Scientific,

Question and Aswer Session

10:00 - 10:30 **Coffee Break**

10:30 - 11.00 **Open Discussion:** How National Competent Authorities Can Have Confidence in the Work Products of CABs in Other Countries

Theme #3 - How to Grow a Medical Technology Sector at the National and Regional ASEAN Levels

11:00 – 1:00 Panel Discussion – How Multinational Medical Device Firms Make Foreign Investment Decisions

Moderator: ***Jeffrey Gren,*** U.S. Department of Commerce

Panelists:

1) ***Michael Gropp***, Medtronic;
2) ***Brad Hossack***, Boston Scientific; and
3) ***Ashoke Bhattacharjya***, Johnson & Johnson

Question and Aswer Session

1:00 - 2:00 **Lunch and Prayer**

2.00 - 3:30 **Panel Discussion - Case Studies - Successful Examples of Growing a Medical Technology Sector**

Moderator: ***Brad Hossack***, Boston Scientific

Panelists:

1) United States - ***Jeffrey Gren,*** U.S. Department of Commerce;

2) Europe - ***Brad Hossack,*** Boston Scientific
3) Malaysia - TBD, Malaysia Industries Development Authority (MIDA), Topic - Malaysia Government Activities Related to Medical Devices Manufacturing
4) Singapore - ***Alfred Kwek,*** Singapore HSA
5) Examples of the Relationship Between Innovation and Patient Access to Advance Medical Technologies, ***Ashoke Bhattacharjya,*** Johnson & Johnson

Question and Aswer Session

3.30 - 3:45 **Coffee Break**

3:45 - 5:45 **Theme #4 - Wrap-Up, Conclusion and Future Activities - How GHTF Founding Member Regulators and Industry Representatives Can Help the ASEAN Economic Community Establish a Harmonized Medical Devices Regulatory Regime**

Moderators:

Jeffrey Gren, U.S. Department of Commerce,
and
Ahmad Shariff Hambali, Ministry of Health, Malaysia

Summary of Workshop and Future Enhanced ASEAN - US Partnership Activities

- Discussion of Follow-up Activities and Next Steps
- Development of an Action Plan
- Topics and Timing for Future Workshops

5:45 **Adjournment**

List of Speakers and Panelists:

Mr. Zamane Abdul Rahman, *Director, Medical Device Bureau, Ministry of Health Malaysia*

Mr. Ahmad Shariff Hambali *Medical Device Bureau, Ministry of Health Malaysia*

Michael Flood, *Australia Therapeutic Goods Administration (TGA), Representing GHTF, Welcome Remarks*

Mr. Jeffrey Gren *Director, Office of Health and Consumer Goods, U.S. Department of Commerce,*

Ms. Janet Trunzo *Executive Vice President Technology and Regulatory Affairs, AdvaMed*

Mr. Wang Hwee Beng MMDA Advisor

Mr. Alfred Kwek *Singapore HAS*

Michael Gropp, *Medtronic*

Michael Flood*, Australia TGA*

Miang Chadaporn Tanakasemsub, *Bausch and Lomb*

Christine Nelson, Consultant/Trainer, Retired from U.S. FDA

Tim Missios, *Boston Scientific*

Ashoke Bhattacharjya, Johnson and Johnson

Brad Hossack, Boston Scientific

Manickam Palaniappan, Underwriters Laboratories