Asian Harmonization Working Party Technical Committee Leaders Meeting

26 – 27th Feb 2013

Bangkok Thailand

Mrs Joanna Koh
TC Chair
Health Sciences Authority, Singapore

Agenda: Day 1

26 Feb Morning Session (Closed)

No.	Item	Name
1	Opening remarks	Joanna Koh
2	Adoption of the Agenda	Joanna Koh
3	Roll Call	Bryan So
4	AHWP Strategic Framework	Bryan So
5	AHWP Member Economies current status	Bryan So
	Tea Break	
6	Objective of AHWP TC Leaders meeting in Bangkok	Joanna Koh
7	SWOT analysis for AHWP TC	Ali M Al-Dalaan
8	Discussion on the role of Consultants in AHWP	Bryan So All participants
	Lunch	
9	AHWP TC's current status Individual WG work plan discussion (i)WG team members; (ii)Work items (previous and new) (iii)WG update since the Chinese Taipei meeting.	All Participants
10	AHWP/RAPS Conference update	Tran Quan

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Agenda: Day 2

27 Feb 2013 Morning Session (Open)

No.	Item	Name
11	Closed Sessions for TC Leaders and Advisors in own Groups	TC Leaders Advisors
12	Discussion on Roles 1. Role of TC and WGs -Where are we, where are we going? and what can we achieve 2. What we would hope Advisors role to encompass	All Participants Lead by Joanna Miang ,Ali & Bryan
13	Advisors sharing of GHTF experience 1. What are the concrete steps AHWPTC can take to achieve its goals & objectives 2. What role do Advisors see themselves playing in the AHWP TC a. Support to WGs work plans b. Support to WGs to move towards alignment with Strategic Framework	Advisors
14	Upcoming AHWP meetings: (i)AHWP TC meeting (Malaysia) (ii) AHWP main meeting (Malaysia) (iii) AHWP Conference (Malaysia	Bryan So

AHWP Technical Committee Leaders

- TC Chair: Mrs Joanna Koh, Singapore Health Sciences Authority
- TC co-chair (regulator): Eng. Ali M. Al-Dalaan, Saudi Food & Drug Authority
- TC co-chair (non-regulator): Ms Chadaporn TANAKASEMSUB (Miang), Zimmer, Asia Pacific
- TC Secretariat: Prof Jack Wong, Terumo Medical Singapore

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Roll Call

(by Bryan)

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AHWP Technical Committee

WG1: Pre-Market Submission and CSDT

- ~~BAI Huifen~~ (Tentative: WONG Woei Jiuang)
- Alfred KWEK

WG1a: IVDD

- Li-Ling LIU
- Jeffrey CHEN

WG2: Post-Market Surveillance and Vigilance

- Yorkie CHOW
- Saini KULWANT

WG3: Quality Management System

- Ali M AL-DALAAN
- Ee Bin LIEW

WG4: Quality System Audit

- Abdulah AL RASHEED
- Eun Hee CHO

WG5: Clinical Safety/Performance

- ~~Regulator Chair~~(Tentative: Yuwadee PATTANAWONG)
- Sumati RANDEO

WG6: Capacity Building and Regulatory Training

- Rama SETHURAMAN(Tentative: TAN Ming Hao)
- Jack WONG

STG: Medical Device Nomenclature

- YANG Lian Chun
- Carol YAN

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AHWP Technical Committee Advisory Panel

No.	Title / Given Name / Surname	Company
1	Dr Philippe Auclair	Abbott Laboratories
2	Mr Michael Gropp	Medtronic, Inc.
3	Mr Leighton Hansel	Abbott
4	Dr Eamonn Hoxey	J&J
5	Dr Petra Kaars-Wiele	Abbott
6	Mr Greg Leblanc	Cook Canada
7	Dr Peter Linders	Philips Healthcare
8	Mr Benny Ons	BD Europe
9	Mr Grant Ramley	Aseptico Inc
10	Mr Scott Sardeson	3M Health Care

* Surnames in alphabetic order

AHWP Technical Committee Advisory Panel

Dr Philippe Auclair

Senior Director, Regulatory Strategy & Advocary

Abbott Laboratories

- Involved in EMEA
- Post-market Surveillance & Clinical Investigation of EUCOMED
- Secretary of GHTF SG2
- Trainer experiences in various geographies, including EU, South America, North America and Asian Regions
- Third-body assessment procedure (e.g. notified body)
- Auditing experiences with practical manufacturing perspective

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Michael Gropp

Vice President, Global Regulatory Strategy

Medtronic, Inc.

- Held various engineering, regulatory affairs, quality assurance, and compliance positions
- Experiences in Clinical Research for Vascular Intervention
- Rep. for international affairs and policy to the BOD of AdvaMed
- Chair of Eucomed (Brussels)International Affairs Task Force
- Experiences with GHTF SG1
- Leadership involvement to industry delegation to APEC RHSC
- Involvement in WHO Scientific Advisory Group (clinical trials registry platform project)

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Leighton Hansel

Director, Regulatory Affairs

ABBOTT

- Over 30 yrs of employment by USFDA
- Experiences in Pre-market & post-market
  - Device registration, listing, product code system
  - AE reporting program
- Experiences in Combination Products and UDI
- Eperiences in Compliance management
- Represented FDA, ISO, AdvaMed on various GMDN policy groups
- BOD involvement in AAMI, ANSI ISO Council, and AAMI Committee on Standards Strategy

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Eamonn Hoxey

Vice President, Regulatory Compliance, Medical Devices & Diagnostics

Johnson & Johnson

- Experiences in Quality Management
- Experiences in Regulatory Compliance of Asia Pacific Region and global compliance
- 20yr more experiences in standards preparations
- Chairmanship of ISO/ TC 198
- Chairmanship of ISO/ TC 210

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Petra Kaars-Wiele

Senior Director, International Regulatory Affairs / Division Labeling

ABBOTT

- 30 yrs experiences with Abbott in areas including Regulatory Affairs, Scientific Affairs, and Quality System for IVD products
- Support in addition all IVD MD Divisions (Diabetes Care, Molecular Diagnostics, Point-of-Care)
- Involvements in:-
  - Chairwoman of EDMA Globalization Working Party
  - EUCOMED International Task Force and Blood Safety Working Party
  - RAPS EU Advisory Board, Association of Virology and the German Association of Blood Transfusion
  - GHTF SG1

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Greg Leblanc

Manager, Regulatory Affairs and Quality Systems

Cook Medical / Cook (Canada) Inc.

- Industry association liaison experiences to Canadian regulatory afairs
- Involvement in MEDEC including:-
  - regulatory affairs, government relationship, policy, funding, QS and QS certification etc.
- Member/Vice-Chair of GHTF SG5 since its inception
- Involvement in MEDEC
- Involvement in various committees including:-
  - Regulatory Affairs Steering Committee and subcommittees, Ontario Committee, Federal Affairs Committee, Policy Committee, Value of Technology Committee
- Experiences in scientific research

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Dr Peter Linders

Director Development Global Standards & Regulations

Philips Healthcare

- Involvement in ISO and IEC standards development initiatives
  - ISO/TC 210
  - IEC/TC 62
  - IEC 82304-1 on Medical Software
  - IEC 60601-1 and IEC 62304
- BOD involvement in COCIR
- Chairmanship of COCIR TRAC

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Benny Ons

Director, Regulatory Affairs

BD Europe

- 20yrs more experiences in QA and RA functions
- Regulatory Affairs Committee in the EU industry association EDMA for 10yrs more
- Involvements in GHTF including:-
  - Steering Committee
  - Vice-Chair of SG1 since 2006
  - SG1 IVD subgroup – Chair/Vice-Chair and secretariat since its inception
  - SG5 Clinical Evaluation – linking with IVD subgroup on clinical evidence for IVD MDs

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Grant Ramley

Director, Regulatory Affairs

Aseptico Inc

- Active industry representative to IAF since 2007
- Development of IAF program for ISO 13485 (on QMS)
- Collaboration experiences with GHTF SG4, CABs and Accreditation Body members from every continent
- Representing the Dental Trade Alliance (DTA) since 2001
- Personal experience with the implementation of various MD regulations and standards

Experiences are intensive and extensive. Only part of them are highlighted here.

AHWP Technical Committee Advisory Panel

Mr Scott Sardeson

Director, International Regulatory Affairs

3M Health Care

- Former AdvaMed Reps. for GHTF SG3
- Involvements of AHWP activities since 2004
- Involvement in ASEAN Medical Device Products Working Group
- Adjunct Professor for International Regulatory Affairs courses
- Involvement in ISO / TC 210 WG1
- Training experiences in Asia and Latin America

Experiences are intensive and extensive. Only part of them are highlighted here.

ASIAN HARMONIZATION WORKING PARTY

Goals of AHWP

To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

THANK YOU