AHWP WG1a IVDD Subgroup Update

AHWP TC Leaders Meeting

Bangkok, Thailand

Feb 26-27, 2013

Members of AHWP WG1a

	Position	Name	Member Economy	Organization	Remark
1	**Chair**	Ms. Li Ling LIU	Chinese Taipei	Division of Medical Devices and Cosmetics, Food and Drug Administration, DOH	Reg
2	**Co-Chair**	Mr. Jeffrey CHERN	Chinese Taipei	Center for Measurement Standards, Industrial Technology Research Institute	Ind
3	**Advisor**	Nancy SHADEED	Canada	Health Canada, Device Licensing Division Medical Devices Bureau	Reg
4	**Advisor**	Dr. Petra KAARS-WIELE	Germany	Abbott GmbH & Co, International Regulatory Affairs & Division Labeling	Ind
5	**Advisor**	Ms. Shelley Tang	Australia	Stellar Consulting	Ind
6	**Advisor**	Mr. Benny Ons	Belgium	BD Europe	Ind
7	Member	Ms Maria Cecilia MATIENZO	Philippines	Center for Device Regulation, Radiation Health, and Research - Food and Drug Administration - Department of Health	Reg
8	Member	Mr. Shekhar GANU	India	Ortho Clinical Diagnostics, a Johnson & Johnson Company	Ind
9	Member	Ms. Fan-Yin LIU	Chinese Taipei	Division of Medical Devices and Cosmetics, Food and Drug Administration, DOH	Reg
10	Member	Mr. Albert Ka-Fat POON	Hong Kong, China	Hong Kong Government (retired)	Reg

Members of AHWP WG1a

	Position	Name	Member Economy	Organization	Remark
11	Member	Dr. Jane TSAI	Chinese Taipei	Biomedical Technology and Device Research Laboratories, Industrial Technology Research Institute	Ind
12	Member	Mr.Lun Au Yeung	Hong Kong, China	Medical Device Control Office, Department of Health Hong Kong	Reg
13	Member	Dr.Phana Chieng	Cambodia	Ministry of Health	Reg
14	Member	Mrs. SAR Kuy Heang	Cambodia	Ministry of Health	Reg
15	Member	Ms.Jeong Jin JO	Korea	Korea Food & Drug Administration	Reg
16	Member	Ms. Suhoung Thitastthayakorn	Thailand	Food and Drug Administration	Reg
17	Member	Mr. Sanoj Prabhakaran	UAE	Becton Dickinson	Ind
18	Member	Mr.Ming-Che Wang	Chinese Taipei	Center for Drug Evaluation	Ind
19	Member	Mr.Bryan So	Hong Kong	Hong Kong Productivity Council	Ind
20	Member	Ms. Lisa Yang	Singapore	PharmEng Technology Pte. Ltd.	Ind

2012-2014
Missions of AHWP WG1a

- To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices
  - Developing AHWP guidances on IVD medical devices on a TPLC basis
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices
  - Facilitating harmonization and regulatory convergence
- To facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations
  - Capacity building and training through AHWP as a common platform
  - Regulations updates and gap analyses
  - Experience sharing and case studies on IVD medical devices regulations

AHWP WG1a Projects

To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices			
Project	**Kick-off (DD/ MMM/YY)**	**Checkpoint (DD/ MMM/YY)**	**Actual Date of Completion (DD/MMM/YY)**
Development of GHTF Guidances on IVDs	1/1/2012	2/6/2012	2/6/2012
Revision of GHTF Documents	1/3/2012	13/7/2012	13/7/2012
List of Recognized Standards for IVDs	1/5/2012	30/6/2013	30/9/2012
Best practices for clinical evaluation and investigation	1/5/2012	30/6/2013	30/12/2012
Development of AHWP Guidances on IVD Medical Devices	1/1/2013	30/11/2013	Not yet

To facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations			
Project	**Kick-off (DD/MMM/YY)**	**Checkpoint (DD/MMM/YY)**	**Actual Date of Completion (DD/MMM/YY)**
Training for AHWP Member Economies	30/9/2012	30/10/2014	Not yet
Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)	1/1/2013	30/10/2014	Not yet

Completed
Undergoing

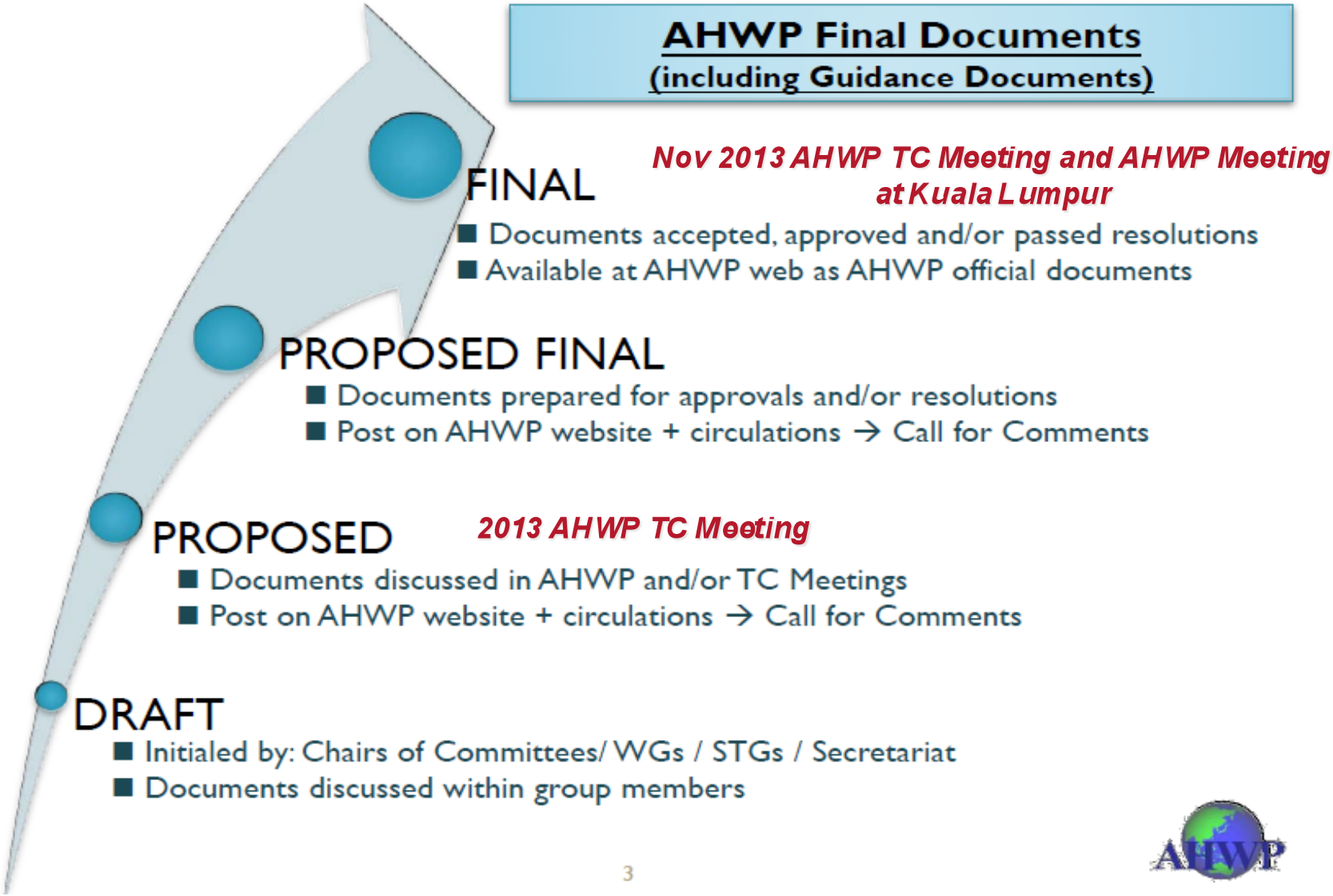
2012 Achievements

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices made
- 2 international conferences on IVD medical devices regulations held
  - May 17-18, 2012 "Conference for Convergence on IVD Medical Devices Regulations"
  - Nov 6, 2012 "Conference for Regulatory Convergence on New and Emerging IVD Medical Devices"

2013 Milestones

- Development of Regulatory Guidances on IVD Medical Devices
- Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

The 4-step Procedure with 4-Type of Doc



Source: The 4-Step Procedure for Preparing AHWP Official Documents, AHWP, Jun 7, 2012

AHWP WG1a Proposed Documents (Draft)

Doc. No.	Title	Status
AHWP/WG1a/PD001	Strategies for Implementing Regulatory Framework and Affordable Access to IVD Medical Devices	▪ Draft of Proposed Document ▪ Circulated among advisors on Feb 20
AHWP/WG1a/PD002	Essential Principles of Safety and Performance of Medical Devices	▪ Draft of Proposed Document ▪ Circulated among advisors on Feb 20
AHWP/WG1a/PD003	STED for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	▪ Draft of Proposed Document ▪ Circulated among advisors on Feb 20
AHWP/WG1a/PD004	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	Draft of Proposed Document
AHWP/WG1a/PD005	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	Draft of Proposed Document
AHWP/WG1a/PD006	Role of Standards in the Assessment of Medical Devices	Draft of Proposed Document

Proposed Topics of IVD Medical Devices Regulations Conference

- To be held in Aug./Sep. 2013
- **Proposed Topics**
  - Regulations updates (US, EU, Japan, China/Korea, Taiwan)
  - Safety and performance evaluation
  - Case studies
  - Harmonization and regulatory convergence
- Speakers (to be invited)
  - Francis Kalush (US FDA), Marie-Lise Migueres (Afssaps, France), Miyamoto Daisei (PMDA, Japan), Hye-Won Roh (KFDA, Korea), James Creeden (Roche, US), Rosanna Peeling (LSHTM, UK)

Thank You

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謝謝

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