Progress Report of WG01a IVDD Subgroup

Jeffrey J.F. Chern
ITRI, Chinese Taipei
November 6, 2009

AHWP WG01a IVD Subgroup

Chair:	Essam Mohammad Al MOHANDIS Saudi Food & Drug Authority Kingdom of Saudi Arabia	regulator
Co-Chair:	Mr Jeffrey Jiin Feng CHERN Industrial Technology Research Institute Chinese Taipei	NON-regulator
Advisor:	Mr Abdulrahman AL-GIFAR Director IVD Department Saudi Food & Drug Authority Kingdom of Saudi Arabia	regulator
Member:	Mr Lun AU YEUNG Engineer Medical Device Control Office, Department of Health Hong Kong SAR, China	regulator
Member:	Dr Phana CHHIENG Deputy Director Ministry of Health Cambodia	regulator
Member:	Mrs SAR Kuy HEANG Chief Bureau of Products Registration Ministry of Health Cambodia	regulator
Member:	Ms Jeong Jin JO Korea Food & Drug Administration Korea	regulator

AHWP WG01a IVD Subgroup

Member:	Ms Pauline LAW Director, RAQS-EHS Asia Pacific Global Customer Management Siemens Healthcare Diagnostics Singapore	NON-regulator
Member:	Ms Maria Cecilia MATIENZO Division Chief Department of Health Philippines	regulator
Member:	Ms Suhoung THITISATTHAYAKORN Pharmacist Medical Devices Control Division Food and Drug Administration Thailand	regulator
Member:	Mr Benjamin CHAN Director MediConcepts Ltd Hong Kong SAR, China	NON-regulator
Member:	Mr Alan CHANG Director of President Office Taiwan Medical and Biotech Industry Association Chinese Taipei	NON-regulator

AHWP WG01a IVD Subgroup

Member:	Mr Shekhar GANU General Manager, RA, ASPAC Ortho-Clinical Diagnostics	NON-regulator
Member:	Devi LALEETHA Kimberly Clark Malaysia	NON-regulator
Member:	Mr Bryan SO Senior Consultant Hong Kong Productivity Council Hong Kong SAR, China	NON-regulator
Member:	Mr Ming-Che WANG Director Division of Medical Devices Center for Drug Evaluation Chinese Taipei	NON-regulator

Achievements

- The subgroup has been cooperating with GHTF to review or draft the following documents:
  - SG1-N45:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
  - SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
  - SG1(PD)/N063 “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices”
  - “Clinical Evidence for IVD medical devices–Key Definitions and Concepts” (Draft)
  - ”Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation” (Draft)

Ongoing Work Items

Work Item	Deadline
Collecting comments from member economies on SG1(PD)/N063 (IVD STED)	Dec 31, 2009
Conducting a *"Survey on IVD Medical Devices Regulations"* from member economies	Jan 31, 2010

Kindly send us your comments by Dec 31, 2009.

PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: March 26, 2009

Survey on IVD Medical Devices Regulations

- Survey on the current regulatory element:
  - Definition
  - Classification
  - Conformity assessment
    - QMS
    - Risk management
    - Performance evaluation
    - Use of standards
    - IVD STED
    - Clinical evidence
  - Post-market surveillance and vigilance
- Experience sharing, difficulties met and proposed resolution

Kindly send us your feedbacks by Jan 31, 2010.

ASIAN HARMONIZATION WORKING PARTY
Working towards medical device harmonization in Asia

AHWP TC WG01a IVD Subgroup

Survey on IVD Medical Device Regulations

Name:_____

Email Address:_____

Organization:_____

Country/Economy:_____

Section 1: Definition of IVD Medical Devices

1. How do you define an "IVD medical device" in your country/economy?

_____

_____

_____

2. Does the definition differ to that of GHTF?

☐ No there's no difference.

☐ Yes, the difference is like the following:

_____

_____

_____

_____

Section 2: Classification of IVD Medical Devices

1. How many classes of IVD medical devices are there in your country?

(a) The classes:

_____

_____

Version 1.0
Date: 2009.07.06

Future Work Items

Work Item	Deadline
•Gap analysis of classification and conformity assessment of IVD medical devices in member economies •Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF	Mar 28, 2010
Liaise to GHTF in revising the following documents: ●"Clinical Evidence for IVD medical devices–Key Definitions and Concepts" (Draft) ●"Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation" (Draft)	Jul 31, 2010
Liaise to GHTF in drafting documents on the following topics •Essential principles for demonstrating the safety and performance of IVD medical devices •Labeling (including graphical symbols) of IVD medical devices	Dec 31, 2010

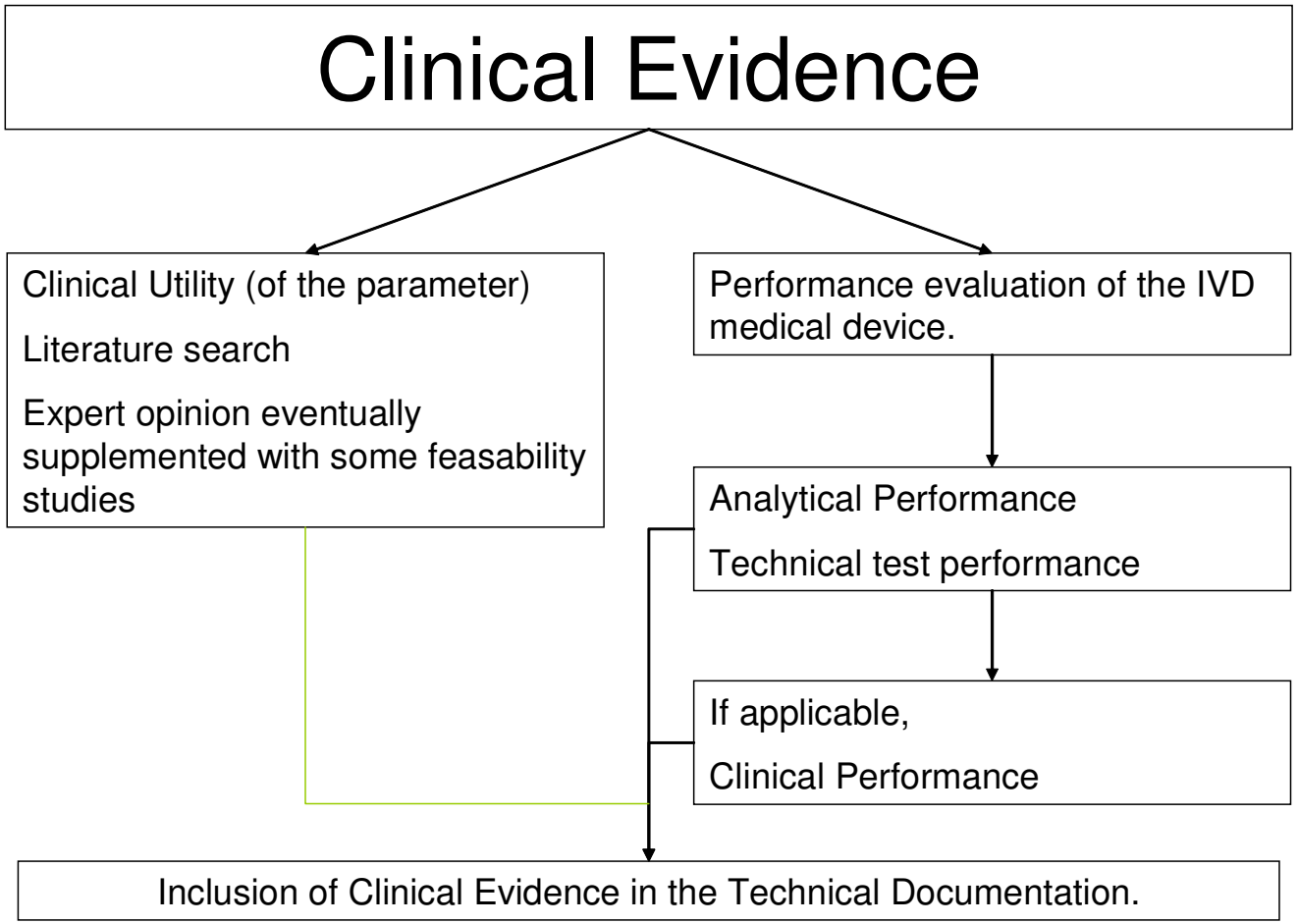
Future Work Items

Work Item	Deadline
Holding training on IVD medical devices regulations: •Classification •Conformity assessment •Performance evaluation	The next AHWP meeting (Nov 2010)
Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF	Sep, 2011

IVD Regulatory Elements and Corresponding GHTF Guidances

Regulatory Element	Status	Posted on
Definition	SG1/N045:2008	June 23, 2008
Classification	SG1/N045:2008	June 23, 2008
Conformity Assessment	SG1/N046:2008	Aug 26, 2008
Technical Documentation	SG1(PD)/N063	Mar 26, 2009 (Open for public comments until Jan, 2010)
Clinical Evaluation and Investigation	"Clinical Evidence for IVD medical devices–Key definitions and concepts" (Draft)	N/A
	"Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation" (Draft)	N/A

“Clinical Evidence for IVD medical devices–Key Definitions and Concepts” (Draft)



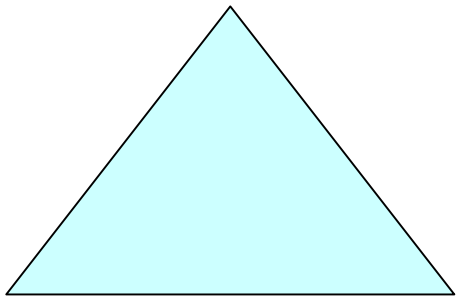
”Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation” (Draft)

Table of Contents

Future Work Items

The following guidances will be revised in terms of specific IVD elements in the coming GHTF SG1 IVD Subgroup Meeting next week (Nov 16-19, 2009 in San Jose, USA) :

- SG1-N41R9:2005 ”Essential Principles of Safety and Performance for Medical Devices”
- SG1-N43:2005 ”Labelling for Medical Devices”



Thank you for your attention!