ASIAN HARMONIZATION WORKING PARTY

18th AHWP Annual Meeting Report by AHWP TC

AHWP TC Chair: Mrs Joanna Koh
HSA, Singapore

5 Dec 2013

WG1- Pre-Market Submission and CSDT

Status of Work Items Completed

No.	Previous Work Item	Status
1	**Mapping of CSDT to STED**	Completed mid 2012 Information published on AHWP website *AHWP/WG1/R001:2012*
2	**Review of amended GHTF definition of medical device**	Completed end 2012
3	**Introduce software overview** **Training on Medical Software**	Completed mid 2012 Catered for training on software in Manila meeting (Jun 2012)

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WG1- Pre-Market Submission and CSDT

Work Items in Progress

No.	Work Item	Deliverables	Action Plan & Timeline
1	**Medical software pre-market guidelines**	• Summary of current classification practices in regulatory agencies, globally • Draft for classification circulated for comments • Publish guidelines on classification	**Q1 (Mar) 2014** **Q2 (Jun) 2014** **Q3 (Sept) 2014**
		• Summary of current pre-market submission guidelines in regulatory agencies, globally • Gap analysis and proposal of pre-market registration guidelines on best practices	**Q4 (Dec) 2014** **Q1 (Mar) 2015**
2	**Combination products (Medical Device) guidelines**	• Information gathering on combination product classification & review practices in ASEAN and IMDRF member economies • White paper on summary of combination products guidelines in AHWP and IMDRF jurisdictions • Gap analysis & circulation of draft AHWP guidelines for comments • Publication of guidance	**Q1 (Feb) 2014** **Q1 (Mar) 2014** **Q2 (Jun) 2014** **Q4 (Dec) 2014**
3	**Medical Device Grouping guidelines (new)**	• Data search on jurisdictions that currently have grouping guidelines & tabulate and present results • Identify best practices & perform gap analysis of guidelines. Road map proposal to bridge the gaps – Position paper • Propose a guideline document	**Q2 (Jun) 2014** **Q3 (Sept) 2014** **Q2 (Jun) 2015**

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WG1a - IVD
Status of Work Items Completed

No.	Previous Work Item	Status
1	Development of GHTF Guidances on IVDs	Completion Date 2/6/2012
2	Revision of GHTF Documents	Completion Date 13/7/2012
3	List of Recognized Standards for IVDs	Completion Date 30/9/2012
4	Best practices for clinical evaluation and investigation	Completion Date 30/12/2012

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WG1a - IVD

Work Items in Progress

No.	Work Item	Action Plan & Timeline
1	Development of AHWP Guidances on IVD Medical Devices	**On-going since 1/1/2013** **Target completion Date - 30/11/2013**
2	Training for AHWP Member Economies on IVD Documents	**On-going since 30/9/2012** **Target completion Date - 30/10/2013**
3	Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)	**On-going since 1/1/2013** **Target completion Date - 30/10/2014**

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WG2 – Post-market Surveillance and Vigilance
Status of Work Items Completed

	Work Item	Status & Action
1	**Harmonized Definitions of PMS Terms i.e. AE, PMS etc. (N54)**	Nov 2012 **COMPLETED** Finalized Guidance Document uploaded into the AHWP website
2	**AE Reporting Form**	Nov 2012 **COMPLETED** Finalized AE form uploaded into the AHWP website
3	**Electronic AE Reporting Form**	Nov 2013 **COMPLETED** Electronic AE form are available in the AHWP website under >Documents> Forms
4	**Formal Training of SG02/WG2 Guidance Document**	May 2012 **COMPLETED** • Training needs finalized 1.PMS, laying the roadmap 2.WG2 output implementation on AE/FSCA

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WG2 – Post-market Surveillance and Vigilance

Work Items in Progress

	Work Item	Output	Status	Target Date
1	Safety Alert Dissemination System (SADS) Upgrade	Secured SADS	• 1st Trial run completed	Oct 2013
			• List of SADS members being updated	Dec 2013
			• Secured SADS ready for implementation	Q1 2014
			• SADS guidance documents to be revised, if necessary	Q2 2014
2	AE Reporting Requirements & Timelines for all Stakeholders	Proposed Document AE Reporting Guidance for the Medical Device Manufacturers or its Authorized Representatives (AWHP/WG2/PMS/004)	• Proposed document to be endorsed in 18th AHWP Annual meeting and uploaded into the AHWP website	Q1 2014
			• AE Reporting Timelines to be developed	Q2 2014

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WG3 – Quality Management System

Status of Work Items Completed

	Work Item	Deliverables	Action Plan and Timeline
1	**Joint AHWP - WG3 GHTF SG3 activity**	N19 "Nonconformity Grading System for Regulatory Purposes and Information Exchange"	**Completed, N19 released**
2	**Joint AHWP WG3 GHTF SG3, ISO/TC210 /WG1 meetings**	ISO13485 update (user requirements survey, TC210 collaboration etc.) AHWP join ISO/TC210 Continue working and providing input on the revision of ISO 13485 -2003	**WG3 participated Mar 27-29 2012 (Completed)** **AHWP as a Liaison Member with ISO. Completed.** **Comments for CD completed**, awaiting TC210 meeting

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WG3 – Quality Management System

Work Items in Progress

	Work Item	Deliverables	Action Plan and Timeline
1	AHWP QMS Survey; QMS Adoption and Implementation	Completed and analyzed all member economies survey forms Needs for guidance document for ISO13485 is recognized	**Survey completed** **Draft in progress.**
2	Guidance document for the application of ISO13485 for importers / distributors / small manufacturers	Complete Phase 1 guidance document for importers / distributors Complete Phase 2 guidance document for small manufacturers in the same document	Review by members, complete review by **Jan 2014.** Draft by **March 2014**, review by members **Apr – Jun 2014,** complete by **Jul 2014**
3	Review released documents N17, N18, N15 *R8/2005,* N99-10 (Ed2)	Revised to be more useful and usable guidance documents for adoption in AHWP member economies	To complete by **2014**

WG4 – Quality System Audit
Status of Work Items Completed

	Work Item	Action Plan and Timeline
1	Survey the reference documents on Audit and Development of training module	Completed
2	Survey the demands for Importer and Distributor Guidance	Completed
3	Training Module Development and Pilot of first version in Sep 2013	Completed

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WG4 – Quality System Audit

Work Items in Progress

	Work Item	Action Plan and Timeline
1	Developing the auditing guidance for importers and distributors	2014
2	Developing training module for basic and intermediate level on auditing	2014

WG5 – Clinical Safety/Performance

Status of Work Items Completed

	Work Item	Action Plan and Timeline
1	**Mapping with ICH GCP, SG5 GN and latest version of ISO 14155** **Provide inputs to the next ISO/TC 194/WG 4 "Clinical investigations of medical devices in humans"**	**Completed Q2 2013**
2	**Comparative study of regulations & related guidance on Clinical Trial Requirements** Keep tracking the emerging regulations regarding Clinical Investigations in the member economies	Presentation of updates in the TC meetings & Annual Meeting

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WG5 – Clinical Safety/ Performance

Work Items in Progress

	Work Item	Action Plan and Timeline
1	Consensus on framing the guidance Survey: On the regulation and implementation of Clinical Investigation including clinical trial requirements	On-going Timeline – **31 Mar 2014**
2	Partner with other TC Work groups' initiatives to provide expertise & input relating to the clinical safety/performance	**On-going item**
3	Nominating second Advisor (non industry) to the WG	Take advisor on board by next WG meeting in **May 2014**

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WG6 – Capacity Building/Regulatory Training

Status of Work Items Completed

	Work Item	Action Plan and Timeline
1	To provide links of relevant online course providers on AHWP website for AHWP members' ease of access	Completed
2	Collation of training needs from various work groups and prioritization of requests	Completed

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WG6 – Capacity Building/Regulatory Training

Work Items in Progress

	Work Item	Action Plan and Timeline
1	To develop training strategy for AHWP TC – including quality and impact assessment procedures	**Q2 2014**
2	To coordinate with Secretariat in advance to leverage on AHWP meeting resources to plan training for AHWP member economies	**On-going**
3	Training on the AHWP guidance documents and Standards	**Q3 2014**
4	Identify areas of focus in training for other organizations WHO, APEC, RAPS etc. and explore working together	**Q4 2014**

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STG – MD Nomenclature

Status of Work Items Completed

	Work Item	Action Plan and Timeline
1	Continue participation of nomenclature work at GMDN, IMDRF and WHO, provide AHWP comments	**Completed and to be continued** Meet with EU DG SANCO and GMDN Agency from Sept.21st-23rd, 2013
2	GMDN pilot program in China with start of feasibility study for sharing	**Completed** Conducted 5 workshops & discussions in China for the feasibility analysis of GMDN application in China and drafted a report.
3	Keep close follow-up and participate in IMDRF UDI working group	**Completed** Discussed the suggestions and comments towards the UDI System for Medical Devices (Version 2.0) drafted by IMDRF

STG – MD Nomenclature

Work Items in Progress

	Work Item	Action Plan and Timeline
1	Follow member economy UDI implementation status, and provide support as necessary to ensure the alignment with IMDRF global model	**On-going** Conducted a workshop involving CMDSA and AdvaMed
2	Continuously involve in the harmonization work in device nomenclature	**On-going**
3	Guide the AHWP member economies on the harmonized approach of the UDI system.	**On-going**

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Thank You