WG6 – Capacity Building/ Regulatory Training

Chair: **Rama Sethuraman, HSA, Singapore**

Co-Chair: **Jack Wong, Industry, Singapore**

No. of WG members: 19

Content

- Work plan finalized in TC Leaders meeting (March 2012)

- Progress Updates

Proposed Work Plan 2012 - 2014

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Assess training platforms e.g. university, RAPS, WMDO www.wmdo.org	Platforms to be reviewed and proposed **Identified and links published on website – To seek TC inputs**	2012
2	To collate training needs of different workgroups. Consolidate and prioritize the training needs based on WG and TC inputs	To send out a template wish list format to all WGs to populate → **complete** Prioritized list to be prepared → **complete**	**mid 2012** Compile by mid 2012 Roadmap by end 2012
3	To explore available training materials that caters to our WG needs above To work to create materials for those AHWP TC WG specific topics	Course and trainers available to be explored – **Ongoing work item** To work with individual WGs – **In Progress**	Ongoing (timelines based on WGs wish list and prioritization)

Proposed Work Plan 2012 – 2014 (cont)

Priority	Work Item	Deliverables	Action Plan and Timeline
4	Mapping our training requirements with other organizations to tap on their existing or ongoing programs e.g. WHO, APEC	Identify areas of focus in training for WHO, APEC etc. and consider working together	2012 - 2013
5	Establish and Implement basic on-line system and program for each WGs	On line course	2013

Training Needs of TC Work Groups

- Template wish list format was emailed to all WGs to populate

- Compilation and Prioritization of returns

- Training Sessions – Progress Updates

Training wish list of TC WG01

S/N	Training Topics *<Arrange from high to low priority>*	Time line *<When you need this>*	Known Training Resource for this Topic (if any) *<Online platform/ Trainer with expertise/ Upcoming training by other organisations>*	Expected Content/ Scope of the Training *<Brief points will do>*	Relevance to AHWP members *<Potential benefit to AHWP members>*
1	Grouping	Dec-12	Health Sciences Authority Singapore	Grouping of accessories / systems / families of devices impacts # of CSDT submitted. Consequently, this affects adoption and harmonisation of CSDT.	Widespread adoption of CSDT. Harmonised premarket registration requirements.
2	Borderline products	Jun-13	USFDA	Current thinking on regulatory control of borderline products	Harmonised premarket registration requirements without force fitting new / innovative products under MD regulations.

Training wish list of TC WG02

S/N	Training Topics *<Arrange from high to low priority>*	Time line *<When you need this>*	Known Training Resource for this Topic (if any) *<Online platform/ Trainer with expertise/ Upcoming training by other organisations>*	Expected Content/ Scope of the Training *<Brief points will do>*	Relevance to AHWP members *<Potential benefit to AHWP members>*
1	Training for the software validation	During the Annual AHWP meeting – **Current AHWP meeting**	USFDA	21 CFR Part 11	MD industry and regulators use various soft ware for manufacturing, distribution and tracking and hence need to be aware of the validation requirements for the data integrity
2	Training on PMS	During the Annual AHWP meeting – **Current AHWP meeting**	IMDRF (GHTF) Study Group member	Direction of the IMDRF on PMS	Laying the road map for the WG 2 members
3	Training on WG2 output implementation on AE/FSCA	During the annual AHWP meeting	Can be done by WG2, WG6 and IT support together	New AE and FSCA form developed by WG2	Awareness on AE/FSCA in context with what would be implemented for AHWP member economies

Training wish list of TC WG03

S/N	Training Topics *<Arrange from high to low priority>*	Time line *<When you need this>*	Known Training Resource for this Topic (if any) *<Online platform/ Trainer with expertise/ Upcoming training by other organisations>*	Expected Content/ Scope of the Training *<Brief points will do>*	Relevance to AHWP members *<Potential benefit to AHWP members>*
1	Basic Training on Quality Management System	During 17th AHWP meeting - **Current AHWP meeting**	0.5 to 1 day face to face training	Jack	
2	Global RA training Certificate	TBC	1 day face to face training with examination paper from ARPA	Jack	

Pending:
Returns on the relevance to AHWP members and also course content is required to prioritize these topics.

Training wish list of TC WG04

S/N	Training Topics *\<Arrange from high to low priority\>*	Time line *\<When you need this\>*	Known Training Resource for this Topic (if any) *\<Online platform/ Trainer with expertise/ Upcoming training by other organisations\>*	Expected Content/ Scope of the Training *\<Brief points will do\>*	Relevance to AHWP members *\<Potential benefit to AHWP members\>*
1	1 day workshop	AHWP meeting in Taiwan	Albert T.W. Li from ITRI. Dr. Chee Choong, Vincent from BSI. Or any expert from SG4(can be arranged by Albert).	2 modules. Module 1 during morning session will cover part 1&3. Module 2 afternoon session will cover part 2, 4&5	This is one day workshop during annual official AHWP meeting in Taiwan for all member economies.

Training wish list of TC WG05

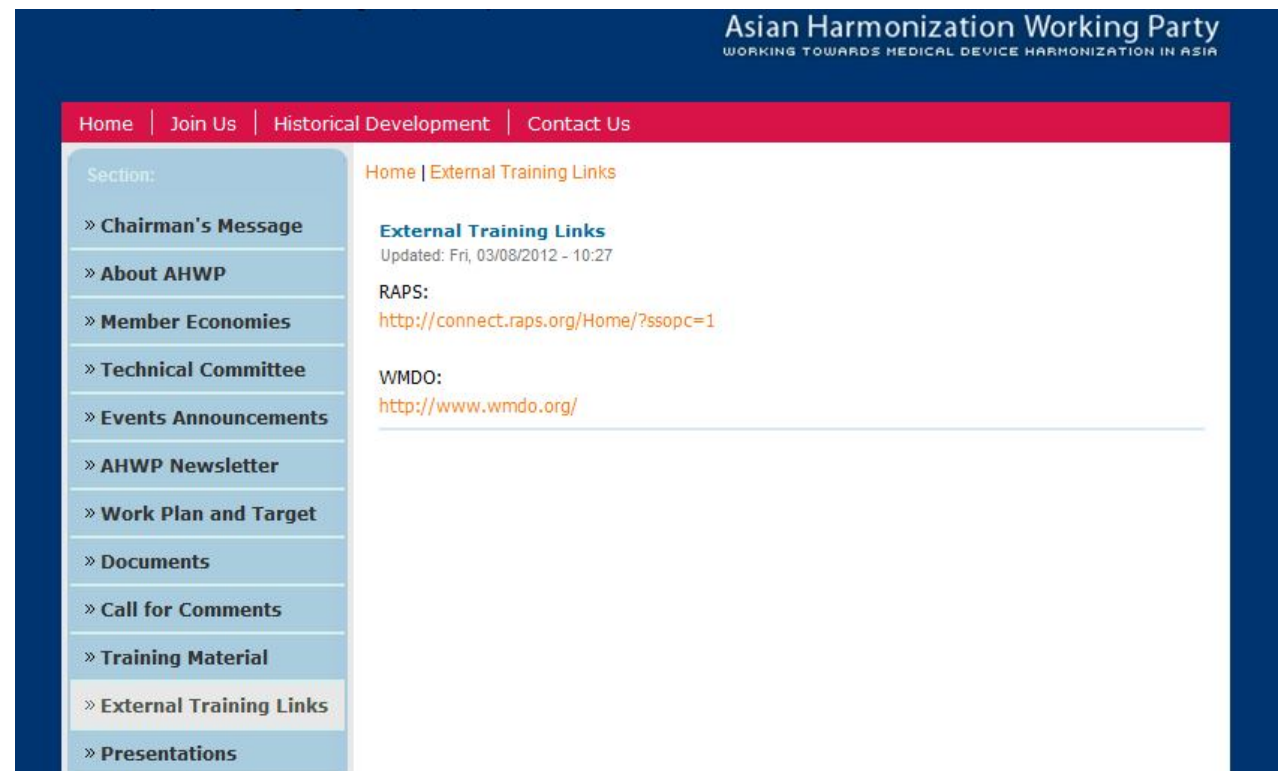| S/N	Training Topics	Time line	Known Training Resource for this Topic (if any)	Expected Content/ Scope of the Training	Relevance to AHWP members
1	Training on GHTF 5G5 GN and latest version of ISO 14155		1. Glen Van Landeghem, Manager Clinical Quality Abbott Vascular 2. Dr. Dieter R. Dannhorn Underwriters Laboratories Inc (UL)	This international standard has been revised (ISO 14155:2011), the training presents the strategies and requirements of the new standard EN ISO 14155:20111	
2	Training on SG5 Documents - clinical Evaluation and Investigational Plan like: monitoring and site audit etc			introduce the concepts of clinical evaluation and clinical evidence; examine the relationship between clinical investigation, clinical data, clinical evaluation and clinical evidence;	

Next Steps...

- To seek feedback from respective WG chairs/co-chairs post-training session on

    - Coverage of the training session – content and depth

    - Gap analysis – topics not covered or not adequately covered in the training

    - Follow on training needs if any

    - Outcome analysis – Impact of the training from WG's perspective

- To analyse and share above feedback with AHWP TC members and propose next steps.

Other Work Items

- To assess the existing online training platforms and materials and their relevance (e.g. RAPS) – *In Progress*
  - Links of existing online training platforms provided on AHWP website for ease of reference

Timeline:
2012 -2013

- Identify areas of focus in training for other organizations WHO, APEC etc. and consider working together

Other Work Items

- Establish and Implement basic on-line system and training platform/program for each TC WGs

  Timeline:
  2013

  For TC's Discussion and Consensus

Thank You