Work Group 5
Clinical Safety/Performance

AHWP TC Meeting,
KL, Malaysia
Dec 3rd ' 2013

Work Group V - Overview

Chair: **Ms. Yuwadee PATANAWONG**
Food and Drug Administration (Thai FDA)
Thailand

Co-chair: **Ms. SUMATI Randeo**
Abbott Laboratories, India

Number of members: **14 (includes one Advisor)**

Extend Covers **9 member economies** i.e. India, China, Saudi Arabia, Malaysia, Thailand, Singapore, Chinese Taipei, Hong Kong, Korea

Three Sub Groups

Comparative Study | **Document Review & Adoption** | **Trainings**

WG V – STAR Vision

- Prioritize objectives
- Discuss goals
- Decide what needs to be addressed first.

Strategize

Track

- Track evolving Regulations
- Regularly review the progress
- Constantly Apprise the Group

- Gather Information
- Analyze / Evaluate
- Propose Recommendations to frame guidance
- Propose convergence

Action

FASTER CONVERGENCE → **Result**

2013 Plan & Status

WI Priority	Deliverables	Action Plan	Target & Status
W1	Consensus on framing the guidance	Survey: On the regulation and implementation of Clinical Investigation including clinical trial requirements	Initiated, Inputs received from …… member economies by Nov 13; extended timeline to Mar 31st 2014
W2	Nominating second Advisor (non industry) to the WG	To prepare the list of suitable candidates and WG chair to approach them for their availability	Initiated
W3	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"	Q2 2013 (25th & 26th April 2013) Completed participated in the meeting in Italy

2013 Plan & Status

WI Priority	Deliverables	Action Plan	Target & Status
W4	Comparative study of regulations & related guidance on Clinical Trial Requirements	Keep tracking the emerging regulations regarding Clinical Investigations in the member economies	Present the updates in the TC meetings & Annual Meeting inputs will be shared as part of the survey conducted
W5	IMDRF initiatives with respect to their WG on Risk / Benefit Analysis	Keep track of the developments at IMDRF and apprise TC at annual Meeting	This Work Item "Cancelled" as this is not included as area of priority by IMDRF WG

2013 Plan & Status

WI Priority	Deliverables	Action Plan	Target & Status
W6	Partner with other TC Work Groups, ISO 14155 committee to provide inputs relating to medical device clinical evidence and investigation	Participate in various meetings and provide inputs to draft documents	On going. Participated in ISO 14155 meeting in April at Pavia – Italy

Updates from ISO 14155 Meeting

- **2013 committee meeting outcome**
  - Gap analysis between SPIRIT 2013 Checklist and ISO 14155: 2011 Annex A
  - HSA Singapore proposal to add the basic GCP principles summary of ICH 6 to the introduction of ISO 14155
  - Draft position paper on Registries
- **Action item for AHWP WG5**
  - to Consider concept of registry; make proposal how to address in the standard
  - to share mapping and comments on GHTF and ISO documents and Survey highlights with the ISO committee
- **2014 committee meeting additional goals -** Additional topics for revision with regards to new legislation on MD
  - Introduction of new terminology
  - Additional Ethics Committee requirements
  - IVD – GCP requirements

Plan 2014

WI Priority	Deliverables	Action Plan	Target
W1	Consensus on framing the guidance - SURVEY	To collate the inputs and prepare survey report to be submitted to TC chair	Inputs by Mar 31st 2014 Collate inputs by 30th April 2014 Submit report by 31st May 2014
W2	Nominating second Advisor (non industry) to the WG	Letters to be circulated by Chair	Take advisor on board by next WG meeting in May 2014

Plan 2014

WI Priority	Deliverables	Action Plan	Target
W3	Two Action items listed from ISO 14155 committee meeting to be completed	Identify members who can support with their inputs. Take inputs from WG advisors Share the survey report with ISO committee	To be confirmed in May 2014 WG meeting
W4	Partner with other TC Work groups' initiatives to provide expertise & input relating to the clinical safety/performance	To provide comments on ISO 13485 draft pertaining to clinical evidence vs indication	To be confirmed

Training Plan

Deliverables	Action Plan	Target
Training on ICH GCP, GHTF SG5 GN and latest version of ISO 14155	Conduct the workshop for WG 5 and facilitate it with the help of WG 6	Request forwarded to WG6
Training on Clinical Evaluation & Investigation plan like 1. Monitoring 2. Site Audits 3. Data Evaluation	Conduct the workshop for WG 5 and facilitate it with the help of WG 6	

AHWP

THANK YOU !

Working Towards
Medical Device
Harmonization
in Asia