WG 5:Clinical Performance and Safety (formerly WG5: Clinical Safety/performance)

AHWP TC Meeting,
Nov 19th ' 2014; Seoul Korea

Work Group 5 - Overview

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

Co-chair: **Ms. Sumati RANDEO**
Abbott Laboratories, India

Number of members: **15**

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**

Comparative Study Work Item

WI Priority	Deliverables	Target	Status
W1	Comparative Study or Survey Result and Feedback on Medical Device Regulations of Clinical Investigation from Member Economies	Gap analysis on Medical Device Regulations of Clinical Investigation among Member Economies	Completed Report presented in 17th AHWPTC Meeting 4th December 2013, Malaysia

Document Review Work Item

WI Priority	Deliverables	Target	Status
W2	Comparative Study on ISO 14155: 2003, ISO14155:2011 and study on ICH GCP and Asian country specific requirements	Analysis of international standards, guidelines and regulatory requirements of AHWP member Economies	*Completed Analysis Report prepared comparing ISO 14155: 2011 , ICH GCP and Asian country specific requirements and presented at the WG 5 meeting in Bangkok in May 2014

Acknowledgements :

Mie Ohama

Clinical Quality Manager APAC, Medtronic, Australia

Document Review Work Item

WI Priority	Deliverables	Target	Status
W3	Liaise with ISO 14155 TC committee on the following 1.Inclusion of GCP principles in the Standard body 2.Separate Standard for Clinical Evaluation for IVDs 3.Include explanation on Registry and post Market Studies in the Standard 4.Share the survey report with ISO committee to build consensus for member state to adopt ISO 14155	First Draft at ISO 14155 TC meeting in Mishima Japan – April 2014 Second Draft at ISO 14155 meeting in Arlington USA Oct - 2014	presented the recommendations and share inputs of the members with ISO 14155 TC and ISO 14155 committee accepted the proposals

AHWP Document Review Work Item

WI Priority	Deliverables	Action Plan	Target	Status
W4	Partner with other AHWP TC WG 3 initiatives to provide expertise & input relating to the clinical safety/performance	Evaluate the proposed changes in ISO 13485 pertaining to clinical evidence versus indication	1. Make suggestions to AHWP WG 3 2. Seek inputs from ISO 14155 TC	Deliberations held with WG 3 during TC meeting in May 2014 in Singapore. These were shared at ISO 14155 TC Committee meeting in April 2014 **Proposals under consideration by ISO committee**

Training Work Item

Deliverables	Action Plan	Target	Status
Training on ISO 14155: 2011	Facilitate the training workshop during WG 5 meeting	Complete the trainings by May, 2014	There were two training sessions conducted in May 2014 meeting in Bangkok. These sessions were 1.Changes in the ISO 14155: 2011 Version 2.Comparing ISO 14155: 2011 and ICH GCP, Clinical Investigation Regulatory Requirements in some Asian country specific requirements

Updates from ISO 14155 Meeting

ISO TC 194 WG 4 - ISO 14155 Revision - Mishima, Japan. April 24 /25, 2014

- CIP Content – Changes to annex A

Gap analysis with SPIRIT Recommendations was presented.

Six items of ISO 14155 may need additional information (trial registration/study setting/allocation/blinding/access to data/dissemination policy).

- Report on need to incorporate Registries

The committee agreed for providing clarification on post market studies and registries, differentiating the different kinds (sponsored, investigator driven, organized by scientific associations or authorities, etc.) AHRQ 2010 User's Guide can be a used as a source for a gap analysis with ISO 14155.

- Risk Management

A flowchart as an annex in ISO Revision will be inserted and routed for comments.

Updates from ISO 14155 Meeting

ISO TC 194 WG 4 - ISO 14155 Revision - Mishima, Japan. April 24 /25, 2014

- Proposal for including Public Health Threat

Serious health threat/hazard: *Any SAE that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons and that requires prompt remedial action for other subjects, users or other persons.*

- Request to change the name of the TC 194 from biological evaluation for medical devices to Biological and Clinical evaluation for medical devices.

This was received very positively and adopted at the TC 194 plenary meeting on Saturday 26th April. The name will change and it is likely be adopted by the CEN mirror committee.

Updates from ISO 14155 Meeting

ISO TC 194 WG 4 - ISO 14155 Meeting in Arlington USA

- 3 definitions of registries were presented, from different sources. The FDA follows the AHRQ definition.
- The retrospective data collection is not mentioned in these definitions.
- Next steps:
- Include the definition of “Registry” in the draft standard.
- Define interventional and non-interventional.
- Define which basic principles/part of the standard are applicable for the different types of studies/registries.
- Add an annex, including the flow-charts.
- Sub-group to keep on working on the topic and provide input for the draft standard.

Future Action Plan

- require Training for common understanding and further decision making on adoption of GCP standards and Establishing appropriate AHWP guidelines

AHWP

THANK YOU !

Working Towards
Medical Device
Harmonization
in Asia