WG5 Comparative Study Result and Feedback on Medical Device Regulations of Clinical Investigation from Member Economies

Yuwadee Patanawong WG5 Chair

Sumati Randeo WG5 Co-chair

17th AHWPTC Meeting

4th December 2013, Malaysia

13 responses from regulatory authorities from all 23 member economies

No GCP Regulations/Guidelines 10 (76 %)	Have GCP Regulations/Guidelines 3 (23 %)
Hong Kong*, Indonesia, Lao, Malaysia*, Myanmar, Philippines*, Singapore*, Thailand*, Yemen, Saudi Arabia* * = Plan to have GCP Regulation in the future	China, Chinese Taipei, Korea

GCP Standards of interest from 10 member economies currently no GCP Regulations

ISO 14155:2011	Malaysia, Singapore, Philippines, Saudi Arabia
ISO 14155:2003 and ISO 14155:2011	Indonesia
ICH GCP and/or ISO 14155:2011	Hong Kong, Thailand
AMDD	Myanmar
Not Yet Planned	Lao, Yemen

Existing GCP Regulations and Standards of 3 member economies

China	Provisions for Clinical Trials of Medical Devices (SFDA No. 5) issued on Jan 17th, 2004	Chinese GCP	A new version will be issued soon based on ISO 14155:2003
Chinese Taipei	Guidance for Clinical investigation of medical devices, issued on May 17,1996	Adopted ISO14155 :2003	will adopt ISO 14155: 2011
Korea	Good Clinical Practice of medical devices under the Asterisk 2-2; the Article 13 of the Enforcement Rule under the Medical Devices Act of Korea, the Enforcement Rule was enacted July, 2004 and was amended March 23, 2013.	Adopted ICH GCP and ISO 14155:2011	

Direction of AHWP GCP Regulations/Guidelines (1)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
China	Yes	Need more info/study	To protect the interests of subjects and guarantee their safety in the medical device clinical trials, ensure standard process of medical device clinical trials and obtain authentic, scientific, reliable and traceable results.	Better align with IMDRF and/or International Standards within AHWP economies
CT	Yes	ISO 14155	Definition of terms, formats of protocol, PI qualification, the requirement of preclinical testings, standard of inspection.	AHWP member economics should strength the implementation of the guidelines

Direction of AHWP GCP Regulations/Guidelines (2)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
HK	Yes	- WHO GCP / ICH GCP and/or ISO 14155 - Need more info/study	The guidance on clinical investigations should include (1) the assessment criteria of the safety and performance/efficacy of the medical devices; and (2) appropriate evaluation method(s) according to the international standards, e.g. ISO 14155 or ICH GCP	Some member economies may already have their own regulations or requirements on clinical investigation of medical devices.

Direction of AHWP GCP Regulations/Guidelines (3)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
IND	Yes	ISO 14155 and AMDD and then AHWP-GHTF	-The regulation/ guidance should be efficient and implementable by the industry with affordable cost. - The regulation/ guidance can ensure the safety, quality and efficacy of the medical device to increase the patient safety.	Indonesia will adopt the AMDD first due it's a mandatory to ASEAN member states. But we are open to the global guidelines like AHWP and GHTF because some of the guidelines has the same sources. We try to implement and establish AMDD to our local industry first. After they are able to well implement the regional guideline, then the global guideline will be followed.

Direction of AHWP GCP Regulations/Guidelines (4)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
Korea	Yes	ISO 14155: 2011	Protection of the rights, safety and well-being of human subjects should prevail over interests of science and society. And another important objective is to secure scientific evidence of the clinical investigation.	-
Lao	-	Need more info/study	To harmonize the regulation and implementation the clear rule for both industries side and regulators must be followed.	-

Direction of AHWP GCP Regulations/Guidelines (5)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
MY	Yes	- ISO 14155: 2011 - Need more info/study	To ensure the safety and efficacy of a new medical device before it is introduced to patients / or study population. IVD medical device need to ensure the accuracy of screening and conformation of high risk category devices	-
PHP	Yes	GHTF Guidelines	To ensure safety of medical devices	There is no binding agreement signed by the head of the member states will be one of the barriers that will prevent in achieving harmonization in framing AHWP guidelines. Unlike the ASEAN where all member states are bound to commit and implement

Direction of AHWP GCP Regulations/Guidelines (6)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
SG	Yes	- ISO 14155: 2011 - Need more info/study	To ensure that the investigational medical devices used in clinical trials are acceptably safe and the design and conduct of the trials provide adequate levels of protection for participants, and that the clinical data are credible.	-
THA	Yes	- ICH GCP and/or ISO 14155 - Need more info/study	To protect the rights, safety and welfare of human participants and to assure the credibility of clinical data.	-

Direction of AHWP GCP Regulations/Guidelines (7)

	Need to have harmonized AHWP GCP guidelines	Suggested standard	Main objectives	Suggestion/barriers in achievement harmonization
SAUDI	Yes		Ensuring devices performance and effectiveness	Conduct awareness training
Kuwait		- Need more info/study		Medical devices classification (Risk Factor)
Myanmar		AMDD	To evaluate safety and efficacy of the performance of medical device.	Capacity building and the infrastructure development of member economy. This development can facilitate the participation of member economy to follow the AHWP guideline.

Adoption status of GHTF guidance documents of all 13 member economies (1)

		Yes	No	Not yet but interested to adopt	Need to be harmonized using this guideline*	Need more info/study before making decision
SG5/N1R 8:2007	Clinical Evidence	Chinese Taipei, Korea SG	China, HK Yemen, Mynmar	IND, Lao, MY, SAUD, PH	CT, IND, SG, SAUD. PH	China, HK THA,Yemen
SG5/N3: 2010	Clinical Investigations	Chinese Taipei, Korea	China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	CT,SAUD, PH	China, HK THA,Yemen
SG5/N2R 8:2007	Clinical Evaluation	Korea, SG	Chinese Taipei, China, HK Yemen, Myanmar	IND, Lao, MY, SAUD, PH	CT, IND, SG, SAUD, PH	China, HK THA,Yemen

* Korea suggested using GCP from ISO14155, HK suggested using GHTF/WHO GCP/ICH GCP, Malaysia suggested ASEAN CSDT

Adoption status of GHTF guidance documents of all 12 member economies (2)

		Yes	No	Not yet but interested to adopt	Need to be harmonized using this guideline*	Need more info/study before making decision
SG5/N5: 2012	Reportable Events during Pre-Market Clinical Investigations	Chinese Taipei, Korea	China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	CT, SAUD, PH	China, HK THA,Yemen
SG5/N4: 2010	Post-Market Clinical Follow-Up Studies	Korea	Chinese Taipei, China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	CT, SAUD, PH	China, HK THA,Yemen
SG5/N6: 2012	Clinical Evidence for IVD medical devices	Chinese Taipei, Korea	China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	IND, SG, SAUD, PH	China, HK THA,Yemen

Adoption status of GHTF guidance documents of all 12 member economies (3)

		Yes	No	Not yet but interested to adopt	Need to be harmonized using this guideline*	Need more info/study before making decision
SG5/N7: 2012	Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation	Chinese Taipei, , Korea	China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	IND, SG, SAUD, PH	China, HK THA,Yemen

Adoption status of GHTF guidance documents of all 12 member economies (3)

		Yes	No	Not yet but interested to adopt	Need to be harmonized using this guideline*	Need more info/study before making decision
SG5/N8: 2012	Clinical Evidence for IVD medical devices – Clinical Performance Studies for IVD medical Devices	Chinese Taipei	China, HK Yemen, Myanmar	IND, Lao, MY, SG, SAUD, PH	SG, SAUD, PH	China, HK THA,Yemen

Local Clinical Investigation Requirements for pre-market approval (1)

- Not required [SG,HK(current voluntary system), PH]
- Not required for local production of medical devices such as needle, catheter, infusion set (Lao)
- Not yet required [Myanmar(Because only low risk category of medical devices (eg, syringe) are produced in our economy.When we need to perform a clinical investigation, we will comply with AMDD)]
- Use only International Standard based on ISO 14155 and Helsinki declaration [Indonesia]
- Not for current interim regulation, will be required when having main frame regulation [Saudi Arabia]

Local Clinical Investigation Requirements for pre-market approval (2)

- We need it, but till now we didn't do the local clinical investigation [Yemen]
- Required if there is no sound evidence from other routes(via systemic reviews and clinical judgement) [Malaysia]
- Required if foreign data are not sufficiently scientific sound and some cases such as HIV test kits for diagnosis purpose [Thailand]

Local Clinical Investigation Requirements for pre-market approval (3)

- Required in case that the Minister of the MFDS determines due to ethnic differences[Korea]
- Required in case of contact lenses with some exemption, special considerations in issues such as racial differences, clinical practice, culture, new devices associated with new technology, or the foreign data are not sufficient to support safety and effectiveness of the devices [Chinese Taipei]

Local Clinical Investigation Requirements for pre-market approval (4)

[China] Required in following circumstances:

- Foreign products in Category III with no market permits in its homeland (region) from competent authorities in charge of medical device of foreign government
- Implantable medical devices in Category III under the condition that domestic product has not obtained market permit, or foreign product has obtained market permit in its homeland (region) from competent authorities in charge of medical device of foreign government.
- Medical Device in Category II under the condition that domestic product has not obtained market permit, or foreign product has not obtained market permit in its homeland (region) from competent authorities in charge of medical device of related foreign government

Trainings needed

1. **ISO 14155:2011 (12 except SG)**
2. **ICH GCP (9- Lao,IND,Chinese Taipei,Korea, HK,Yemen,PH, Myanmar, THA)**
3. **GHTF guidance documents (9-Lao,IND, Korea, Chinese Taipei, Yemen, Saudi Arabia, Malaysia, Myanmar, THA)**

especially Clinical Evidence, Clinical Evaluation, Clinical Investigations, Post-market clinnical follow-up studies, Reportable Events during pre-market clinical investigations

Conclusion

What did we find?

- **Gap in regulations and standards**
- **Almost all member economies need Harmonized AHWP GCP Guidelines & Guidelines on Clinical Safety/Performance information and evaluation of medical devices**
- **Still some difference in technical understanding, need more information or training**

Require Training for common understanding, further decision making and establishing guidelines