Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Latest Development in GHTF IVD related documents and Progress Report of WG01a IVDD Subgroup

Jeffrey J.F. Chern

ITRI, Chinese Taipei

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Outline

- **Part I**

  Latest Development in GHTF IVD related documents

- **Part II**

  Progress Report of WG01a IVDD Subgroup

Part I: Latest Development in GHTF IVD related documents

IVD Regulatory Elements and Corresponding GHTF Guidances

Regulatory Element	Status	Posted on
Definition	SG1/N045:2008	June 23, 2008
Classification	SG1/N045:2008	June 23, 2008
Conformity Assessment	SG1/N046:2008	Aug 26, 2008
Declaration of conformity and Technical Documentation	SG1(PD)/NO63/ R2; Draft	--

Part I: Latest Development in GHTF IVD related documents

Discussion on the contents of GHTF SG1/N046R3 (IVD STED Guidance)

Comments from EU regulators	Discussion
Batch release data is required by the EU for the submission of high-risk IVD medical devices (e.g.class D IVD medical devices), while this requirement is not included in this document.	The current document does not exclude that whenever necessary, the competent authority may ask the manufacturers to submit the batch release QC data. Besides, the regulations of most GHTF member countries by far do not have such requirement.
The current document does not require low-risk IVD medical devices (Class A devices) manufacturers to submit risk analysis and control data ;	The manufacturers of low-risk IVD medical devices should still be responsible for the safety and effectiveness of the devices. Risk management system should also be integrated into the QMS of the manufacturers. Hence, related risk analysis and control data could be accessed and controlled through regulatory audit.

Part I: Latest Development in GHTF IVD related documents

Discussion on the contents of GHTF SG1/N046R3 (IVD STED Guidance)

They suggest to include ISO13485 and ISO14971 as normative standards for medical devices QMS and risk management.	Not all GHTF members adopt ISO13485 and ISO14971 as normative standards for medical devices QMS and risk management. (e.g. USA) Afterall, the use of standard is not mandatory. It is always reasonable for the manufacturers to demonstrate the conformity of the their QMS and risk management by using suitable standards.

Part I: Latest Development in GHTF IVD related documents

Status of each chapter of "GHTF SG1(PD)/N063/R1" discussed

No	Chapter	Status
1	Introduction	Finished
2	Rationale, Purpose and Scope	
3	References	
4	Definitions	
5	Preparation and Use of the STED	
6	Device Description including Variants (Configurations) and Accessories	
7	Essential Principles (EP) Checklist	
8	Risk analysis and control summary	

Part I: Latest Development in GHTF IVD related documents

Status of each chapter of "GHTF SG1(PD)/N063/R1" discussed

No	Chapter	Status
9	Design and Manufacturing Information	
10	Device Design	
11	Product Verification and Validation	In progress, will be continued in the next meeting
12	Labelling	Will be discussed in the next meeting
13	Declaration of Conformity	
14	Appendix A	

Part I: Latest Development in GHTF IVD related documents

Functions of STED

- STED is prepared from the technical documentation of the manufacturer, which is quite similar to an index of the subsystems of the QMS.
- It is a “snapshot” of the product prior to the premarket submission instead of a “live documentation”.

Part I: Latest Development in GHTF IVD related documents

Acceptance Criteria of Summary Documentation

- If a recognized standard including specific acceptance criteria is used, declaration of conformity could be accepted instead of raw data.
- If a recognized standard without specific acceptance criteria is used, justification of using that standard as well as arranged and analyzed data should be submitted.
- If a professional guideline/standard or in-house standard is used, the rationale of using the standard, method of the experiment, arranged and analyzed data as well as conclusion of the experiment should be submitted.

Part I: Latest Development in GHTF IVD related documents

Contents of Detailed Documentation

- Study design
- Methods, procedure, including acceptance criteria
- Study report including arranged and analyzed data (when appropriate, the report should include raw data/ line listing, e.g. in the case of a Class D product)
- Conclusion of the study
- All claims (e.g. intended use and performance characteristics) mentioned in the submission should be verified and validated.

Part I: Latest Development in GHTF IVD related documents

Discussion on the IVD STED Guidance

- Not to literally stress on “verification and validation” of the product, since most of the regulators do not classify the data as “verification data” or “validation data”.
- Manufacturers are asked to submit related information on performance characteristics of the device.
- Under an effective QMS, at the stage of design control, the manufacturer should have completed product verification and validation. Related documents and records could be accessed from a regulatory audit.
- Not to ask for information on the uncertainty of measurement because it is related to metrology accreditation instead of premarket submission.

Part I: Latest Development in GHTF IVD related documents

Discussion on the IVD STED Guidance

- The "Verification and Validation" chapter is into four parts, based on the performance characteristics of IVD medical devices：
  - Analytical Performance Data
  - Clinical Performance Data
  - Traceability of Calibrators and Control Materials
  - Stability
- By far, the depth and thoroughness of the documentation tends to be more detailed
- "Software Verification and Validation" is included in this chapter, in case an instrument is submitted.
- It is beyond the ability of the group to specify the requirements on product verification and validation of IVD medical devices based on different intended uses or contexts (e.g. qualitative analysis, quantitative analysis, semi-quantitative analysis, OTC, POC, ect.)
- Hence, it is a high level discussion without going into specific technical details. But, the possibility of writing related supplements on these topics is not excluded.

Part II: Progress Report of WG01a IVDD Subgroup

Action	Proposed Time	Progress
Confirming nomination and recruitment policy with TC	Last TC meeting in Chengdu	Nomination of the leaders and members of the subgroup is complete.
Building a Strong Network amongst Member Economies	3-6 months; 2007 – Q1 2008	▪ Contact person in each economy is located. ▪ GHTF's work has been updated to member economies via holding telecons and emails. ▪ The subgroup has continuously collected input from member economies and reflect them to GHTF

Part II: Progress Report of WG01a IVDD Subgroup

Action	Proposed Time	Progress
Creating a Common Basis for Discussion	3-6 months; 2007 – Q1 2008	▪ Consensus on the adoption of the GHTF definition and classification ▪ Experiences, obstacles, difficulties in each economy have been discussed in the subgroup
Safety and Performance Evaluation Methods of IVD Medical Devices Developed	6-9 months Q2 2008 – Q4 2008	▪ The subgroup has been liaising to GHTF IVD Subgroup. ▪ The subgroup has approached several experts in the IVD industry to seek for technical input.

Part II: Progress Report of WG01a IVDD Subgroup

Action	Proposed Time	Progress
Development of the Know-How in Preparing Technical Documentation	6~9 months 1st Quarter 2009~3rd Quarter 2009	▪ The subgroup has been liaising to GHTF IVD Subgroup. ▪ The subgroup has approached several experts in the IVD industry to seek for technical input.

Thank you for your attention!