Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Progress Report of WG01a IVDD Subgroup

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Members

- **Chair:** Al Gifari Abdulrahman(Saudi FDA)
- **Co-chair:** Jeffrey Chern (ITRI, Chinese Taipei)
- **Members:**
  - Shekhar Ganu (OCD, India)
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  - Viola Peters (Abbott, Malaysia)
  - Maria Cecelia Matienzo (DOH, Philippines)
  - David Harrison (Siemens, Asia Pacific, Singapore)
  - Su Hong Bo (Invitrogen, China)

Achievements in the Past

- The subgroup has built a communication network amongst member economies to frequently share experiences, hurdles and obstacles in regulating IVD medical devices
- The subgroup has consolidated the comments from member economies on GHTF proposed documents on IVD medical device regulations and reflected them to GHTF IVD Subgroup:
  - SG1/N045:2008 Principles of IVD medical devices classification
  - SG1/N046:2008 Principles of conformity assessment for IVD medical devices
- The subgroup has its representation to the GHTF IVD Subgroup meeting held in Chicago on May 6-10 to discuss:
  - SG1/N046R3 Principles of conformity assessment for IVD medical devices
  - SG1(PD)/NO63/R2 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices (STED)

Pre-Market 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	--

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.

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

Comments from EU regulators	Discussion
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.

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	
9	Design and Manufacturing Information	
10	Device Design	
11	Product Verification and Validation (in progress)	Will be discussed in the next meeting
12	Labelling	
13	Declaration of Conformity	
14	Appendix A	

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”.

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.

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.

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. The “Verification and Validation” chapter is into four parts, based on the performance characteristics of IVD medical devices:

Discussion on the IVD STED Guidance

- 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.

Future Perspective

- The subgroup will keep liaising to GHTF IVD Subgroup to finalize the IVD STED guidance.
- The subgroup will help the member economies to implement the IVD STED by:
  - Developing EP checklist for IVD medical devices based on different intended uses or contexts (e.g. qualitative analysis, quantitative analysis, semi-quantitative analysis, OTC, POC, etc)
  - Developing templates for IVD STED

Thank you for your attention!