Asian Harmonization Working Party
Technical Committee
WG01 Updates

27 Nov 2010, Riyadh, Kingdom of Saudi Arabia

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STED – CSDT Comparison

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STED – CSDT Comparison Task Force

- GHTF SG1
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- AHWP WG1
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STED - CSDT Comparison

- Documents used in discussions:
  - AHWP CSDT
  - GHTF/SG1/N011:2008, Final document, STED for MD
  - GHTF/SG1/N063 Proposed document, STED for IVDD
- Discussion template capturing comments

Comparison of STED and CSDT

Summary of Differences

Item	GHTF STED (MD & IVD)	AHWP CSDT
Purpose/Scope	• STED (MD) • STED (IVD) For pre-market (for class C and D devices) and post-market submission (if required by the Authority) to regulatory authority.	• Single CSDT document (MD & IVD) Intended for regulatory submissions for all classes of MDs, but did not specify what circumstances (pre- or post-market phase) will require the submission.
Executive summary	No	Yes This overview facilitates the review of the dossier. It also includes the regulatory status of the device in other countries and commercial marketing history.
Declaration of Conformity	Yes – Recognized CA results from NB/Self-Declaration	No – dependent on Member Economy's requirements
Arrangement of sections	Different	

Comparison of STED and CSDT

Summary of Similarities

Item	GHTF STED (MD & IVD)	AHWP CSDT
Essential Principles	Checklist, Evidence of Conformity – Editorial differences	
Device Description	Similar	
Device Labelling	Similar – AHWP to consider guidance document on Labelling, including inclusion of ‘medicinal substances’ in CSDT	
Risk Analysis	Similar	
Verification and Validation	Similar	
Clinical Evidence	Similar – AHWP to consider referencing WG5 Clinical Evidence Requirements	

Comparison of STED and CSDT

STED status in five founding members:

Members	Status	Applicable Medical Device
USA	STED Pilot Program (prior notification and discussion with FDA reviewing division	PMAs (FDA Class III, => GHTF Class D 510(k) (FDA Class II, => GHTF Class B or C)
Canada	Notice published to implement STED for MD by July 1, 2011. Once GHTF STED for IVD is published, same procedure will apply.	For MD and IVD.
EU	So far, STED has no regulatory status in the EU. The use of STED based on GHTF guidance may be considered in the forthcoming revision.	For MD
Japan	Since 2005, by the partial revision of PAL, STED format application is required	For MD: • Class 1 – STED Not Required • MD with certification standard - data subset is not required)
Australia	TGA is recommending the draft GHTF STED to industry as the preferred means of demonstrating conformity to the EP. Non Mandatory	For MD and IVD

Comparison of STED and CSDT

CSDT status in ACCSQ members:

Members	Status	Applicable Medical Device
Singapore	Mandatory format of submission from May 2010	For MD and IVD
Others ACCSQ	CSDT finalised and adopted, detailed implementation TBD.	

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WG01's Proposal for Member Economies

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Proposal 1:
Consider STED and other GHTF SG1 guidance document together

- STED is supported by other GHTF guidance document: roles of standards, EP, Conformity assessment…
- STED is part of the GHTF global regulatory model and part of quality system document
- STED and the other guidance document are reviewed every three years to keep updated.

Proposal 2:
Consider CSDT and refer to AHWP CSDT-STED Mapping Document

For submission to AHWP member economies that have adopted CSDT:

- The AHWP WG01 Mapping document lists the differences of CSDT from STED.
- With this mapping guidance, industry can easily re-arrange their STED dossier to CSDT.

CSDT-STED Mapping Document

	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
3.0	**Executive Summary** • commercial marketing history; • intended uses and indications in labelling • list of regulatory approval or marketing clearance obtained; • status of any pending request for market clearance; and • important safety/performance related information.		- - - - - -		- - - - - -
4.0	**Elements of the Common Submission Dossier Template**	PART 2 Page 9	CONTENTS OF THE STED	PART 2 Page 11	CONTENTS OF THE STED
4.1 4.1.1	**Relevant Essential Principles and Method Used to Demonstrate Conformity** **Essential Principles and Evidence of Conformity** .	9.0	**Essential Principles (EP) Checklist**	7.0	**Essential Principles (EP) Checklist**
4.2	**Device Description (According to GHTF Classification)** **Description A B C D**	6.0	**Device Description and Product Specification, Including Variants and Accessories**	6.0	**Device Description including Variants (Configurations) and Accessories**
4.2.1	**Device description & features**	**6.1**	**Device Description**	**6.1**	**Device Description**
4.2.2	**Intended use**	6.1a)	A general description including its intended use/purpose	6.1a)	The intended use.
4.2.3	**Indications**	6.1b)	…the intended patient population and medical condition to be diagnosed and/or treated and other consideration such as patient selection criteria	6.1d)	…the intended user (lay person or professional)

	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
4.2.4	Instructions of use	7.0	**Labelling** • instructions for use	11.0	**Labelling** • instructions for use
4.2.5	Contraindications		-		-
4.2.6	Warnings		-		-
4.2.7	Precautions		-		-
4.2.8	Potential adverse effects		-		-
4.2.9	Alternative therapy		-		-
4.2.10	Materials	6.1 i)	a description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporial circulation of body fluids.		
4.2.11	Other Relevant Specifications	11.3	**Medicinal Substance**		
4.2.12	Other Descriptive Information		-		-

	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
4.3	Summary of Design Verification and Validation Documents	11.0 11.1 11.2 11.3 11.4 11.5 11.6	Product Verification and Validation General Biocompatibility Medicinal Substances Biological Safety Sterilisation Software Verification and Validation	10.0	Product Verification and Validation
	-		-	10.1 10.1.1 10 .1.2 10.1.2.1 10.1.2.1.1 10.1.2.1.2 10.1.2.1.2.1 10.1.2.1.2.2 10.1.2..2 10.1.2.4 10.1.2.5 10.1.2.6 10.2 10.2.1 10.2.2 10.2.3	Analytical Studies **Specimen type** Analytical Performance Characteristics Accuracy of measurement Trueness of measurement Precision of measurement Repeatability Reproducibility Analytical sensitivity Metrological traceability of calibrator and control material values Measuring range of the assay Definition of Assay Cut-off Stability (excluding specimen stability) Claimed Shelf life In use stability Shipping stability
4.3.1	Pre-clinical Studies	11.7	Animal Studies		-
4.3.1.1	Software Validation Studies (if applicable) .	11.6	Software Verification and Validation	10.3	Software Verification and Validation
4.3.1.2	Devices Containing Biological Material	11.4	Biological Safety		
4.3.2	Clinical Evidence	11.8	Clinical Evidence	10.4	Clinical Evidence
4.3.2.1	Use of Existing Bibliography	11.8	Clinical Evidence … to address the elements contained in the clinical Evaluation Report described in guidance GHTF/SG5/N2	10.4	Clinical Evidence

	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
4.4	Device Labelling	7.0	Labelling	11.0	Labelling
4.4.1	Samples of Labels on the Device and its Packaging .	7.0	Labelling - labels on the device and its packaging	11.0	Labelling - labels on the device and its packaging
4.4.2	Instructions for Use, Training Materials & Instructions for Installation and Maintenance	7.0	Labelling . instructions for use; and • promotional material	11.0	Labelling instructions for use; and • promotional material
4.5	Risk Analysis	10.0	Risk Analysis and Control Summary	8.0	Risk Analysis and Control Summary
4.5.1	Results of Risk Analysis .	10.0	Risk Analysis and Control Summary	8.0	Risk Analysis and Control Summary
4.6	Manufacturer Information	8.0	Design and Manufacturing Information	9.0	Design and Manufacturing Information
4.6.1	Manufacturing Process .	8.2	Manufacturing Processes	9.2	Manufacturing Processes

STED PARTS NOT INCLUDED IN CSDT					
	- .	6.2	**Product Specification** The STED should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories (if such are within the scope of the STED), **that would typically appear in the product specification** made available to the end user, e.g. in brochures, catalogues and the like.		
		6.3	**Reference to similar and previous generations of the device**	**6.2**	**Reference to Previous Device Generation(s) and/or Similar Devices or Device History**
	-	**8.1**	**Device Design**	**9.1**	**Device Design**
	-	**12.0**	**Format of the STED**	**12.0**	**Format of the STED**
	-	**13.0**	**Declaration of Conformity**	**13.0**	**Declaration of Conformity**

Proposal 3:
Develop Pre-market Requirements Step by Step

- SG1 developed various document to support the set up of regulatory frame work:

- Registration of manufacturers and listing of medical device
- Definition of MD
- Classification of MD
- Definition of manufacturers, authorized representatives …

If the above mentioned SG1 documents is not sufficient, AHWP WG01 can recommend to SG1

Thank you for your attention.