Adoption of the Summary TEchnical Documentation (STED)

-

An efficient approach

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From the AWHP website:

… there are challenges ahead. We are the most diverse region; we are diverse politically, economically and socially. We lack resources, funds, infrastructure and expertise. But, these shortcomings should not hinder us from working towards achieving our set goals …

Introduction

there's a clear line between industry efforts and Global Harmonisation …

We will discuss:

- STED – document & brief history
- Successes of STED
- Challenges for STED
- Links to international standards
- Opinions of authorities
- Where to go ?

STED – document & brief history

First question – what is STED?

Summary (of) Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices ***SG1/N011***

STED – document & brief history - 2

Second question – who wants STED?

Everyone (in principle)

- authorities & CAB's
- industry
- users / patients

STED – document & brief history - 3

Third question – what are we waiting for?

Good consensus

- and trust
- and experience
- and … it is getting there !!

STED – document & brief history - 4

GHTF SG1 Document STED (*SG1N011*) …

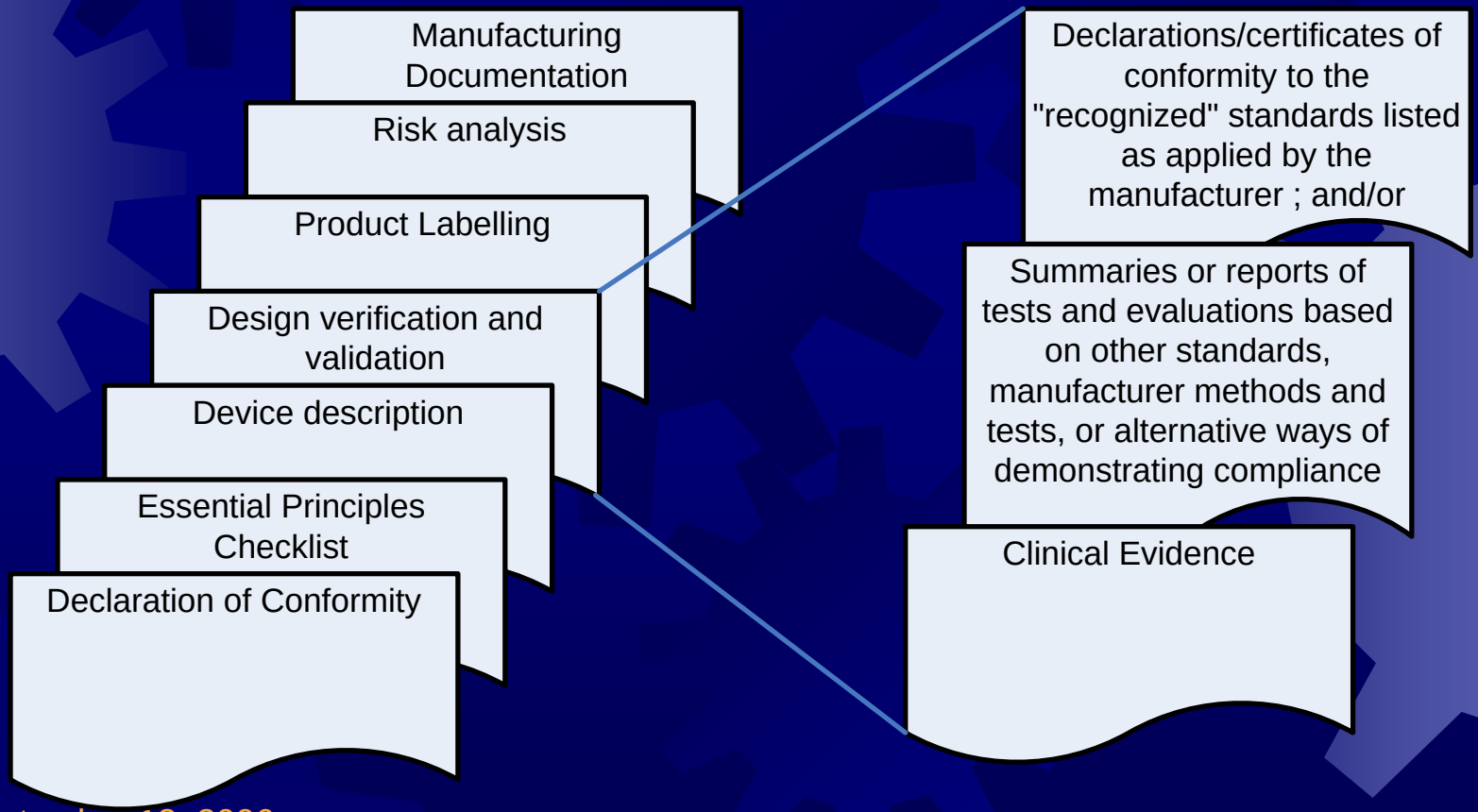
… describes content and format of subset of technical documentation to be held or submitted for conformity assessment procedures …

“Proposed document” since 16 Dec. 2003

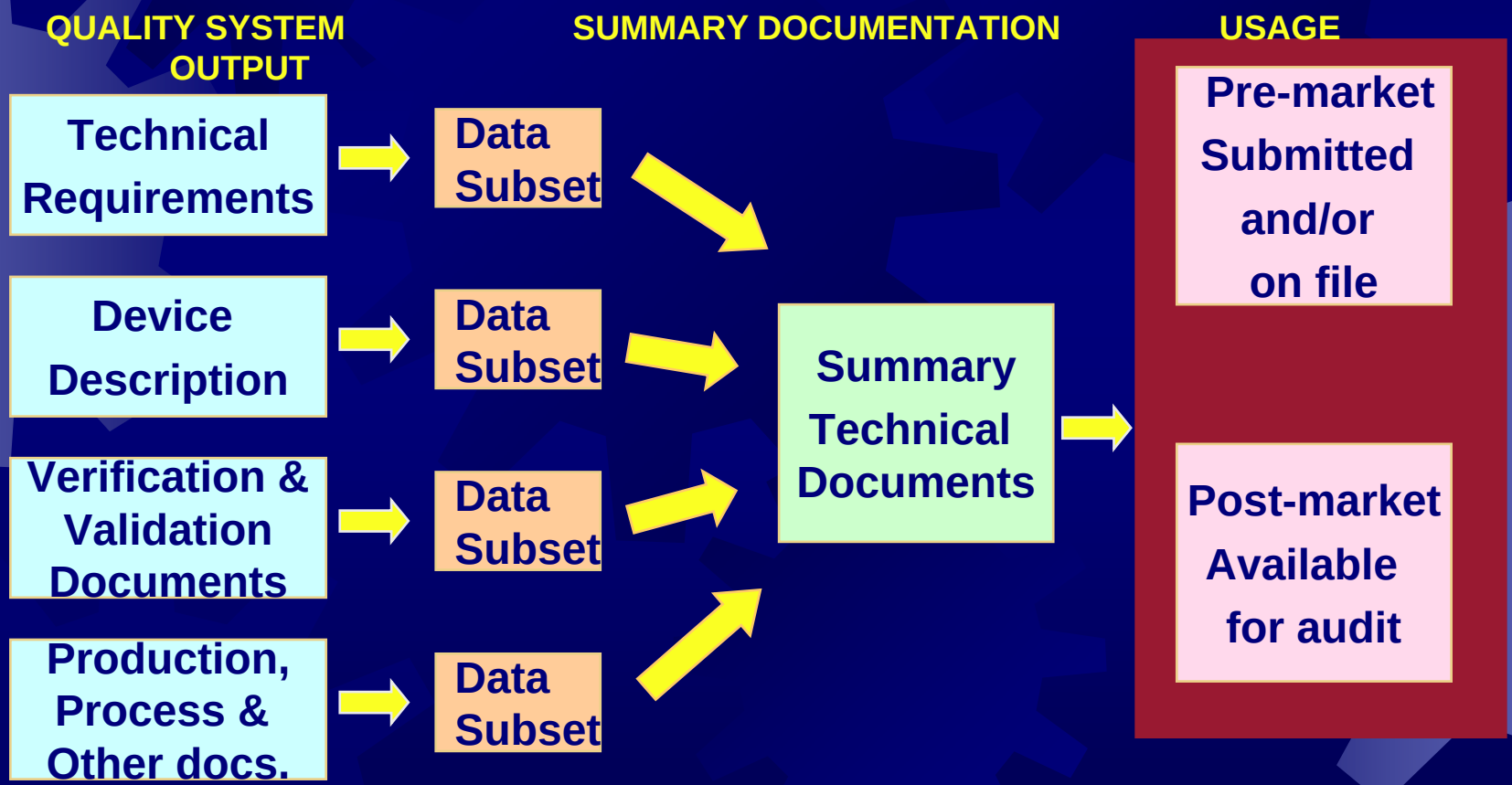
STED – document & brief history - 5

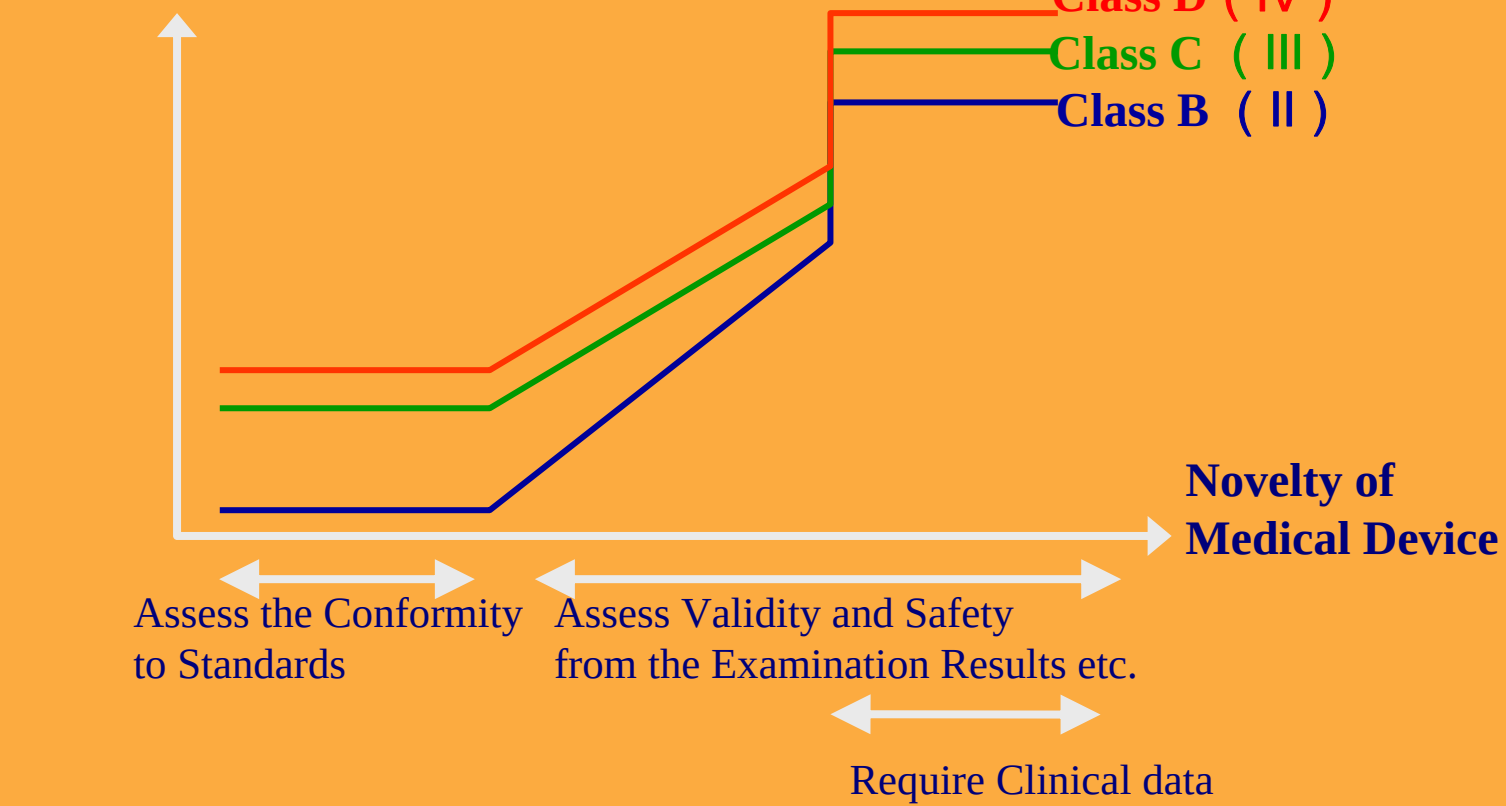
- GHTF SG1 Document STED (*SG1N011*) …
- First pilot phase in 2001
- Since 2003, several pilots held aiming for “solid practical experience”
- Number of reviewed dossiers not very big …

STED – document & brief history - 6



Source and Application




Detail of
the Contents of Data
Class D (Ⅳ)
Class C (Ⅲ)
Class B (Ⅱ)
Novelty of
Medical Device
Assess the Conformity
to Standards
Assess Validity and Safety
from the Examination Results etc.
Require Clinical data

STED – document & brief history - 9

Remember, STED is a

summary

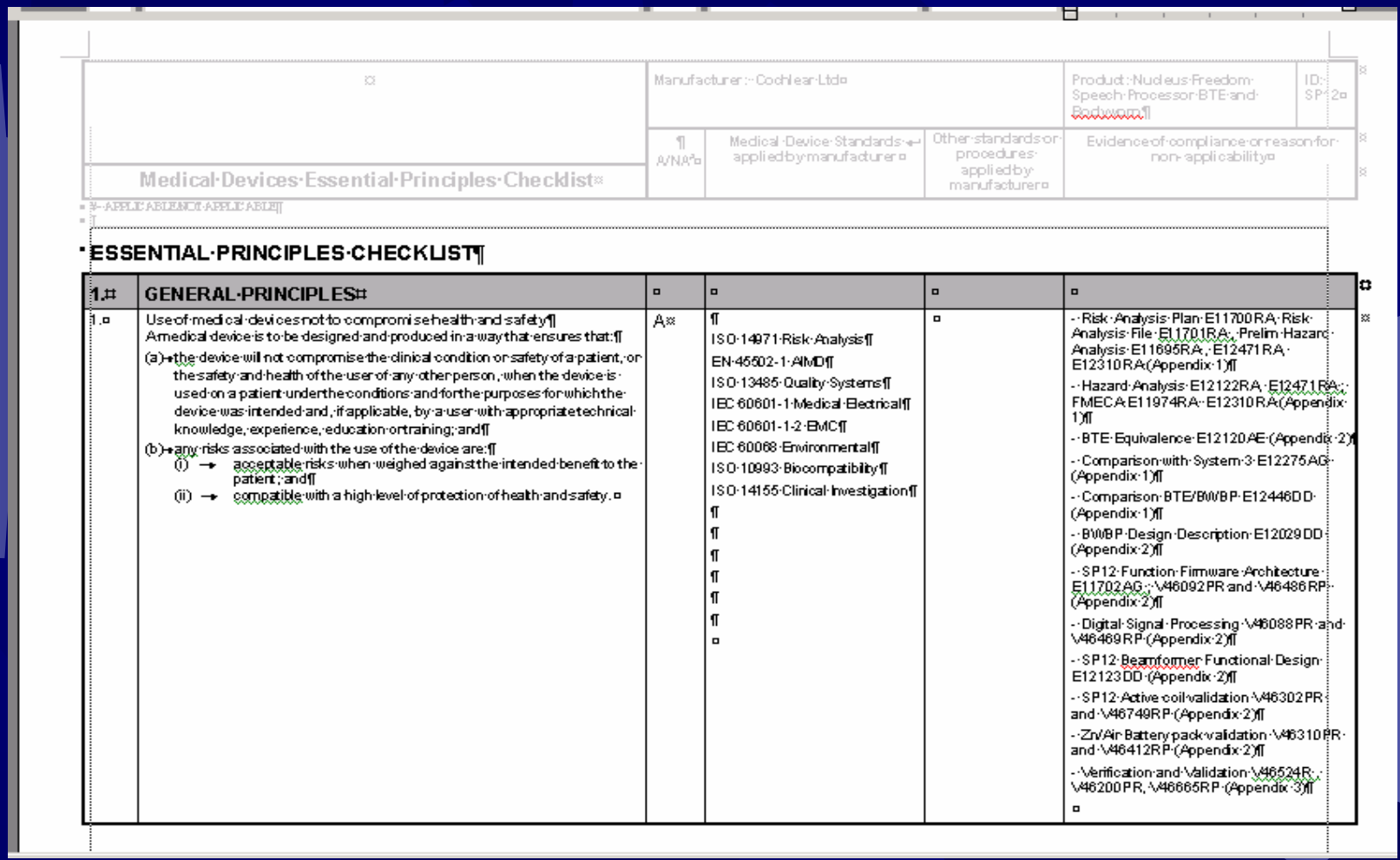
and not …

STED – document & brief history - 10

7.1 Essential Principles checklist

For ease of use in a global situation, it is recommended that the evidence of conformity (*with the Essential Principles*) be provided in tabular form with supporting documentation available for review as required

STED for AHWP meeting



	Manufacturer:-Cochlear-Ltd¤		Product:-Nucleus-Freedom-Speech-Processor-BTE-and-Accessories¶	ID:-SP-12¤
Medical-Devices-Essential-Principles-Checklist¤	¶ A/NA?¤	Medical-Device-Standards-applied-by-manufacturer¤	Other-standards-or-procedures-applied-by-manufacturer¤	Evidence-of-compliance-or-reason-for-non-applicability¤

¤-APPLICABLE/NOT-APPLICABLE¶

ESSENTIAL-PRINCIPLES-CHECKLIST¶

1.¤	GENERAL-PRINCIPLES¤	¤	¤	¤	¤
1.¤	Use-of-medical-devices-not-to-compromise-health-and-safety¶ A-medical-device-is-to-be-designed-and-produced-in-a-way-that-ensures-that:¶ (a)-the-device-will-not-compromise-the-clinical-condition-or-safety-of-a-patient,-or-the-safety-and-health-of-the-user-of-any-other-person,-when-the-device-is-used-on-a-patient-under-the-conditions-and-for-the-purposes-for-which-the-device-was-intended-and,-if-applicable,-by-a-user-with-appropriate-technical-knowledge,-experience,-education-or-training;-and¶ (b)-any-risks-associated-with-the-use-of-the-device-are:¶ (i) → acceptable-risks-when-weighed-against-the-intended-benefit-to-the-patient;-and¶ (ii) → compatible-with-a-high-level-of-protection-of-health-and-safety.¤	A¤	¶ ISO-14971-Risk-Analysis¶ EN-45502-1-AIMD¶ ISO-13485-Quality-Systems¶ IEC-60601-1-Medical-Electrical¶ IEC-60601-1-2-EMC¶ IEC-60068-Environmental¶ ISO-10993-Biocompatibility¶ ISO-14155-Clinical-Investigation¶ ¶ ¶ ¶ ¶ ¶ ¶ ¤	¤	-·Risk-Analysis-Plan-E11700RA-Risk-Analysis-File-E11701RA;-Prelim-Hazard-Analysis-E11695RA;-E12471RA-E12310RA(Appendix-1)¶ -·Hazard-Analysis-E12122RA-E12471RA;-FMECA-E11974RA-E12310RA(Appendix-1)¶ -·BTE-Equivalence-E12120AE-(Appendix-2)¶ -·Comparison-with-System-3-E12275AG-(Appendix-1)¶ -·Comparison-BTE/BWBP-E12446DD-(Appendix-1)¶ -·BWBP-Design-Description-E12029DD-(Appendix-2)¶ -·SP12-Function-Firmware-Architecture-E11702AG;-\46092PR-and-\46486RP-(Appendix-2)¶ -·Digital-Signal-Processing-\46088PR-and-\46469RP-(Appendix-2)¶ -·SP12-Beamformer-Functional-Design-E12123DD-(Appendix-2)¶ -·SP12-Active-coil-validation-\46302PR-and-\46749RP-(Appendix-2)¶ -·Zn/Air-Battery-pack-validation-\46310PR-and-\46412RP-(Appendix-2)¶ -·Verification-and-Validation-\46524R;-\46200PR,-\46665RP-(Appendix-3)¶ ¤

STED – document & brief history - 12

7.2 Device description

- functional purpose
- general description of the device
- the intended patient population(s)
- contraindications
- an explanation of any novel features
- the accessories
- ….

STED – document & brief history - 13

7.3 Verification & validation

STED should summarize or reference or contain (…) design verification and design validation data to the extent appropriate to the complexity and risk class of the device, and ***typically includes***:

- declarations/certificates of conformity to the "recognized" standards, *and/or*
- summaries or reports of tests and evaluations
- clinical data, where that is applicable

STED – document & brief history - 14

7.4 Labelling

- Labels on the device and its packaging
- Instructions for use
- Other literature or training materials
- Instructions for installation and maintenance
- Any information and instructions given to the patient, incl. instructions for any procedure the patient is expected to perform

STED – document & brief history - 15

7.5 Risk analysis

The STED should summarize or reference or contain (…) the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

STED – document & brief history - 16

7.5 Risk analysis – ctd.

- Risk analysis/mgt dossier is BIG
- No prescribed format
- Links to many other documents
- Decisions made by manufacturer
- (How to) interpret all information?

STED – document & brief history - 17

7.5 Risk analysis – ctd.

For the manufacturer

- Include process description in STED
- Give actual device RM process data

For the regulator

- Verify that RM process **IS** in place

Successes of STED

In October 2004, **Australia** included STED in its medical device regulation

In April 2005, **Japan** launched new PAL that accepts STED for certain risk classes

In **USA**, STED pilot program -as parallel route- now “indefinite”

Great news !

Successes of STED - 2

In **Canada**, STED is accepted also as part of ongoing pilot program

In **EU**, STED is acceptable as one way of providing compliance information

STED is accepted in many other countries

Challenges for STED

- STED is a concept, not yet a proven recipe
- Number of reviewed dossiers not very big
- Transition time issues (training, etc.)
- Local STED “dialects”
- Conflicting interests
- “One size fits all” ?

Challenges for STED - 2

Local STED “dialects” have developed

- national guidance
- references to national standards
- additional requirements
- full & detailed test reports needed

Challenges for STED - 3

Additional requirements – examples

- declarations of mental health
- detailed floor plans of factories
- photographs of PCB-layout
- market statistics from other countries
- 510(k) approval letter
- test data for all possible configurations
- requirement for local re-testing

Challenges for STED - 4

"One size fits all?"

- STED developed by GHTF members
- intended to "replace" their existing regulatory schemes
- may not suit "developing" reg. schemes
- parallel routes may be an option then
- and ... joint review of the STED document

Links to international standards

International Standards are a major efficiency option for STED

- Truly international standards
- No unnecessary national deviations
- International recognition of CAB's
- International accreditation body needed ?

Links to international standards

Note from WTO desk

From draft ISO/IEC guide XX:200x on the use of standards for regulatory purposes, on WTO matters:

... the TBT Agreement is articulated in two requirements:

- Members must participate in international standardizing bodies; and
- Members must use international standards, guidelines and recommendations as a basis for their national technical regulations, except when such international standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued.

Opinions of authorities

- Industry does not really want STED
- We need specific info for our country
- STED approach gives better consistency
- Data exchange will become much easier
- Industry may cut corners
- International standards are not good
- Review fees are needed ...
- ... to maintain competence

Where to go ? (from AHWP minutes)

Priorities in AHWP

- Formalization of a post marketing alert system
- Capability building through training
- Work on common denominator for definition of Medical Device & classification; GMDN
- Comparative study on existing medical device regulations in AHWP Member Countries

Where to go ? (from AHWP minutes) - 2

Priorities in AHWP

- Work towards a common submission dossier in alignment with ASEAN project
- Adopting a quality system standard based on internationally recognized and accepted quality system standard for medical devices

Where to go ? (from AHWP minutes) - 3

Priorities in AHWP

- AHWP and SG1: combine approaches
- Internationalisation of standards & accreditation
- Give input to SG1 that will develop STED
- Open exchange with parties: how & what must be in STED

Future outlook