ASIAN HARMONIZATION WORKING PARTY

AHWP

Working Towards Harmonization in Medical Device Regulation

Global Regulatory Model

GHTF Summary Technical Documentation (STED)

Asia Harmonization Working Party Technical Committee

Bangkok; 12-13 December 2002

M. B. Gropp; Guidant Corporation

GHTF

Presentation overview

- **Introduction**
- **STED guidance overview**
- **STED Pilot study**

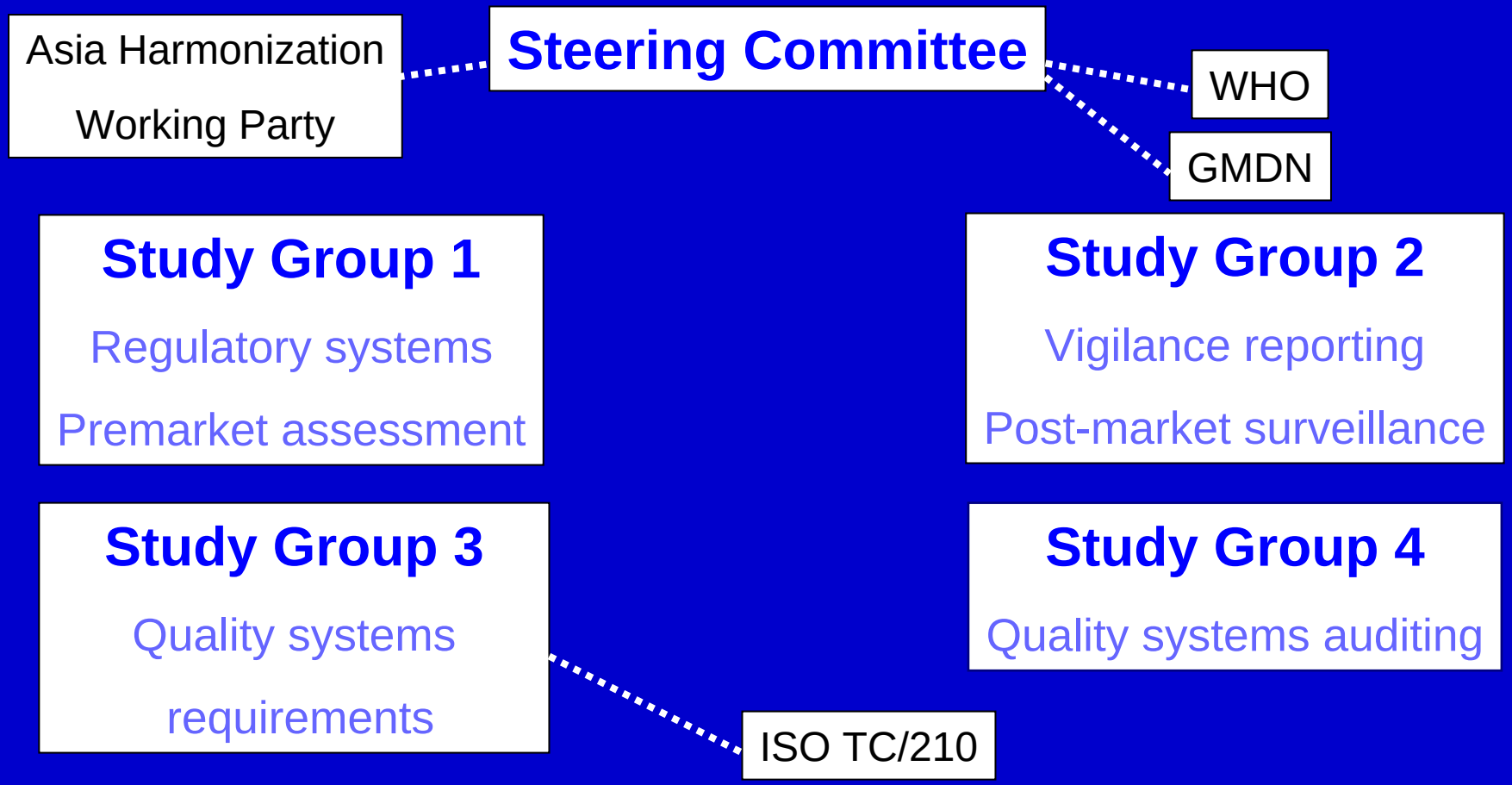
Presentation overview

- **Introduction**

Caveats

- GHTF STED document is still a Study Group 1 “working draft”
- Presentation does not include text from all of document
- Presentation paraphrases document
- “Patient” includes device users
- A companion document on the conformity assessment process is currently at “working draft” stage in Study Group 1

GHTF organizational structure



GHTF regulatory model - STED

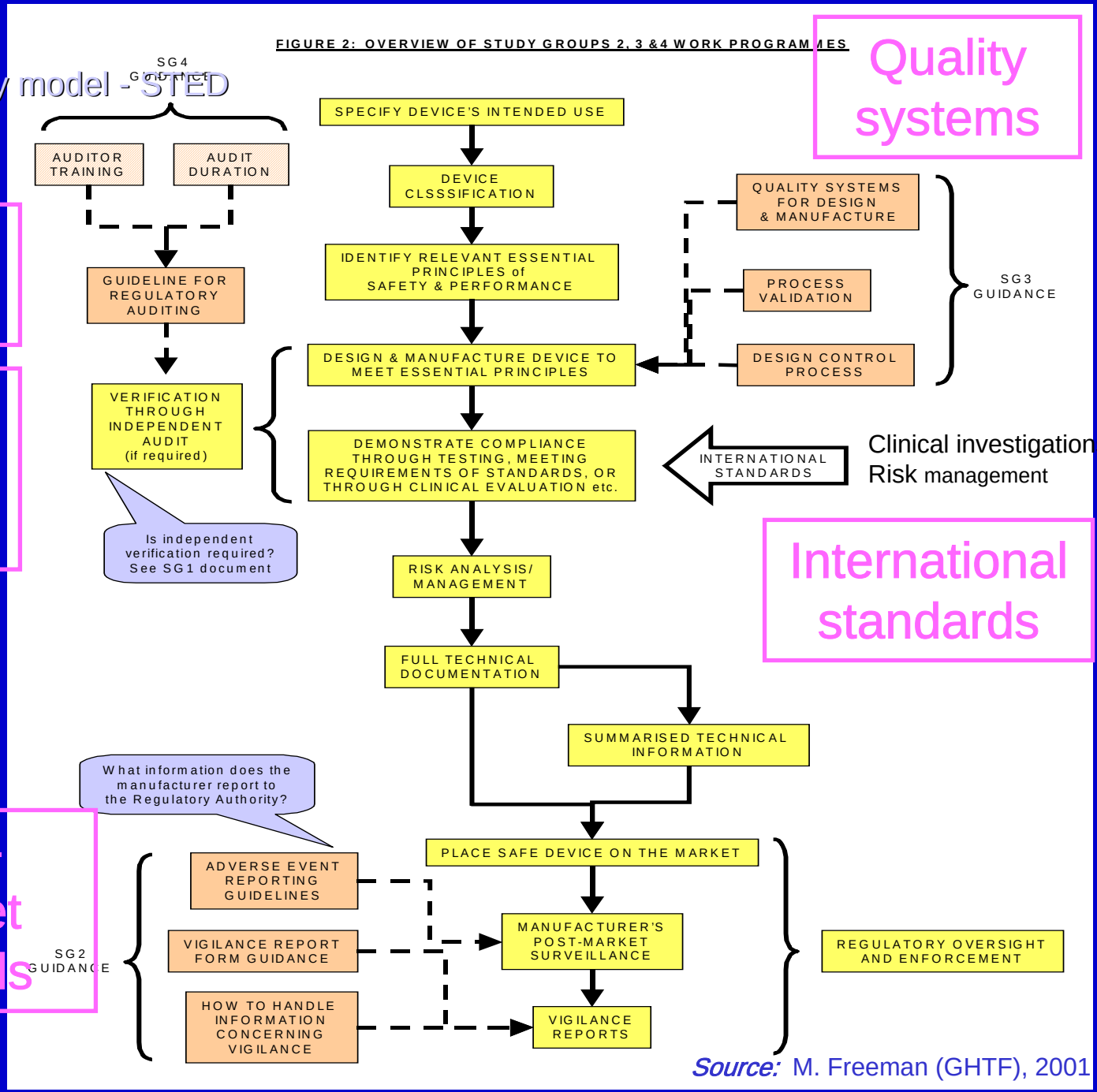
Premarket controls

Quality system auditing

Post-market controls

Quality systems

International standards



Source: M. Freeman (GHTF), 2001

GHTF regulatory model - STED

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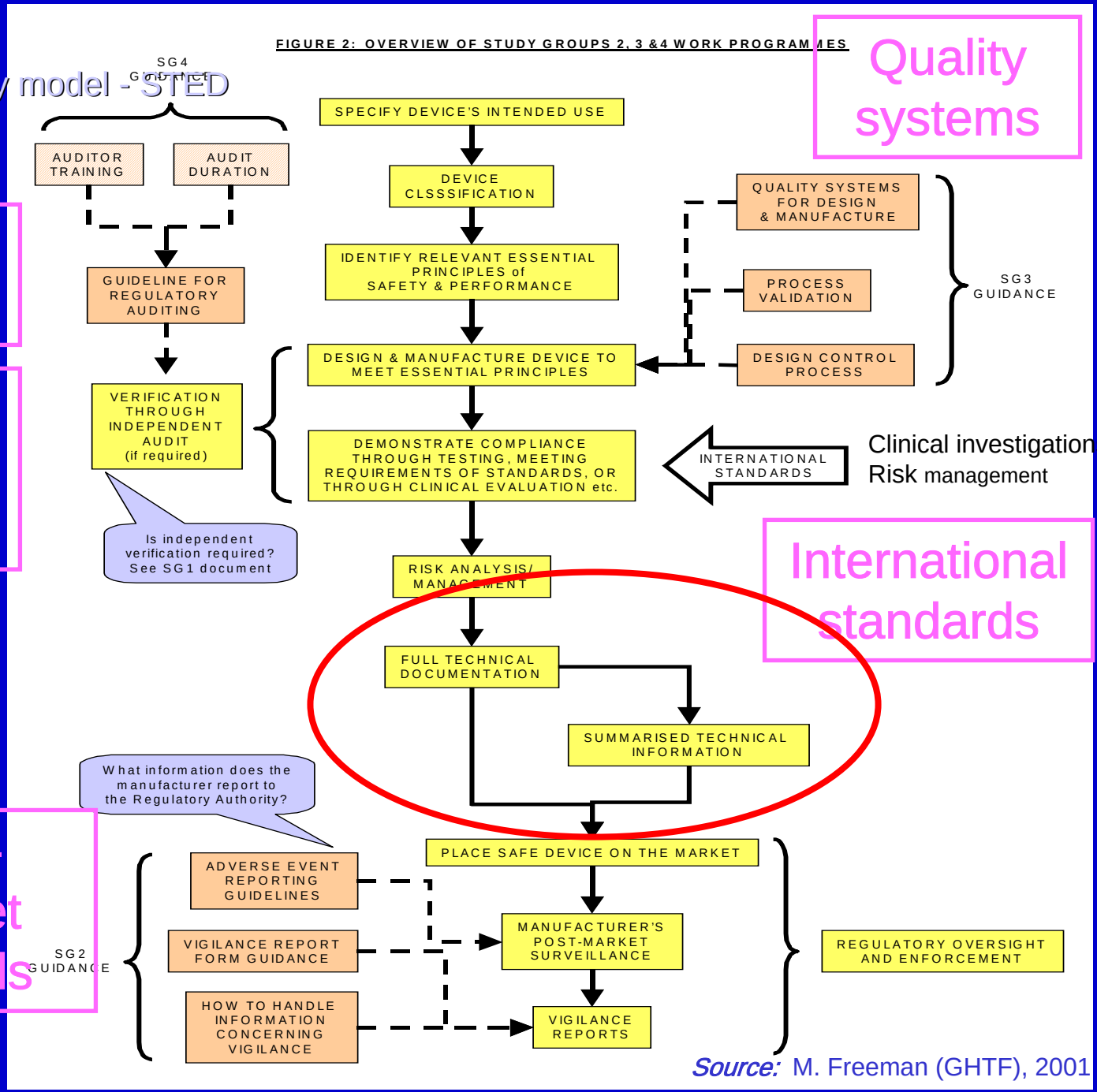
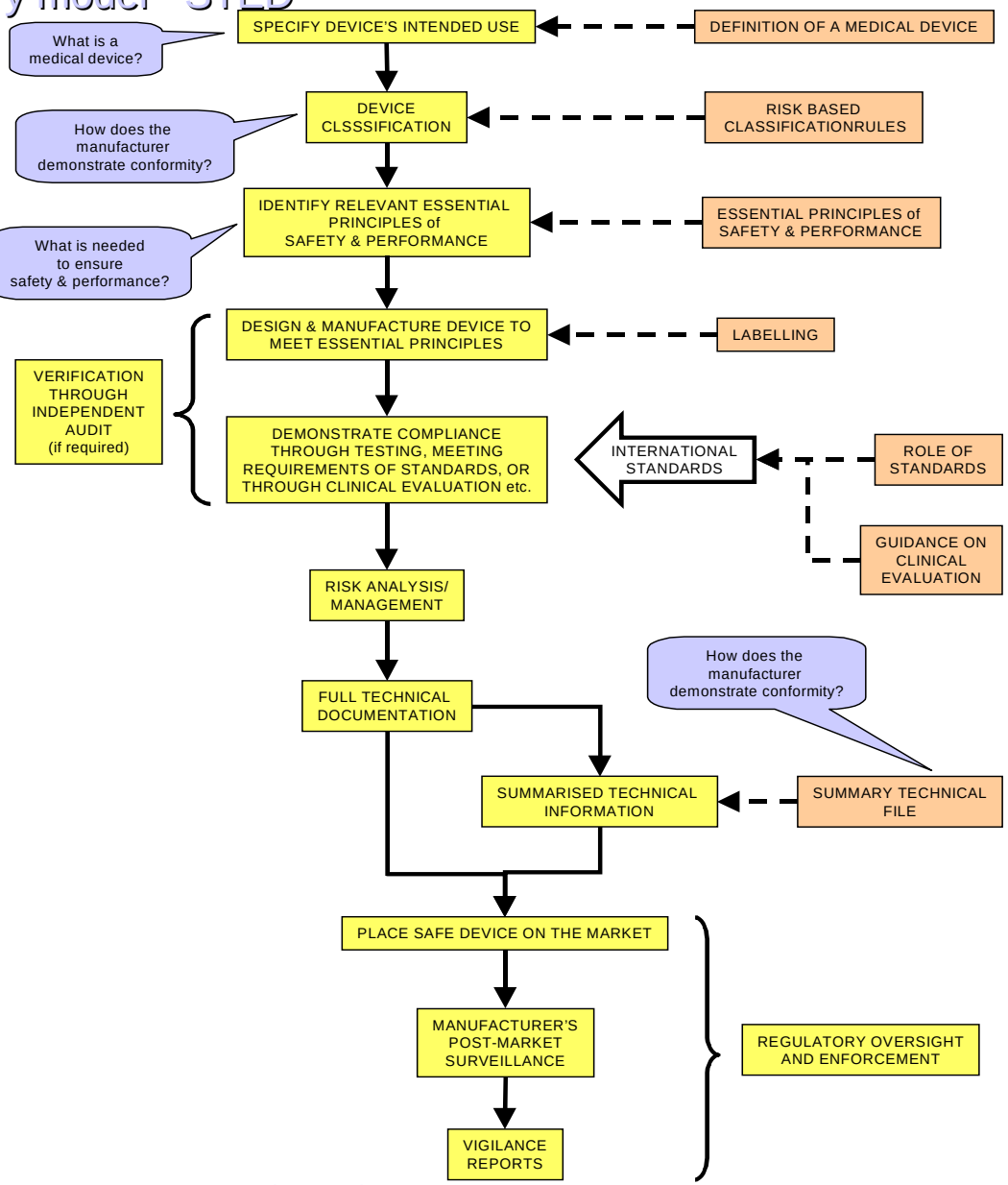


Source: M. Freeman (GHTF), 2001

GHTF regulatory model - STED

Premarket controls

FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME



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GHTF regulatory model - STED

Premarket controls

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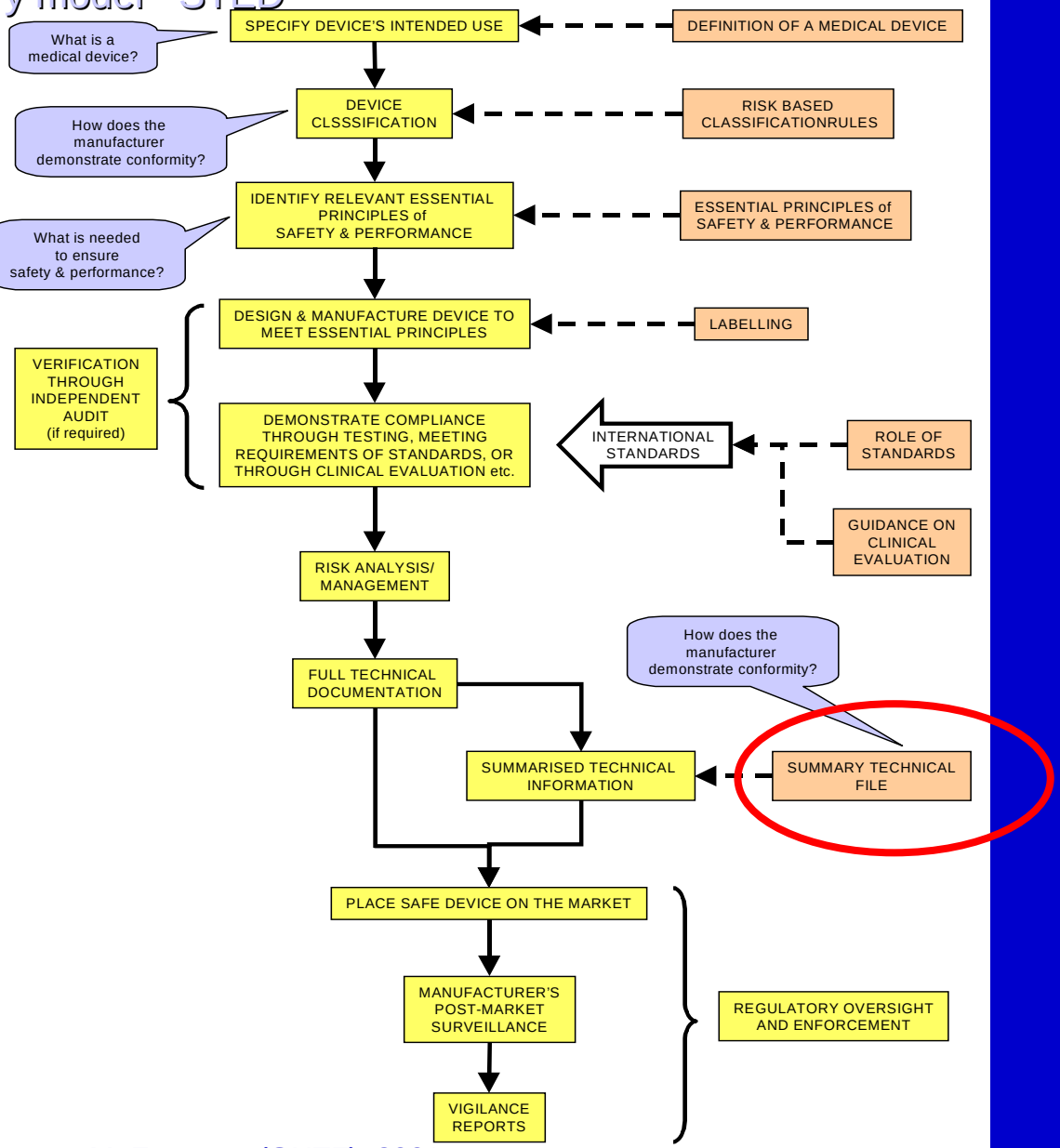

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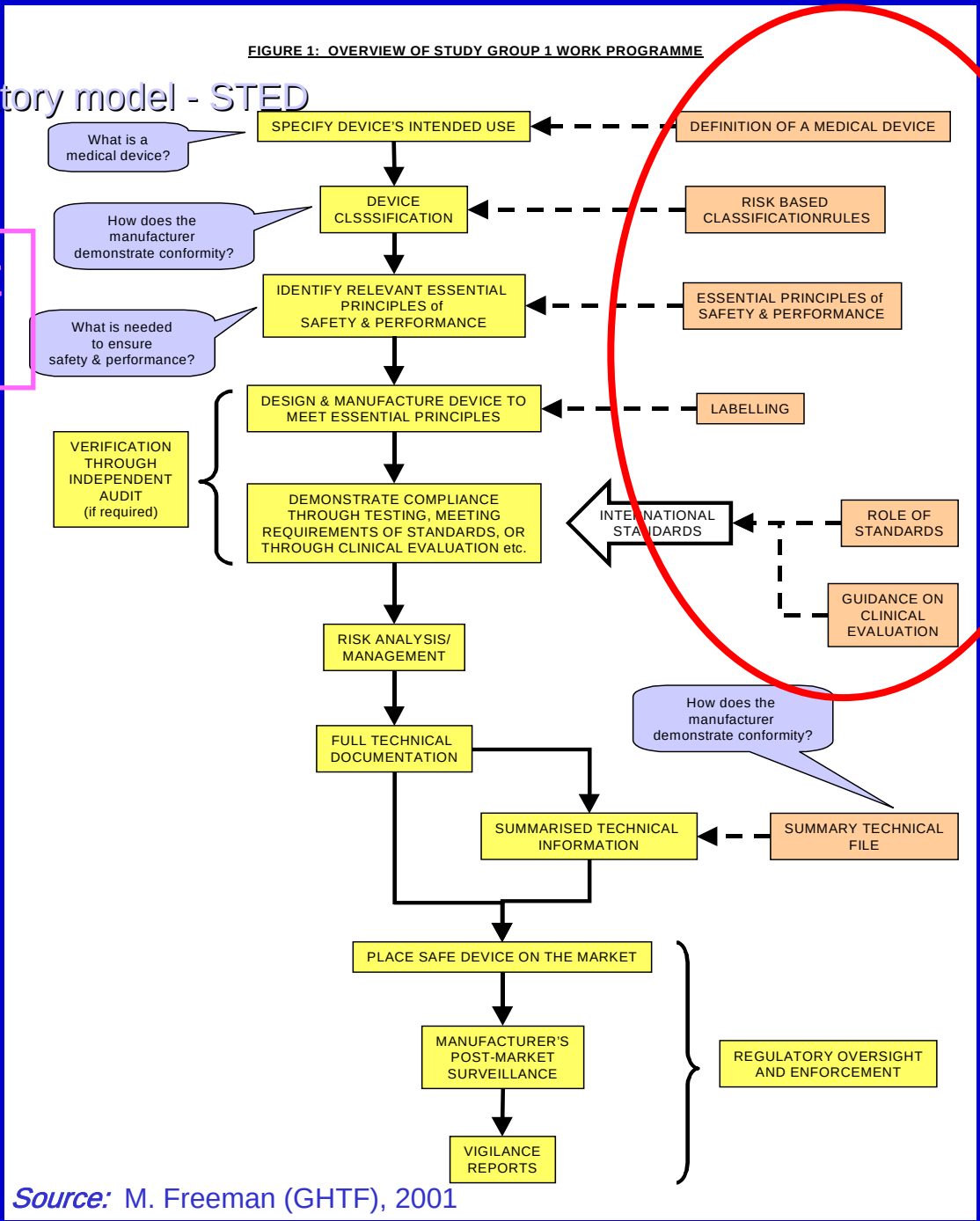
GHTF regulatory model - STED

Premarket controls



Source: M. Freeman (GHTF), 2001

To find GHTF documents

- General:

http://www.ghtf.org/

- STED: http://www.ghtf.org/ > Study Group 1 > Documents > Working Drafts > SG1NO11

SG1 - Working Drafts

Title	*Description*	*Posted Date*	*Size*	*Comments To*
SG1-N044R3 PDF Word	Role of Standards in the Assessment of Medical Devices (including *In Vitro* Diagnostic Devices)	5 August 2002	12 pages, 82Kb-PDF 62Kb-Word	Maurice Freeman by 20 September 2002
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Presentation overview

- Introduction
- **STED guidance overview**

GHTF regulatory model - STED

SG1/N011R16

GHTF

WORKING DRAFT DOCUMENT

Global Harmonization Task Force

Title: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: December 18, 2000

STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- 4.0 Definitions
- 5.0 Intended use of STED and its preparation
- 6.0 Format for STED
- 7.0 Guidance on the elements of STED
- Appendices


SG1/N01R16

GHTF

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Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: December 18, 2000

STED guidance overview

- **1.0 Introduction**

Preface

"This document was produced by the Global Harmonization Task Force, a voluntary consortium of representatives from medical device Regulatory Authorities and Trade Associations from around the world. The document is intended to provide non-binding guidance to Regulatory Authorities for use in the regulation of medical devices and has been subject to consultation throughout its development and endorsement by the current Chair. …."

Preface

"…. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF."

Introduction

"The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable."

Introduction

"The GHTF has identified as a priority the need to harmonize the documentation of evidence of conformity to regulatory requirements. Differences in documentation requirements necessitate additional work for the same device in different jurisdictions, increase costs and between countries pose barriers to the timely international access to medical devices. The barriers also have economic impact."

STED guidance overview

- 1.0 Introduction
- **2.0 Scope**

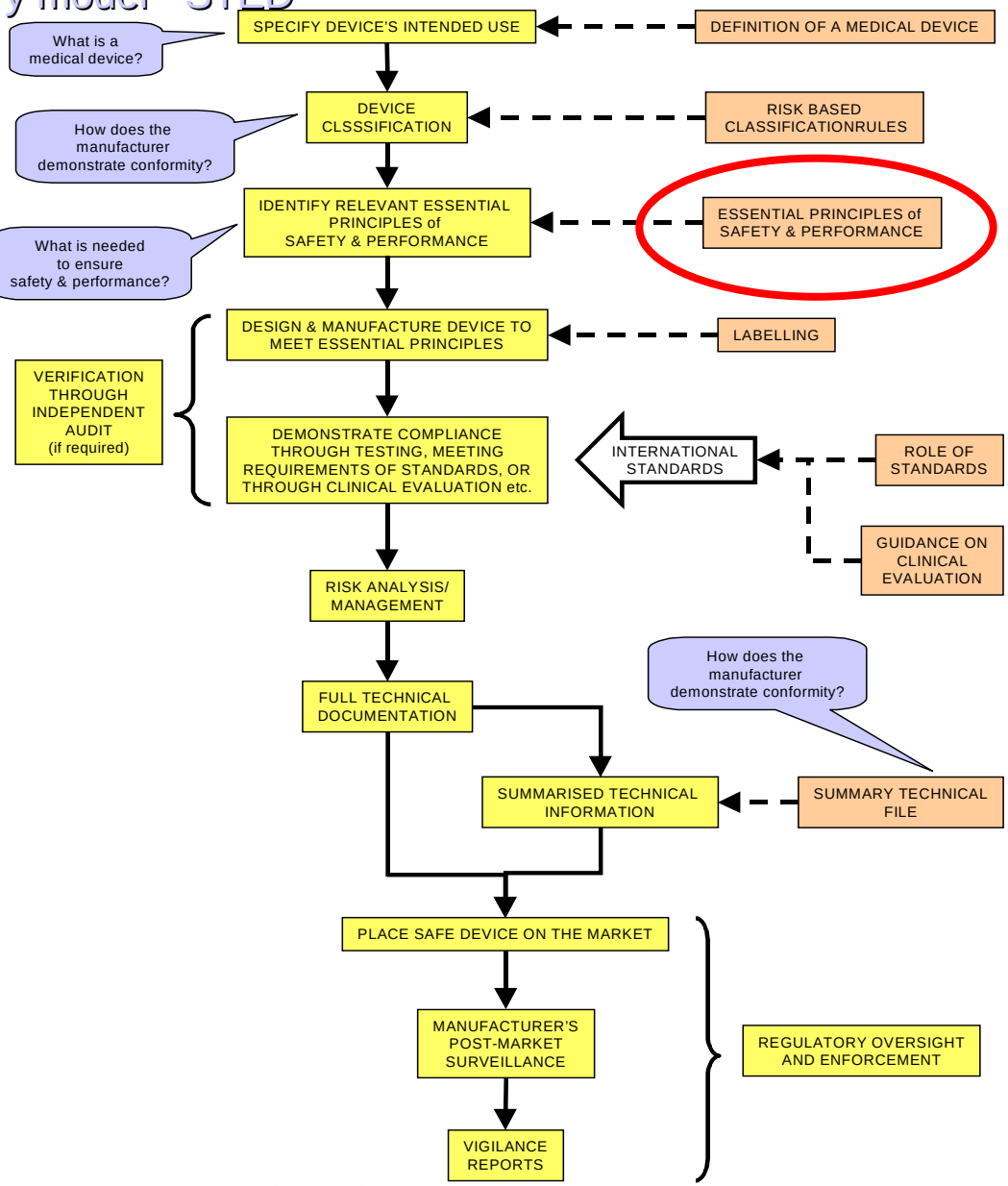
Scope

- Guidance on use of STED to demonstrate conformity with the GHTF *Essential Principles of Safety and Performance of Medical Devices*

GHTF regulatory model - STED

Premarket controls

FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME



Source: M. Freeman (GHTF), 2001

SG1 – Final Documents

Title	*Description*	*Posted Date*	*Size*	*Comments To*
SG1-N020R5 PDF Word	Essential Principles of Safety & Performance of Medical Devices	28 December, 1999 *Re-posted: 23 October 2000	12 pages, 56Kb-PDF 95Kb-Word	
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Essential Requirements

- "…. to further the processes of global harmonization of regulatory requirements, it is necessary to have common guidelines to indicate the Essential Principles of safety and performance of medical devices in the interests of public health

Essential Requirements

- "…. There may be further safety and performance principles for devices incorporating substances derived from tissues of human or animal origin and *in vitro* diagnostic devices.

  This may suggest the need for additional review of this Essential Principles document in the future"

Essential Requirements - General

- “1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. ….”

Essential Requirements - General

- “2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: ….

Essential Requirements - General

- "…. Identify hazards and the associated risks arising from the intended use and foreseeable misuse,
- Eliminate or reduce risks as far as possible (inherently safe design and construction),
- Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- Inform users of the residual risks due to any shortcomings of the protection measures adopted"

Essential Requirements - General

- “3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.”

Essential Requirements - General

- “4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer’s instructions.”

Essential Requirements - General

- “5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.”

Essential Requirements - General

- “6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.”

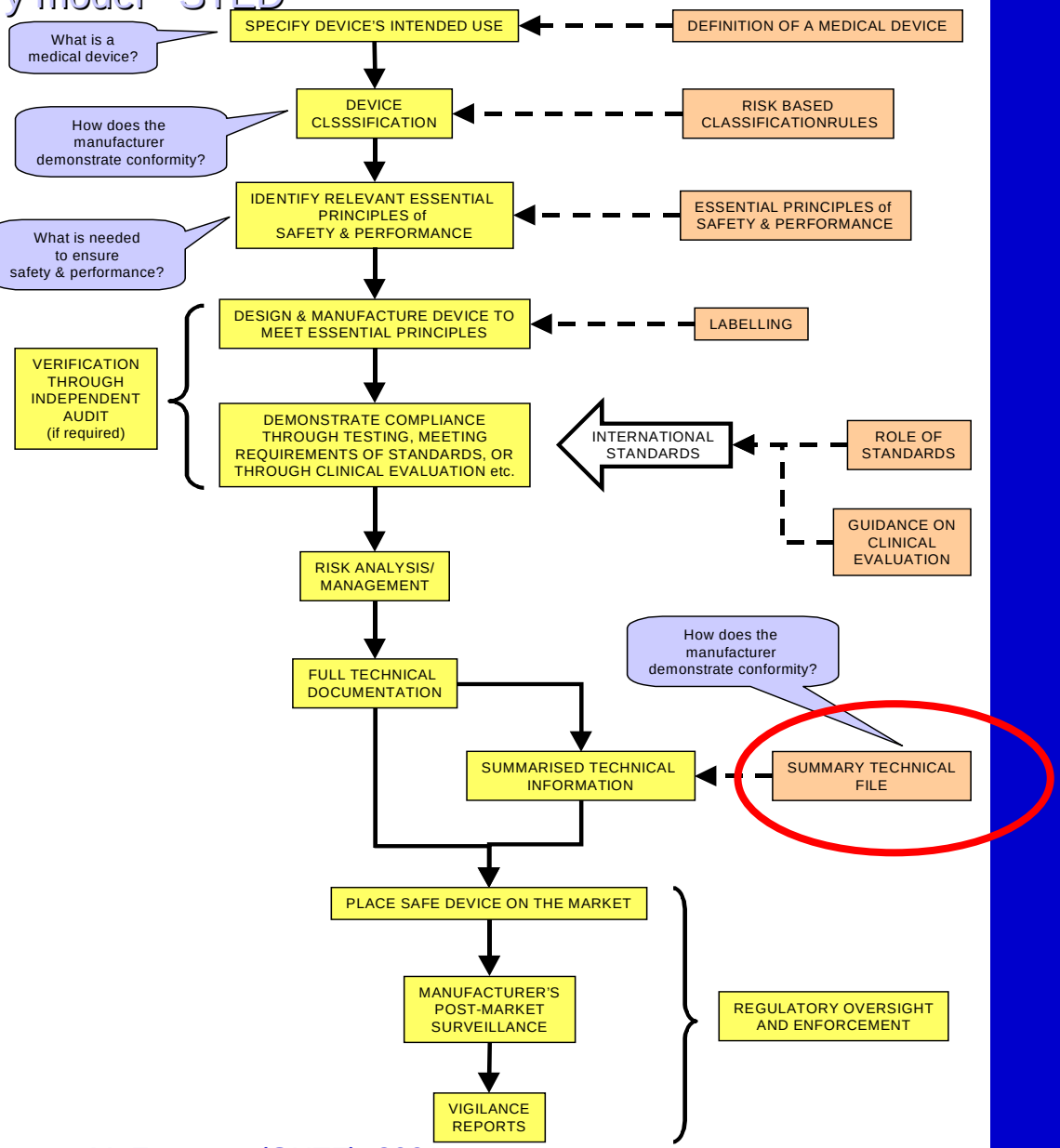
Essential Requirements – Design and construction

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Devices with a measuring function
- Protection against radiation
- Requirements for devices connected or equipped with an energy source
- Information supplied by the manufacturer
- Clinical evaluation

GHTF regulatory model - STED

Premarket controls

FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME



Source: M. Freeman (GHTF), 2001

Scope

- “This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement.
- “It is intended for use by medical devices Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. ….

Scope

- “Regulatory Authorities that are developing new regulatory systems or amending existing ones are encouraged to consider the adoption of this guidance, as this will help to reduce the diversity of systems world-wide and facilitate the process of harmonization”

Scope

- “The regulatory requirements of some countries may not, at present, reflect the contents of this document ….
- “…. It is the goal of the GHTF that country-specific divergences will ultimately be reduced to a minimum”

Scope

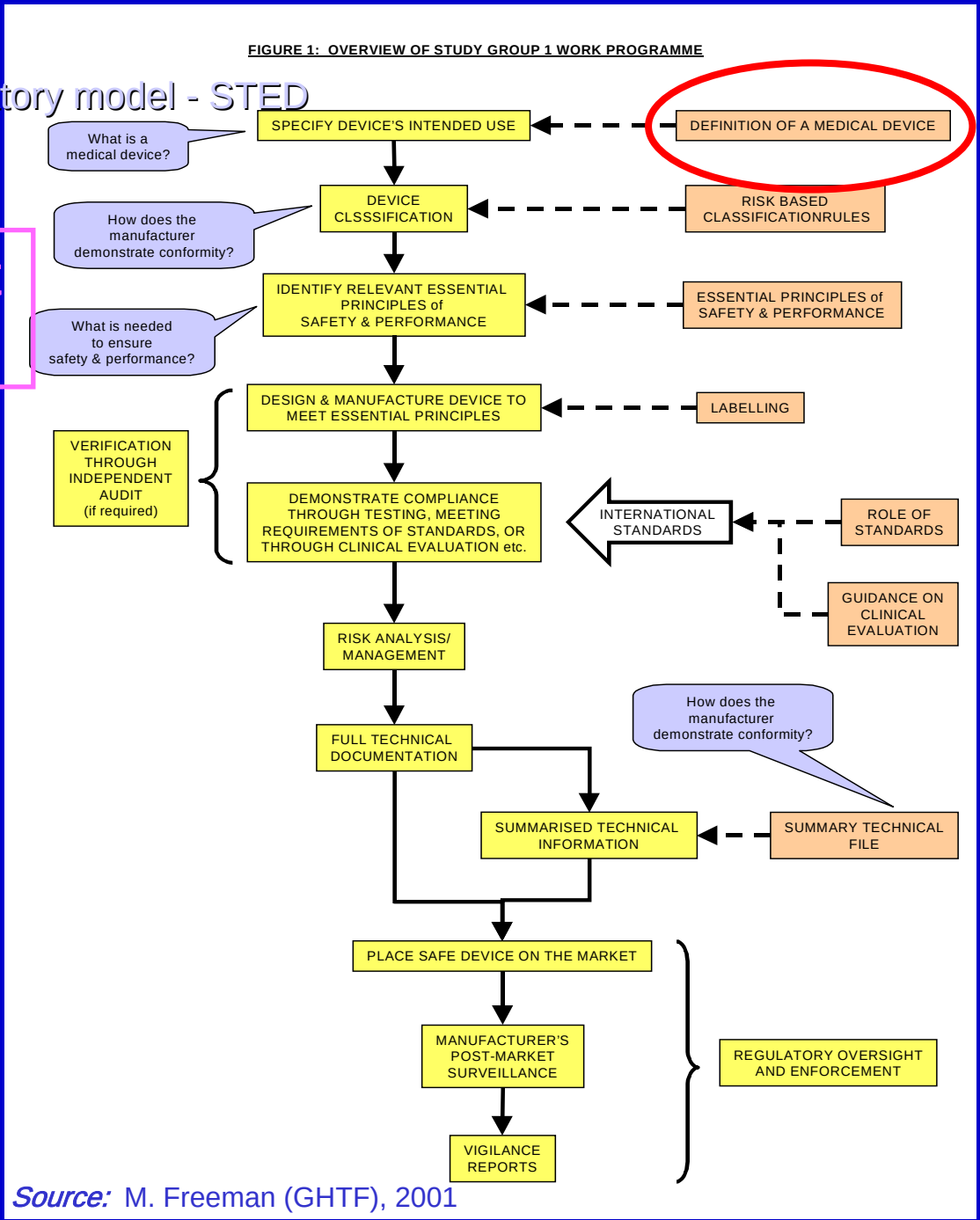
- Format for a globally harmonised STED
- General recommendations on content of elements of STED

Scope

- Applies to all products that fall within GHTF definition of “medical device”
- *In vitro* diagnostic medical devices are outside scope
  - currently – may be revised in future

GHTF regulatory model - STED

Premarket controls



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GHTF definition of “medical device”

“’Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: ……

GHTF definition of “medical device”

“….

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process, ….

GHTF definition of “medical device”

“……

- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body …..

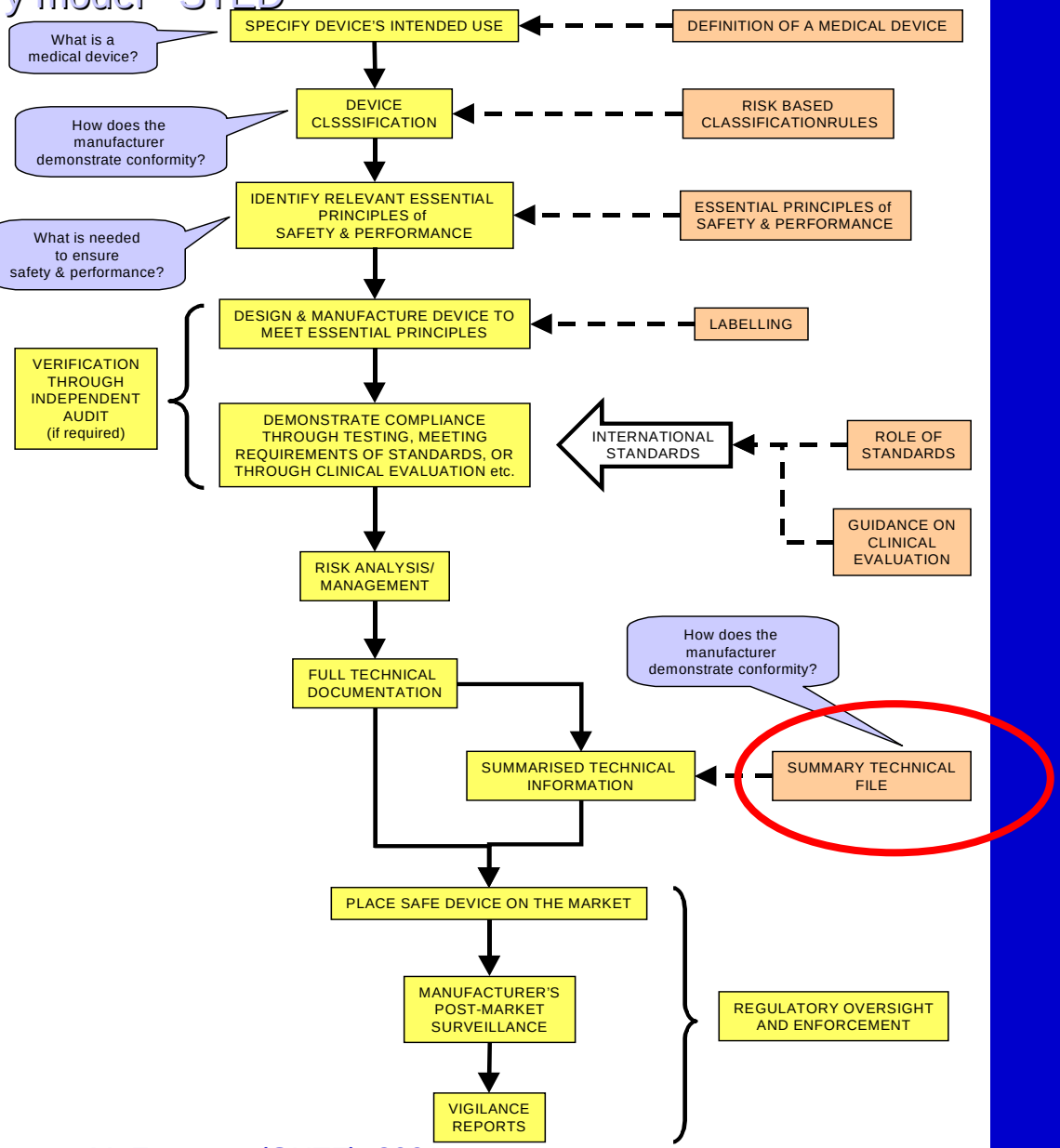
GHTF definition of “medical device”

“…… and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means”

GHTF regulatory model - STED

Premarket controls

FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME



Source: M. Freeman (GHTF), 2001

Scope

- Annexes provide supplementary information
  - Sample conformity checklist
- STED guidance "… does not recommend [creation of] any new or additional technical documents above and beyond what should be created by the manufacturer to comply with existing requirements to demonstrate conformity …."

Scope

- STED is not, and is not a substitute for:
  - “Device master record”
  - “Device history record”
  - “Quality system record”
  - “Design history file”
- If adopted, STED could be used as a substitute for:
  - “Design dossier” (Europe)
  - Other premarket conformity assessment documentation

Scope

- STED "… is based upon the goal of both regulators and manufacturers to strive for the least burdensome means to demonstrate conformity to the *Essential Principles* for all classes of medical devices."
- Until full global harmonization of documentation requirements is achieved, precise contents of STED may have to be augmented by country-specific documentation

Scope

- STED does not cover post-market vigilance, adverse event reporting, or quality systems

STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- **3.0 References**

References

- SG1/N009 *Labelling for Medical Devices.*
- SG1/N012 *Role of Standards in the Assessment of Medical Devices.*
- SG1/N020 *Essential Principles of Safety and Performance of Medical Devices*.
- SG1/N029 *Information Concerning the Definition of the Term "Medical Device".*

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STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- **4.0 Definitions**

Definitions

- **Clinical investigations:** “any specific study in human subjects undertaken to verify the safety and performance of a specific medical device under normal conditions of use”

Definitions

- **Conformity assessment:** “the systematic examination to determine the extent to which a medical device fulfils specified requirements”

Definitions

- **Conformity Assessment Body (CAB):** "a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled.

  A CAB is authorized to undertake specified conformity assessment activities by a regulatory authority that will ensure performance of the CAB is monitored and, if necessary, withdrawal of designation"

Definitions

- **Design Dossier**: “documentation the manufacturer is required to submit to a Conformity Assessment Body to demonstrate conformity of:
  - **a)** certain high risk medical devices with requirements specified in Annex II of the European Directive Concerning Medical Devices or
  - **b)** active implantable medical devices with requirements specified in Annex II of the European Directive Concerning Active Implantable Medical Devices”

Definitions

- **Regulatory Authority:** “a government agency or other entity, that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and to take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements”

Definitions

- **Summary Technical Documentation:** "an abstract of the complete technical records. It is held for conformity assessment purposes"

Definitions

- **Technical File/Technical Documentation:** "documentation required by the European Directives to assess conformity of the medical device with the regulations. Also, general terms describing premarket records"

Definitions

Other terms used in the STED Guidance are derived from *ISO 8402 – Vocabulary*

STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- 4.0 Definitions
- **5.0 Intended use of STED and its preparation**

Intended use of STED and its preparation

- STED is intended for conformity assessment purposes
- The manufacturer creates the STED to demonstrate to a Regulatory Authority that the subject medical device is in conformity with the Essential Principles

Intended use of STED and its preparation

- STED can be
  - a tangible set of documents all centrally located,
  - or a “virtual” set of documents, i.e., a STED with a summary document centrally located but with sections at various locations within the company,
  - at the discretion of the manufacturer

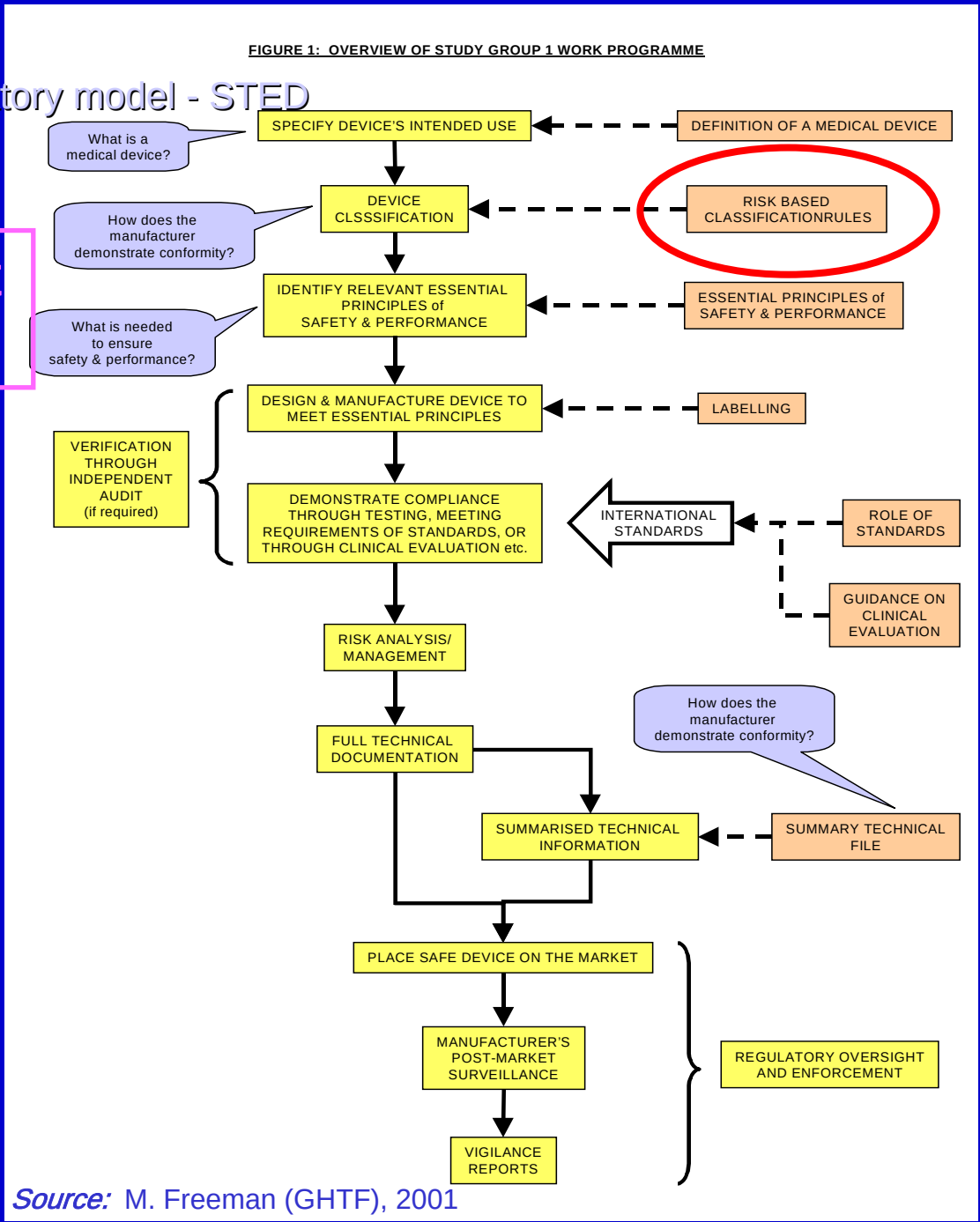
Intended use of STED and its preparation

- For all devices, the manufacturer is required to conduct conformity assessment according to the Essential Principles before placing the device on the market.

  In certain cases (mostly determined by the risk class of the device), the STED may need to be reviewed/ approved by the Regulatory Authority or a Conformity Assessment Body before the applicable device is placed on the market

GHTF regulatory model - STED

Premarket controls



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Intended use of STED and its preparation

- “The class of the device will affect the necessary format and content of the STED and also whether or not the STED needs to be submitted to a Regulatory Authority or Conformity Assessment Body for review and approval or validation before placing the device on the market.

  The extent of that conformity assessment and the required resulting documentation vary according to device class, increasing with higher class”

Intended use of STED and its preparation

- “The manufacturer determines the type and detail of the total technical documentation they believe are needed to demonstrate conformity to the Essential Principles, and to any relevant country-specific requirements.

  The manufacturer holds this documentation”

Intended use of STED and its preparation

- “…. manufacturer derives the content of an STED from the total technical documentation which it has already prepared and is holding to confirm and record that the medical device is in conformity with the Essential Principles”

GHTF regulatory model - STED

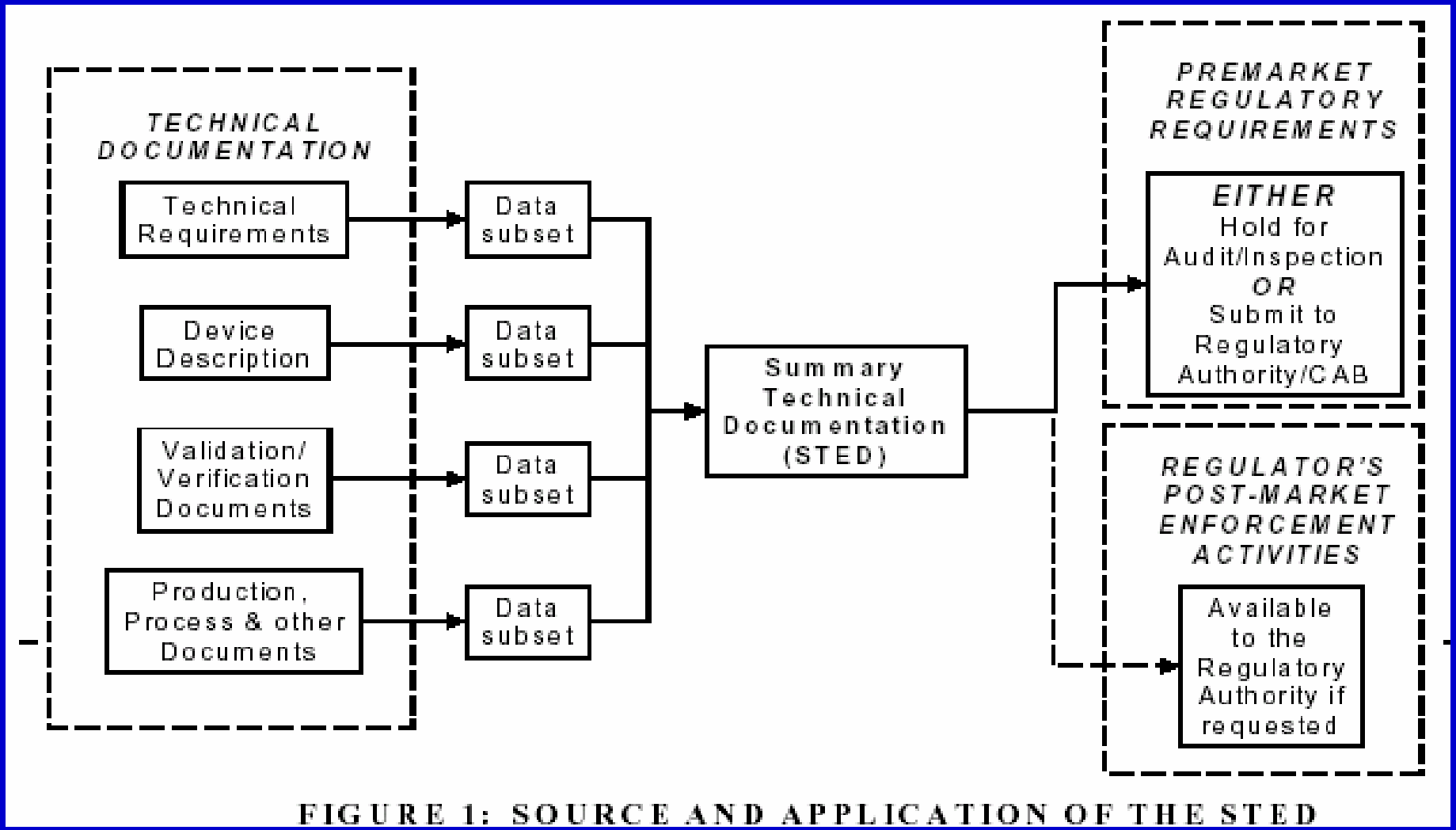

FIGURE 1: SOURCE AND APPLICATION OF THE STED

GHTF regulatory model - STED

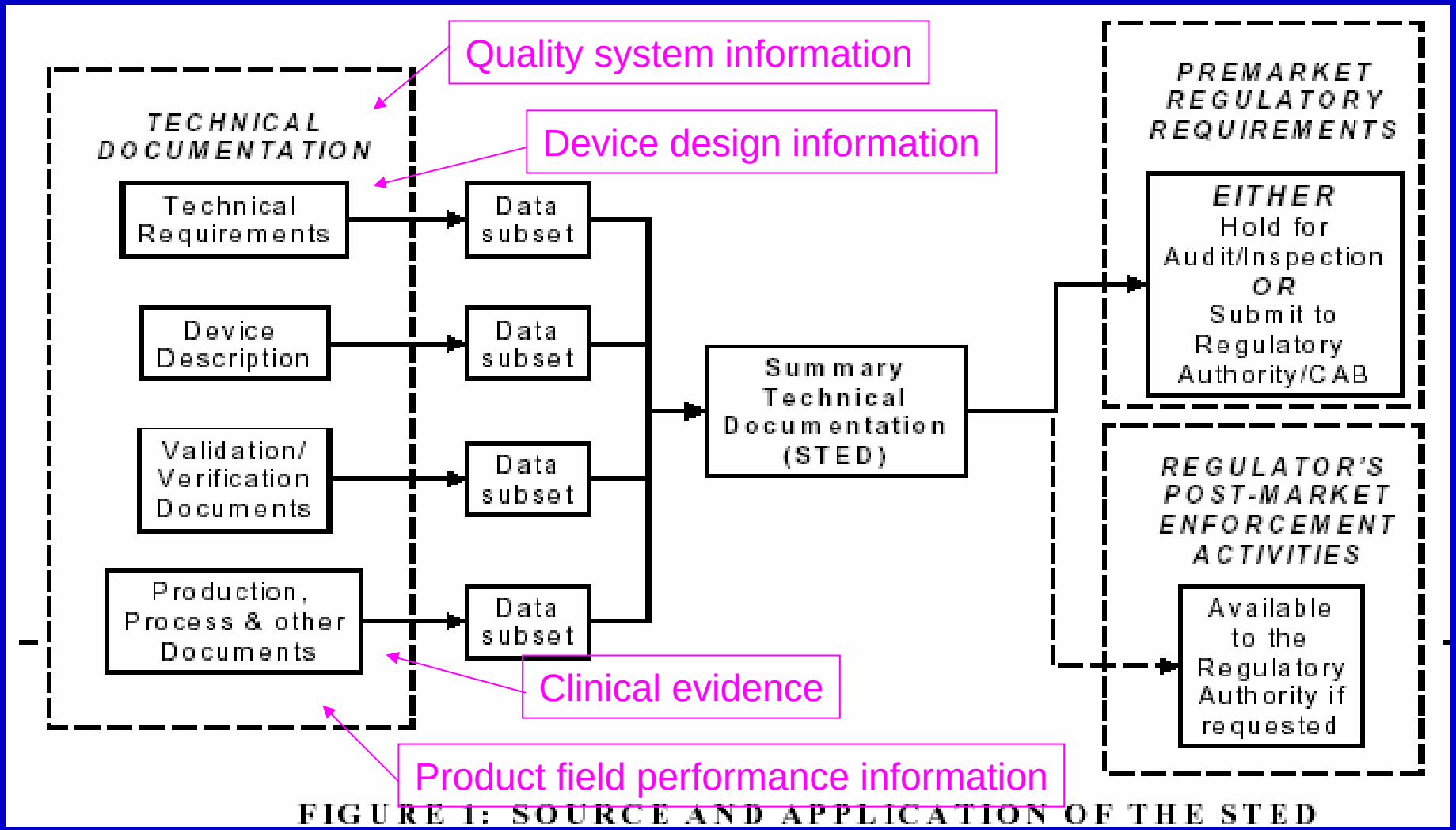

FIGURE 1: SOURCE AND APPLICATION OF THE STED

Intended use of STED and its preparation

- “As an interim measure until full global harmonization of documentation requirements is achieved, the manufacturer must also consider any country-specific requirements, such as product specific guidance, or legal forms, or legal statements

Intended use of STED and its preparation

- "…. assessment of conformity to the Essential Principles by a Regulatory Authority may be required before a medical device is marketed ("pre-market"), or conformity may be audited after the medical device has been marketed ("post-market")"

GHTF regulatory model - STED

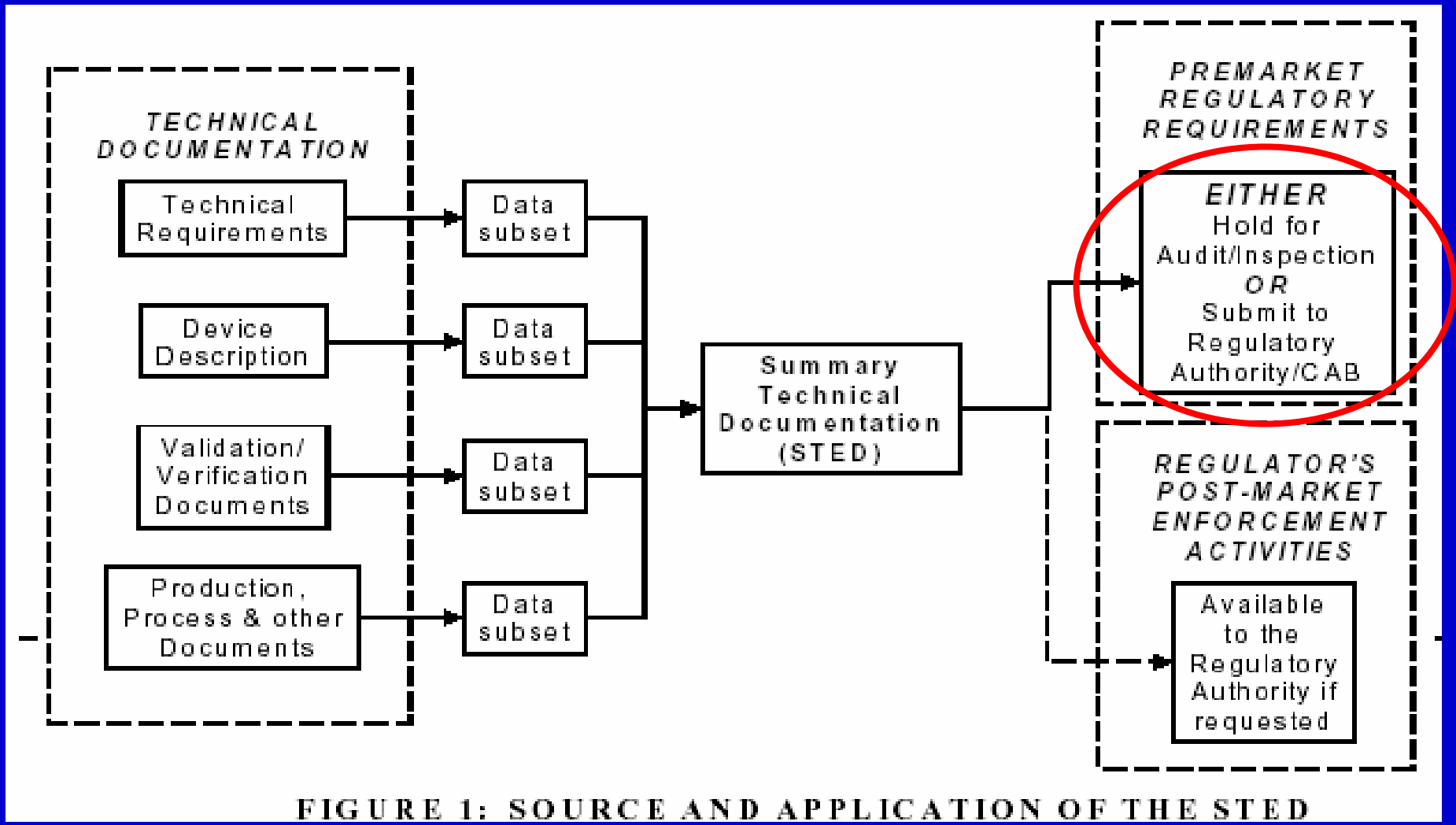

FIGURE 1: SOURCE AND APPLICATION OF THE STED

Intended use of STED and its preparation

- “Medical devices that typically have a high degree of risk are those that require pre-market conformity assessment in all jurisdictions. In such cases, documentation is frequently required to be provided to either a Regulatory Authority or Conformity Assessment Body for review/approval.

  It is intended that the STED be such documentation”

Intended use of STED

Appendix A2: Determining whether to use STED

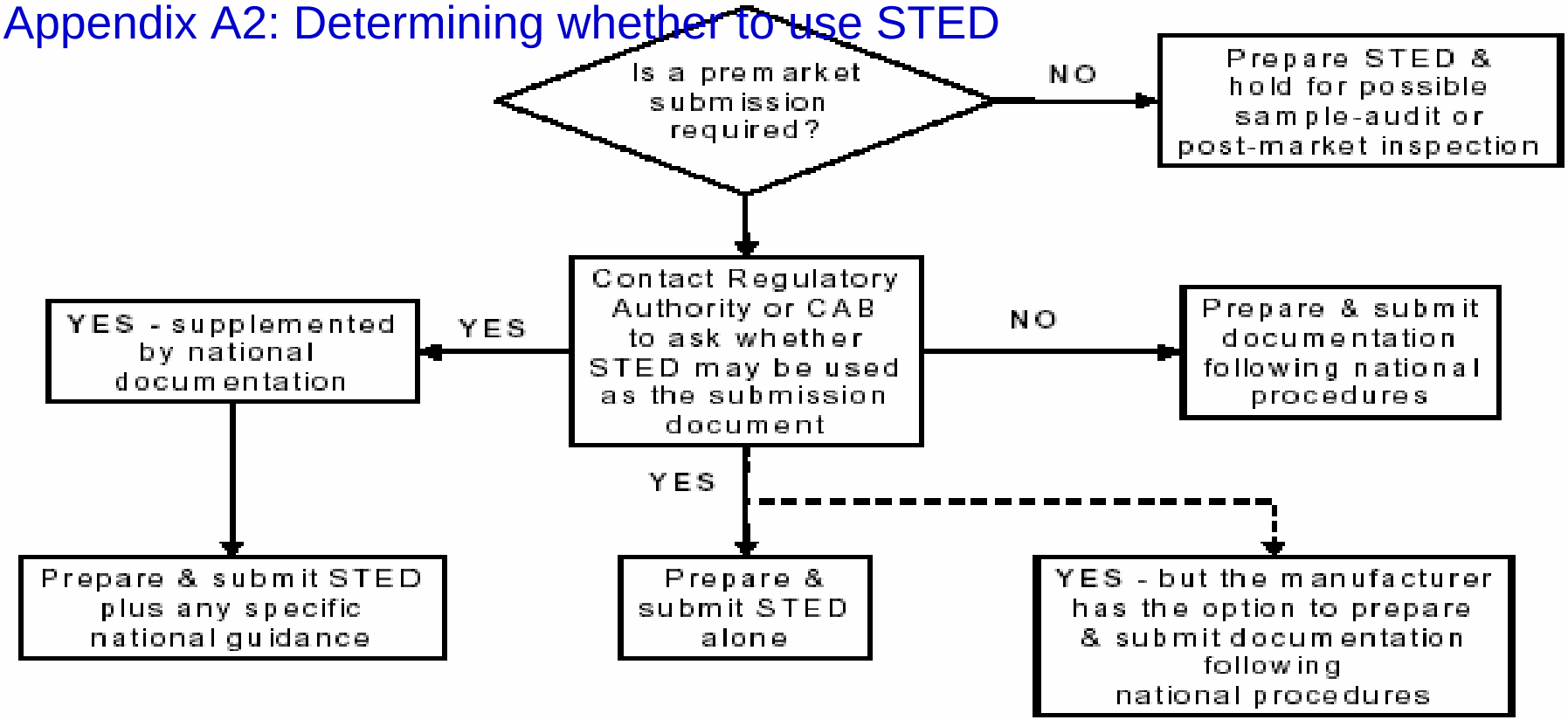

FIGURE 2: DECISION MAKING PROCESS

STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- 4.0 Definitions
- 5.0 Intended use of STED and its preparation
- **6.0 Format for STED**

Format for STED

"For ease of use in a global situation, it is recommended that the STED be formatted as shown

Summary Technical Documentation	Location in this document of expanded guidance
Essential Principles and evidence of conformity	Section 7.1
Device description	Section 7.2
Summary documents of pre-clinical design verification and validation	Section 7.3
Labelling	Section 7.4
Risk analysis	Section 7.5
Manufacturing information	Section 7.6

Format for STED

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Device description	Section 7.2
Summary documents of pre-clinical design verification and validation	Section 7.3
Labelling	Section 7.4
Risk analysis	Section 7.5
Manufacturing information	Section 7.6

Format for STED

"In consideration of the least burdensome means to demonstrate post-market conformity, the manufacturer has the following options for the STED:

- STED based on total documentation
- STED based on summary documentation
- Abbreviated STED (based on table of conformity with Essential principles)
- Combination STED (combination of above options)

STED guidance overview

- 1.0 Introduction
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- 5.0 Intended use of STED and its preparation
- 6.0 Format for STED
- **7.0 Guidance on the elements of STED**

Elements of STED

- Relevant Essential Principles and Method Used to Demonstrate Conformity
  - Identify the Essential Principles that apply to the device
  - Identify the general method used to demonstrate conformity to each applicable Essential Principle
    - Recognised standards
    - State of the art
    - Internal industry methods
    - Comparisons to similar marketed devices

Elements of STED

- Relevant Essential Principles and Method Used to Demonstrate Conformity
  - Identify specific documents demonstrating conformity
  - See Appendix B of STED guidance

Elements of STED

- Summarize or reference or contain the following device description data, to the extent appropriate to the complexity and risk class of the device
  - General Information
    - Intended purpose of device
    - Intended patient population(s) and medical condition(s) to be diagnosed and/or treated
    - Patient selection criteria
    - Contraindications
    - General description of device, including principles of operation

Elements of STED

- Summarize or reference or contain the following device description data, to the extent appropriate to the complexity and risk class of the device
  - General Information (continued)
    - Explanation of novel features
    - Accessories and other equipment intended for use in combination
    - Variants to be marketed
    - General description of functional parts/components
    - Other information needed to describe device, e.g., anatomical location, attachment mechanisms, device *in situ*

Elements of STED

- Summarize or reference or contain the following device description data, to the extent appropriate to the complexity and risk class of the device
  - General Information (continued)
    - Comparisons to other devices (if used to establish conformity with Essential Principles)
  - Materials
    - Description of materials and their physical properties, to extent necessary to demonstrate conformity with Essential Principles

Elements of STED

- Specifications
  - Functional characteristics and technical performance specifications, as relevant
    - Accuracy
    - Sensitivity
    - Specificity
    - Reliability

Elements of STED

- Specifications
  - Other specifications
    - Chemical
    - Physical
    - Electrical
    - Mechanical
    - Biological
    - Software
    - Sterility
    - stability

Elements of STED

- Specifications
  - Other specifications (continued)
    - Storage and transport
    - Packaging
  - Other descriptive information

Elements of STED

- Summary of design verification and validation
  - General
    - Declarations or certificates of conformity to “recognised” standards as applied by manufacturer

Elements of STED

- Summary of design verification and validation
  - General
    - Summaries or reports of tests and evaluations
      - Listing of and conclusions drawn from published reports concerning safety and performance
      - Engineering tests
      - Laboratory tests
      - Biocompatability tests
      - Animal tests
      - Simulated use tests
      - Software validation

Elements of STED

- Summary of design verification and validation
  - Summaries or reports of tests and evaluations
    - Recommended test report format and content in STED guidance Appendix C4

Elements of STED

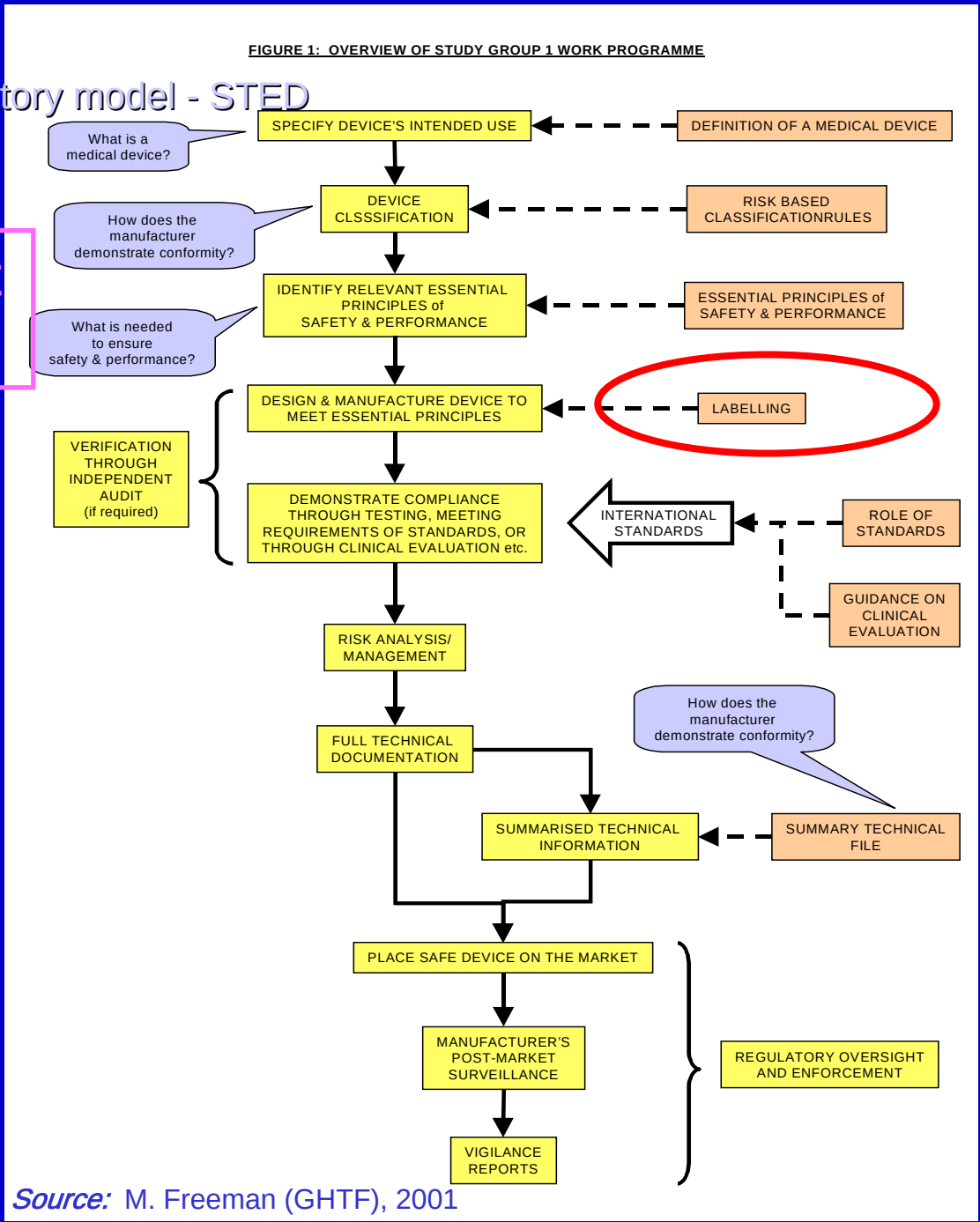
- Clinical evidence
  - “The STED should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met.
  - Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices, or by clinical investigation.
  - Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience”

Elements of STED

- Labelling
  - STED should summarize or reference or contain labelling information to extent appropriate to complexity and risk class of device
    - Labels on device or its packaging
    - Instructions for use
    - Other literature or training materials
    - Instructions for installation and maintenance
    - Any information and instructions given to patient

GHTF regulatory model - STED

Premarket controls



Source: M. Freeman (GHTF), 2001

SG1 – Final Documents

Title	*Description*	*Posted Date*	*Size*	*Comments To*
SG1-N020R5 PDF Word	Essential Principles of Safety & Performance of Medical Devices	28 December, 1999 *Re-posted: 23 October 2000	12 pages, 56Kb-PDF 95Kb-Word	
SG1-N009R6 PDF Word	Labelling for Medical Devices	15 March, 2000 *Re-posted: 23 October 2000	7 pages, 43Kb-PDF 69Kb-Word	
SG1-N012R10 PDF Word	Role of Standards in the Assessment of Medical Devices	15 March, 2000 *Re-posted: 23 October 2000	10 pages, 50Kb-PDF 73Kb-Word	

Risk analysis

- STED should summarize or reference or contain the results of the risk analysis

  This risk analysis should be based upon international [e.g., ISO 14971:2000] or other recognized standards, and be appropriate to the complexity and risk class of the device

http://www.iso.ch/iso/en/ISOOnline.openerpage

Manufacturer information

- STED should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device

STED guidance overview

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- 4.0 Definitions
- 5.0 Intended use of STED and its preparation
- 6.0 Format for STED
- 7.0 Guidance on the elements of STED
- **Appendices**

Appendices

- Relationship of STED to work of GHTF Study Groups 2, 3, and 4
- Decision process to determine whether to use STED
- Essential Principles Conformity Checklist
- Additional recommendations for STEDs provided to regulatory authorities for review/approval

Presentation overview

- Introduction
- STED guidance overview
- **STED Pilot study**

STED Pilot study

- Study Group 1 has done two pilot studies of STED
  - Review of specially-prepared STEDs for devices already in market
    - To determine adequacy of information submitted
    - No change in previous decisions
    - All risk classes of device
    - Different conformity assessment bodies/regulatory authorities
    - Completed study
    - Revised STED guidance based on experience

STED Pilot study

- Study Group 1 has done two pilot studies of STED
  - Ongoing pilot of actual premarket reviews
    - Australia TGA
    - Japan MHLW
    - US FDA pending (?)

GHTF Vision

Enhancing the health of the public worldwide and facilitating innovation by harmonising the global regulatory environment

Source: GHTF Steering Committee Strategic Direction; Singapore, May 2002