

VOLUME 1

TABLE OF CONTENTS

	Page
Content of Summary Technical File	
A. Technical Requirements	5
A1 Standards and Regulatory Information	
A2 Relevant Essential Principles of Safety and Performance of Medical Devices	
A3 Rationale and Justification for the Design Attributes	
B. Device Description	8
B1 General	
B2 Specific Characteristics and Limitations	
C. Compliance with Essential Principles of Safety and Performance of Medical Devices	10
C1 General	
C2 Report Format	
D. Labeling	12
E. Risk Analysis	12
F. Manufacturing Information	12
G. Device Changes	

Annex A:	Background Information	13
Annex B:	GHTF Essential Principles of Safety and Performance of Medical Devices	20
Annex C:	GHTF Guidance on labeling, clinical experience, and standards	21
Annex D:	Administrative Recommendations for Premarket Summary Technical File Submissions	22
Annex E:	Checklist of Summary Technical File Submitted for Conformity Assessment	25

CONTENT OF SUMMARY TECHNICAL FILE

A. TECHNICAL REQUIREMENTS

1. Standards and Regulatory Information

The Summary Technical File (STF) should document the technical requirements, including any design, safety or performance tolerances and pass/fail criteria. Refer to guidance from Study Group 3 for more information on design controls, including technical requirements applied to design inputs and outputs. The STF should document, for example:

Technical Standards

- the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard;
- complete documentation of manufacturer internal “standards” or other solutions that are used for design and testing of the device in the section of the technical file in which the standard is applied;
- declarations of conformity to the “recognized” standards listed as applied by the manufacturer, either in whole or in part, as permitted by the regulatory authority, and with a content and format as specified by the regulatory authority;

NOTE: Refer to ANNEX C for guidance on the role of standards in the assessment of medical devices.

Medicinal or Biological Substances in Combination With a Medical Device

- the technical requirements concerning any medicinal substances that are included as part of the medical device or may be used with or come into contact with the device (i.e. syringes or pumps for pharmaceuticals or biologics);
- the principle intended use of a combination device, drug, or biologic product must meet the statutory definition of a medical device in order for it to be subject primarily to device requirements and the Essential Principles (otherwise, the product may be subject to pharmaceutical or biologics requirements);

Country-specific Regulatory Requirements and Guidance

- any design and test regulatory requirements for the device, and when necessary, requirements for the submission of a premarket technical file to the regulatory authority or conformity assessment body that are applicable to the country where the device is intended to be placed on the market (list both relevant general and

specific regulatory requirements for the device);

- other guidance or direction provided by the regulatory authority or conformity assessment body which was used in developing the technical documentation.

NOTE: *Refer to Volume 2 of this document, which provides relevant country-specific regulatory requirements.*

2. Relevant Essential Principles of Safety and Performance of Medical Devices

The STF should document:

- the GHTF Essential Principles of Safety and Performance for Medical Devices* that are applicable to the device; and
- a cross-reference to the page(s) of the Summary Technical File for the data and information relating to each of the Essential Principles.

NOTE: *Refer to ANNEX B for the document entitled Essential Principles of Safety and Performance of Medical Devices.*

3. Rationale and Justification for the Design Attributes

The STF should document the rationale and justification for the design attributes of the specific device in terms of the following factors:

Functional Requirements

- functional characteristics.
- intended applications.
- intended conditions of use.
- intended benefits to the patient related to the risks involved.

Performance Requirements

- material biocompatibility.
- physical, mechanical and chemical properties of the materials.
- strength of materials.
- effects of wear of the device.
- effects of the manufacturing processes, including sterilization, on the materials and device performance.
- effects of the device and its function due to interaction between its constituent materials and other materials and substances.
- interconnecting parts and their effects.
- dimensions and weight and their effects.

- biocompatibility of the entire device.
- effects of the environment on the device, e.g., temperature, shock, vibration, humidity, electromagnetic compatibility.
- electrical requirements.
- Portability.
- output affecting the physiology or structure of the body.
- ability to place the device, remove and replace.
- microbiological and particulate contamination effects .
- suitability of packaging for storage and transport.
- limits of operation.
- Speed.
- response times.
- accuracy .
- sensitivity.
- Reliability.
- Specificity.

Interface Requirements

- human factors.
- compatibility with other systems.
- electrical, physical or chemical inputs to the device.

B. DEVICE DESCRIPTION

1. General

The STF should document:

- the functional purpose of the device (intended use);
- the intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) and other considerations such as patient selection criteria;
- the medical conditions for which the device is not to be used (contraindications);
- summary of the functional characteristics and technical specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other relevant factors;
- a general description of the device including its principles of operation, (capabilities, the inputs to the device and outputs) ;
- description and physical properties of materials;

Note: Detailed material composition and formulation information may not be accessible to the manufacturer. However, suitability of the materials, in accordance with Essential Principles, must be demonstrated.

- the accessories, and other devices or equipment which are intended to be used in combination with the device;
- the variants of the device to be marketed (the parameters of the range of variants should be documented in a submitted dossier);
- a general description of each of the functional parts/components of the device with labeled pictorial representations of the device (diagrams, photograph, drawing(s)), clearly indicating each part, including sufficient explanation to understand the drawings and diagrams;
- other information as needed to provide a thorough description of the device, e.g., for an implant, a description of the anatomical location of the device in the body, attachment mechanisms for the device, including diagrams or illustrations of the implant in situ;
- as required, design drawings, e.g., diagrams of significant components, algorithms (including how the device takes physiological inputs and processes them), circuits

and sub-assemblies of components, with descriptions and explanations necessary to understand the design drawings and operation of the device; and

- as appropriate, significant chemical, physical, electrical, mechanical, biological, software and sterility specifications.

2. **Specific Characteristics and Limitations**

The STF should document, for example:

- stability and shelf-life
- transport and storage
- packaging specifications.

C. COMPLIANCE with ESSENTIAL PRINCIPLES of SAFETY and PERFORMANCE of MEDICAL DEVICES

1. General

The STF should document summary reports of all design verification and validation analyses, tests, and inspections conducted on the basis of a risk analysis (see Section F. on page 12) to show that the medical device meets the *Essential Principles* *.

Compliance to the *Essential Principles* may be documented by:

- (1) reports of tests and evaluations based on standards, manufacturer methods and tests, or other alternative ways of demonstrating compliance. A common report format is described below.
- (2) a declaration of conformance may be sufficient for submittal purposes, where the standard used has been "recognized" by the Regulatory Authority **.

Country specific requirements may exist that determine which standards are appropriate, the extent and detail of the study reports, and whether information must be submitted to the Regulatory Authority or Conformity Assessment Body ***.

Note:* Refer to Section A for applicable *Essential Principles* listed in ANNEX B

*Note**:* Refer to Section A for standards used and to ANNEX C for guidance on the role of standards.

*Note***:* Refer to Volume 2 for country-specific information

The verification and validation data and information may include, for example:

- a summary review, bibliography, and copies of all published reports, whether adverse or supportive, that concern the safety and performance of the device.
- engineering tests
- animal tests
- simulated use
- clinical experience
- software validation
- biocompatibility
- laboratory tests
- market experience with the device and its materials

2. Report Format

1. report title and other identifying information

2. name and address of facility performing the test
3. name of the responsible person involved
4. dates that testing was initiated and completed
5. study plan, results, and conclusions, including, for example:
 - the study objective and test hypothesis
 - a description of the test system used including relevant specifications (a diagram may be helpful);
 - a description of the differences between the test samples and final specifications, if any;
 - deviations from test plan, if any;
 - a comprehensive summary of the data in the form and manner specified by the Regulatory Authorities which will allow an independent assessment;
 - statistical evaluation of the test results, where appropriate;
 - bibliography of all references pertinent to the report

NOTE: Refer to ANNEX C for guidance on clinical practice.

D. LABELING

The STF should document the following:

1. details of all labeling which may include, for example, labels on the device, instructions for use, and as appropriate, other literature or training materials that is considered labeling;
2. instructions for installation and maintenance; and
3. details of any information and instructions given to the patient, which include detailed instructions for any procedure the patient is expected to perform.

NOTE: Refer to Annex C for guidance on labeling

E. RISK ANALYSIS

The STF should document a risk analysis for the device. Documentation may be based upon international and/or domestic technical standards on risk assessment.

F. MANUFACTURING INFORMATION

The STF should document a summary of the manufacturing process including quality assurance measures.

NOTE: Refer to Annex E, Country-Specific Manufacturing Information, for additional manufacturing information.

G. DEVICE CHANGES

The STF should include records of significant changes to the device design and the reasons for believing these achieve the desired effect and that the device continues to comply with the Essential Principles.

Where the technical file or part thereof has been submitted to the Regulatory Authority or Conformity Assessment Body, such changes should be indicated in a further submission.

ANNEX A

BACKGROUND INFORMATION

A. PURPOSE,

The purpose of this document is:

1. to provide guidance on the layout and content of summary technical information needed to demonstrate conformity to premarket requirements agreed to by the parties to the GHTF;
2. to identify common technical file features; and
3. to identify existing divergence in technical file requirements within various regulatory systems (see Volume 2) with a view to their eventual harmonization.

The Summary Technical File described herein may or may not be required for submission to regulatory bodies. Instead, regulatory bodies may require that it be held for audit. Also, the Summary Technical File will likely represent only a portion of the available technical documentation held by the manufacturer or associated third parties, e.g., suppliers, test labs, if any.

This Summary Technical File guidance document should be used by any person who is considering compiling data and information to be used to support marketing of a medical device, and who wishes to have the information organized in a form and manner that is an acceptable alternative to that currently required by GHTF member countries.

B. SCOPE

This guidance document pertains to summary premarket technical documentation for medical devices, and their accessories. The terminology and concepts in this document are consistent with international and harmonized design control quality systems standards and regulations which establish the process, methods, and procedures for development of the premarket documentation. It does not address postmarket vigilance, adverse event reporting, or quality systems, except as related to common device design technical provisions.

It is recommended by Study Group 1 that those responsible for preparation of device technical files also consider the Study Group 3 document entitled Guidance on Quality Systems for the Design and Manufacture of Medical Devices, issue 7, dated August 1994. That document provides additional guidance regarding the preparation of technical documentation.

C. THE GOALS AND USE OF THE SUMMARY TECHNICAL FILE

COMPARISON OF PREMARKET REQUIREMENTS BETWEEN GHTF MEMBERS

Each GHTF member country has laws and regulations pertaining to premarket requirements. There are similarities and differences between countries in these requirements and related aspects as noted below:

<u>Premarket Requirement or Related Aspect</u>	<u>Similarities Between Countries</u>	<u>Differences Between Countries</u>
Classification	devices are categorized based on risk	<ul style="list-style-type: none"> • the number of categories • the risk category assigned for a device
Use of Standards	Technical standards are utilized	<ul style="list-style-type: none"> • different technical standards may be used • the amount of data or information submitted documenting conformity
Quality System Requirements	records are created and maintained	type and amount of data and information required or recommended
Technical Data and Information	data and information are maintained and available to regulatory authorities or conformity assessment bodies	format and content of data
Premarket Evaluation	degree of evaluation based on risk category of device	who evaluates the data, to what degree it is evaluated, the criteria, and length of the review period

THE GOAL OF THE GHTF/STUDY GROUP 1: HARMONIZATION OF PREMARKET REQUIREMENTS

Each country or community of nations has created their own premarket rules and procedures. While there are many fundamental similarities in requirements and procedures, there are also many differences as noted in the table above. The GHTF is committed to identifying means to decrease the differences through proactive global communication with regulatory authorities on new legislation, harmonization of existing processes, and other innovative solutions.

Study Group 1 will address the divergence with guidance related to Essential Principles for medical devices, standards, clinical studies, classification, labeling, general premarket technical requirements and documentation and related device specific guidance, and other guidance as GHTF member resources permit.

HOW THE SUMMARY TECHNICAL FILE GUIDANCE RELATES TO DESIGN CONTROL STANDARDS AND GHTF/STUDY GROUP 3 GUIDANCE

The **Study Group 3** guidance on quality systems provides harmonized information and recommendations on quality systems subjects, including guidance on design control requirements. Harmonization of quality systems requirements is a building block for harmonization of premarket documentation held by the manufacturer. This **Study Group 1 Summary Technical File** guidance provides information related principally to the format and content of documentation for premarket conformity assessment by regulatory authorities or conformity assessment bodies. It is an alternative to current premarket technical file procedures in each GHTF participating country or community.

SPECIAL FEATURES OF THE STUDY GROUP 1 GHTF PREMARKET SUMMARY TECHNICAL FILE GUIDANCE FOR MEDICAL DEVICES

- The GHTF has proposed common Essential Principles for Medical Devices. The Principles applicable to the device should be met as demonstrated by preproduction records that are condensed into a Summary Technical File held by the manufacturer. Conformity assessment procedures may require that the Summary Technical File be submitted for premarket assessment.
- This guidance provides a common content and format for a Summary Technical File based, in part, upon common aspects of design control quality system standards and existing regulatory requirements. The guidance incorporates current requirements of GHTF member countries, albeit in a manner that may be unlike formats now individually recommended by each country or community. GHTF members have eliminated country-specific requirements that they consider to be addressed by the common processes and procedures. The Annex provides country-specific regulations and guidance which are not common and still considered essential.
- The guidance recommends the use of international voluntary consensus standards as the basis for relevant parts of the Summary Technical File in order to facilitate harmonization.
- The Annex to the guidance includes for reference purposes the full list of the GHTF Essential Principles and expanded GHTF guidance on standards, clinical data, and labeling.

WHO SHOULD USE THIS GUIDANCE

As noted in the scope, this guidance should be used by any person who is considering compiling data and information to support marketing of a medical device, and who wishes to have the information in a form and manner that is readily portable from one GHTF member country to another with minimal modification.

There are two incentives for using this guidance. First, it is sensible that manufacturers and

others should create, maintain, and submit, when necessary, technical documentation in as common a format as possible rather than in different formats which now exist. Second, regulatory authorities who accept technical documentation compiled and submitted in accordance with this guidance will seek to ensure that there are no undue administrative or scientific disadvantages incurred. For example, the authorities will seek to ensure that there is no increased processing time for submissions made according to this guidance compared to those submitted using current procedures, or additional questions posed by the regulatory authority that would not otherwise be posed when using the current procedures. The regulatory authorities who accept this guidance will track and compare activity to ensure that delays are not incurred.

HOW TO USE THIS GHTF GUIDANCE DOCUMENT

Laws and regulations in each country describe how to introduce a device onto the market in that country (see Conformity Assessment Procedures in Volume 2). This guidance can not supersede or replace any premarket requirements that are specified by law. Instead, this guidance is intended to offer a harmonized alternative to current documentation procedures within the framework of existing laws and regulations.

A person intending to introduce a new device should contact the regulatory authority for the country in which marketing is planned, to determine (1) whether this guidance is applicable to the proposed device (e.g., the guidance may apply to only a few types of devices during a pilot evaluation period) and, (2) if there are any GHTF product-specific technical file or implementation guidance, or country-specific device guidance that should be used as supplementary guidance to this GHTF Summary Technical File guidance document.

If this Summary Technical File guidance may be used, then a person may select either the existing regulatory method for marketing the device, or the use of this GHTF guidance. If this GHTF Summary Technical File guidance document, and any available GHTF device-specific guidance is selected, the person intending to market a device should document in their premarket submission, and/or related quality records on file, data and information as recommended in the GHTF guidance documents.

See Figure 1 on page 9 for a flow chart of this decision process.

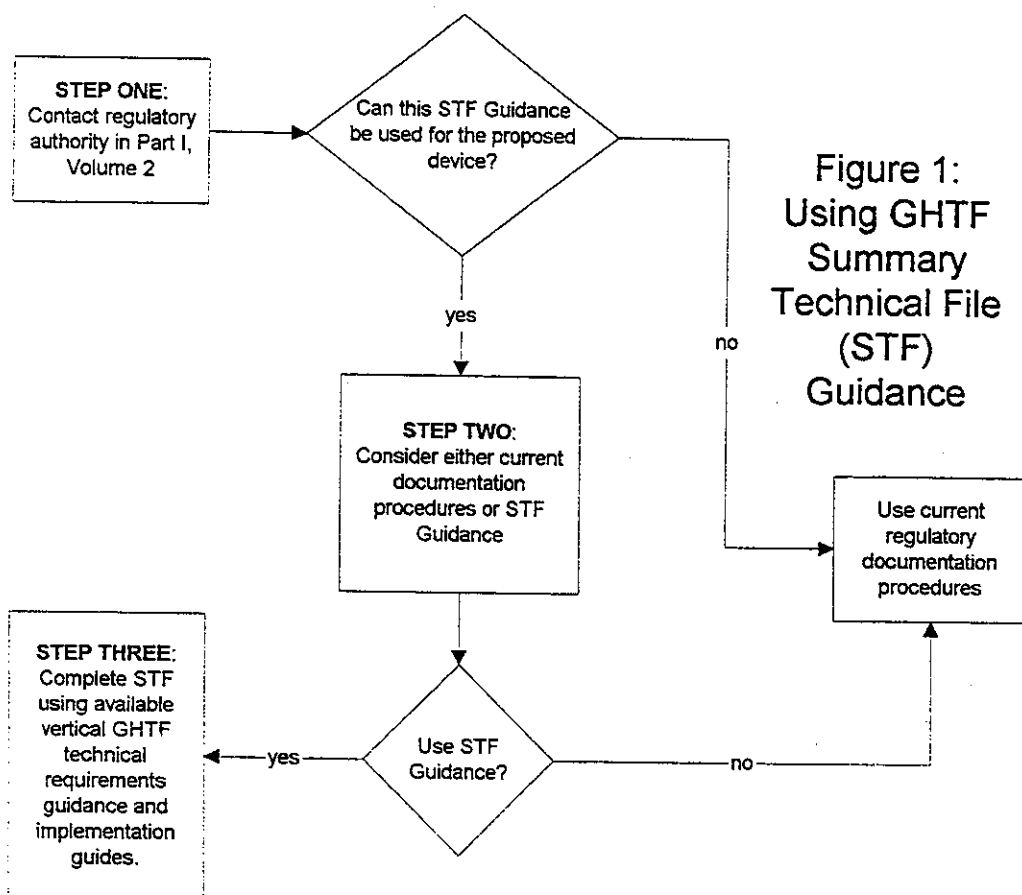


Figure 1:
Using GHTF
Summary
Technical File
(STF)
Guidance

CLASSIFICATION AND THE REQUIREMENT TO SUBMIT DATA TO REGULATORY AUTHORITIES OR CONFORMITY ASSESSMENT BODY

The laws and regulations of each country specify the conformity assessment procedures for medical devices. Devices are classified into risk classes that define the types of regulatory controls imposed on the device. For higher risk device classes data and information must be submitted to a regulatory authority or conformity assessment bodies, e.g., notified body. Even if the class of a device does not require a premarket submission, the manufacturer must still compile and maintain technical data and information on their medical device according to regulatory requirements. The data and information may be compiled and maintained at more than one location by the manufacturer. The data and information on file with the manufacturer are also subject to audit or other inspection.

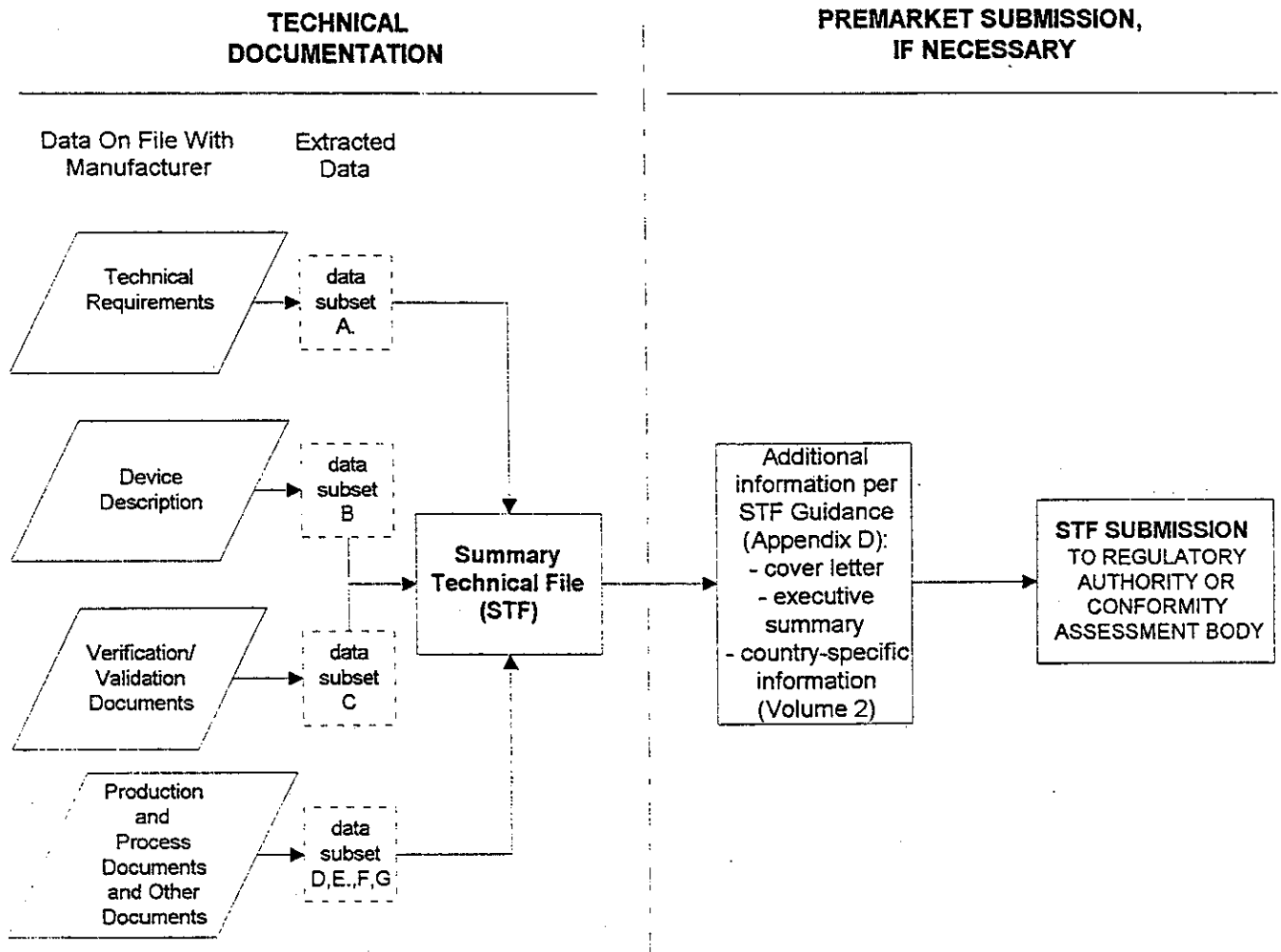
TECHNICAL DOCUMENTATION: THE ROLE OF THE SUMMARY TECHNICAL FILE

This guidance document addresses the content and format for a Summary Technical File to be used for conformity assessment purposes. The contents of this Summary Technical File are derived from the data and information compiled in accord with design control requirements of quality systems regulations. The Summary Technical File is held by the manufacturer and may

be used for audit or inspection purposes. The Summary Technical File should refer to the location of the source documents that are condensed in the Summary Technical File. This guidance and the format and content of the Summary Technical File may be used as a reference for compiling and formatting some of the design control records held by the manufacturer.

When a submission to a regulatory authority or conformity assessment body is required then it is the intent of the GHTF that the Summary Technical File serve as the documentation that is acceptable. When a submission is required the manufacturer will supplement the Summary Technical File with additional administrative and technical information required by the regulatory authority, and format the data and information into a submission (see Figure 2). The submission may be called a "dossier", "application", or "notification" depending on the regulatory authority or conformity assessment body receiving the submission, and the regulatory class of the device.

FIGURE 2: Technical Documentation



D. DEFINITIONS

The GHTF Study Group 1 recognizes the need for harmonization of the definitions of terms used in technical files and regulations. International standards organizations are engaged in this activity. Harmonization of terms is not within the scope of Study Group 1. Terms used by the manufacturer must be in accordance with the current laws and regulations of the regulatory authority, or as accepted by each regulatory authority.

Some of the terms used in this Summary Technical File Guidance are derived from ISO 8402 – Vocabulary.

ANNEX B

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

The GHTF Study Group 1 has developed a document entitled: Essential Principles of Safety and Performance of Medical Devices. The latest revision of 8 December (ref. GHTF.SG1.N020R3) is available for public comment and will be included within this document once it has been finalised.

ANNEX C

GHTF GUIDANCE ON LABELING, STANDARDS AND CLINICAL PRACTICE

The GHTF Study Group 1 has developed a document entitled: Labeling Requirements of Medical Devices. The latest revision of [****] (ref. GHTF.SG1.N009R*) is available for public comment and will be included within this document once it has been finalised.

The GHTF Study Group 1 has developed a document entitled: Role of Standards in the Assessment of Medical Devices. The latest revision of 8 December (ref. GHTF.SG1.N012R6) is available for public comment and will be included within this document once it has been finalised.

The GHTF Study Group 1 has developed a document entitled: Guidelines for Good Clinical Practice for Medical Devices. The latest revision of [*****] (ref. GHTF.SG1.N018R*) is available for public comment and will be included within this document once it has been finalised.

ANNEX D

ADMINISTRATIVE RECOMMENDATIONS FOR PREMARKET SUMMARY TECHNICAL FILE SUBMISSIONS

A. WHERE TO SUBMIT

Submit the STF to the address of the regulatory authority or conformity assessment body as noted in regulations or directions.

B. COMMON FORMAT RECOMMENDATIONS

If an STF must be submitted to a regulatory authority or a conformity assessment body it should conform to the following recommended format:

1. Use paper with the dimensions recommended by the regulatory authority or according to the custom of the country.
2. There should be a margin on each page on the side of the paper and having a width according to the custom of the country or as specified.
3. The STF should be separated into volumes that are not excessively thick, e.g., no greater than 5 cm. Identify volumes by a consecutive numbering system (e.g., Vol.2 of 5). Bind each volume on the side consistent with the custom of the country.
4. Number all pages consecutively.
5. Use a consistent method to differentiate sections and parts of the STF (e.g., tabs, underlines, headings).
6. Use original quality documents (e.g., photographs, plans, and schematics) in at least one set of volumes and accurate and clear copies in all other copies of volumes.
7. Every page should be entirely legible including all alphanumerics, formulas, drawings, and other characters put to paper. Produce in black ink.
8. Include a Table of Contents in all volumes with sections and headings and page numbers.
9. All copies of volumes should be identical in content.
10. The STF should be in the official language(s) as specified by country requirements.
11. When documentation is in an electronic format it should generated using word processing.