

Organising European Technical Documentation to Avoid Duplication

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The development of comprehensive, accurate and well-organised technical documentation that demonstrates compliance with regulatory requirements is a resource-intensive, but critically important activity for medical device manufacturers. This article discusses guidance documents and methods of organising technical documentation that may help avoid costly and time-consuming duplication.

Artwork: Jennifer Field

Importance of technical documentation

Technical documentation is the foundation on which the process of CE-marking is based. Thus, it should be complete and accurate, organised to facilitate examination, properly controlled and maintained for the period specified under the Directives. Considering the resources needed to produce this documentation, every effort should be made to reduce duplication when developing documentation for other regulatory jurisdictions. Fortunately, this is becoming easier with the development of globally harmonised documents. These are gaining increased acceptance in Europe, the United States (US), Japan and elsewhere and are discussed later.

The Notified Body Recommendation

The Active Implantable Medical Device (AIMD) Directive (90/385/EEC), Medical Device (MD) Directive (93/42/EEC), and In Vitro Diagnostic (IVD) Medical Device Directive (98/79/EC) require comprehensive technical documentation to be developed that is made available to Competent Authorities for inspection purposes. In addition, the Directives specify the type of technical information and data that should be submitted to a Notified Body (NB), if NB intervention is required. The development and

control of technical documentation is also an important part of the European medical device quality systems requirements.

It is interesting to note that there is no European MEDDEV guideline on technical documentation. Fortunately, however, a NB Recommendation on Technical Documentation (Recommendation, NB-MED/2.5.1/Rec5) was developed and can be downloaded from www.team-nb.org/. The document aims to provide guidance to NBs, Competent Authorities and manufacturers on the technical documentation needed to meet the requirements of the medical device Directives, specifically, the AIMD and MD Directives; however, the Recommendation states that it may also be helpful in relation to IVDs.

Sections 3.2 to 3.5 of the Recommendation provide detailed guidance on the type of information that should be provided for various categories of technical documentation such as product description, technical requirements, design and administrative details.

Section 4 provides a recommended structure of technical documentation, which divides the technical documentation into two parts, Part A and Part B. This approach was also described in a European guidance document on the New Approach Directives¹ and has been widely accepted →



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→ as a method for avoiding excessive paperwork.

Part A consists of a summary of the essential technical data needed to demonstrate compliance with regulations and standards and the relevant parts of the technical documentation from which it is sourced. The guidance states that when technical documentation is to be submitted to a NB, all that is needed, in addition to Part A, is a statement of the manufacturer's Quality Policy and an overview of the quality system, for example, the quality manual. Part A can also serve as the basis for submission to Competent Authorities, including surveillance of devices in Class I, and also as a starting point for responding to questions related to product problems. Some companies refer to Part A as the Technical File or Technical Dossier, however, standardised usage of these terms has not been universally established. Part B consists of the remaining technical documentation. The importance of organising the technical documentation into two parts extends beyond complying with European regulatory requirements, as discussed below.

Global Harmonisation Task Force guidance

The Global Harmonisation Task Force (GHTF) is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry in Europe, Asia-Pacific and North America. A principal purpose of the GHTF is to harmonise medical device regulatory practices through the publication and dissemination of harmonised guidance documents on basic regulatory practices. These documents can then be adopted and implemented by member national regulatory authorities.

GHTF documents are assuming an increasing importance in Europe. For example, the European Commission website http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm, which lists the European MEDDEV Guidelines, refers to a guidance document on regulatory auditing of quality systems of medical device manufacturers on the GHTF site; a link is provided to the GHTF site, which gives general information. However, the GHTF quality auditing guidance documents are found elsewhere on the GHTF site.²

Another GHTF guidance document that, if globally implemented, can have a significant impact on the harmonisation of medical device regulation is the Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED). This document, which is still in the proposal stage, can be downloaded from the GHTF website.³ In Europe, although a formal pilot programme has not been initiated, some NBs are beginning to propose the use of the STED format in the development of the Technical Dossier, which is submitted for assessment of conformity of devices according to the requirements of the relevant Directive. In general terms, the elements of the STED include

- essential principles and evidence of conformity
- device description

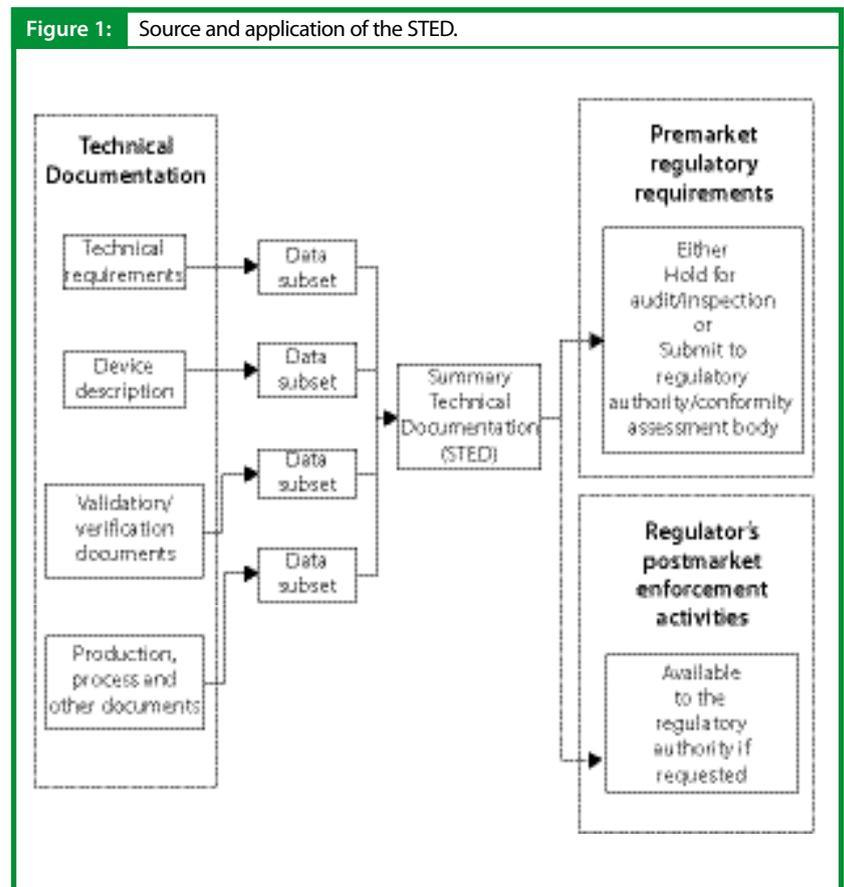
- summary documents of preclinical design verification and validation
- labelling
- risk analysis
- manufacturer information.

These elements are similar to the information listed in Part A of the technical documentation described above. The total technical documentation from which the STED is derived is similar to Part B of the technical documentation. In this regard, readers may find Figure 1, which is taken from the STED guidance document, of interest because it provides an illustration of the relationship between the STED or summary documentation and the total technical documentation, from which it is derived. This relationship is also analogous to the relationship between the Technical Dossier or Part A of the technical documentation and Part B of the technical documentation.

US STED pilot programme

Manufacturers marketing medical devices in Europe may also be interested in a pilot programme that is being conducted in the US. This could provide a means of using the same or similar documentation developed for meeting European requirements in certain types of US submissions. In November 2005, the Food and Drug Administration (FDA) issued a guidance document⁴ that described the extension of a voluntary pilot review programme, Summary

Figure 1: Source and application of the STED.



Technical Documentation (a STED pilot). This pilot programme is being extended to enable FDA to receive an adequate number of submissions to evaluate the STED approach.

The purpose of this programme is to assess the feasibility of using the STED format and content for premarket approval (PMA) applications and 510(k) premarket notification submissions. This programme was described in a previous article.⁵ FDA is encouraging manufacturers who intend to submit PMA applications or 510(k) premarket submissions to participate in this pilot programme. Readers interested in participating should review the FDA guidance document, which specifies which divisions within the FDA Center for Devices and Radiological Health, Office of Device Evaluation, that will participate and the procedures to follow.

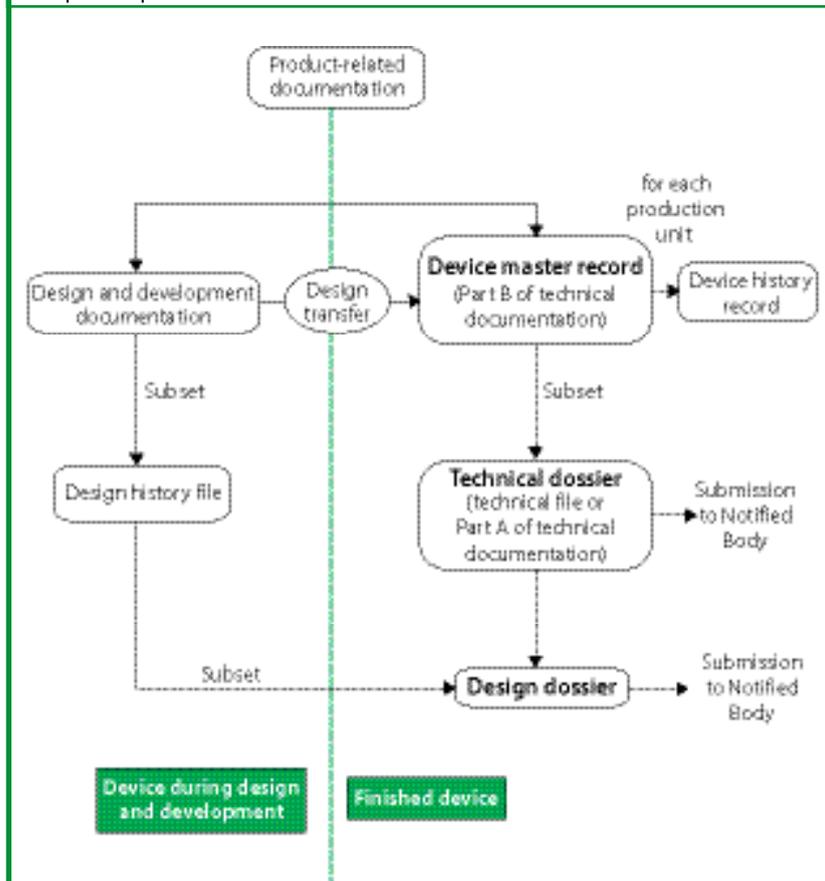
Approaches for avoiding duplication

As stated previously, the development and maintenance of comprehensive technical documentation for demonstrating compliance to medical device regulatory requirements is a resource-intensive, but critically important activity. Although progress is being made to harmonise the requirements for this type of documentation, it has not yet been fully achieved. For this reason, wherever possible, companies

should use techniques for lessening the burden of developing compliant documentation. For example, when the requirements under a regulatory system are more detailed or more stringent than under another system, compliance with the more detailed or stringent requirement will generally ensure compliance with both systems.

An approach taken by some companies in organising the technical documentation that can comply with both European and US documentation requirements is shown in Figure 2. In this case, the device is a high-risk device in Class III under the MD Directive and the company complies with the European harmonised standard for medical device quality systems, EN ISO 13485:2003. The company is also preparing for compliance with US regulatory and quality system requirements. In this example, a Device Master Record, as specified in Section 820.181 of the US Quality System Regulation (21 CFR Part 820), has been developed. It also contains the results of risk analysis, verification tests and validation studies. Therefore, its contents correspond to Part B of the European technical documentation. Other companies may need to develop different approaches to ensure that applicable regulatory requirements are fully met and adapted to their own circumstances. This example is to show only that methods for organising technical documentation to avoid duplication can be developed.

Figure 2: An example of product-related documentation organised to meet US and European requirements.



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