MedTech Europe
from diagnosis to cure

Digitalisation of Technical Documentation

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Introduction

The transition in the European Union (EU) regulatory landscape for medical devices (MD) and *in vitro* diagnostic medical devices (IVD) from the Directives (90/385/EEC, 93/42/EEC and 98/79/EC) to the Regulations ((EU) 2017/745 and (EU) 2017/746) brings with it a large step-up in the volume of documented evidence required to demonstrate the conformity of MDs and IVDs placed on the EU market. With this change comes a significant increase in the density and frequency of data exchanges between key stakeholders, mainly manufacturers, Notified Bodies and Competent Authorities.

The new Regulations and the associated Medical Device Coordination Group (MDCG) guidance documents provide considerably more standardisation for key technical documentation deliverables. Nevertheless, these are structured, controlled, reviewed and audited in a manner analogous to the paper documents that were used when the Directives were written in the 1990s. While the vast majority of manufacturers now manage this documentation electronically, the approved versions of these deliverables are typically exchanged between stakeholders as 'portable document format (PDF) which are functionally equivalent to paper reports. While this type of output was fit-for-purpose under the Directives, it falls short under the Regulations.

Within the defined deliverables of the Regulations, there are many common components that are repeated in multiple parts of the technical documentation, including post-market reports. Examples include Intended Purpose, Benefit-Risk assessment and summaries of Clinical or Performance Evaluation. These common components are reused across multiple outputs, including the Risk Management File, Usability Engineering File, Clinical and Performance Evaluation Report, Periodic Safety Update Report (PSUR), Summary of Safety and (Clinical) Performance (SSCP / SSP) and labelling. This typically results in the substantially manual task of maintaining alignment between these components, while version controlling them at the overarching document level. This is further complicated by the fact that they are often generated, reviewed and edited by multiple individuals at different times. As a result, the common components, which should remain identical, can inadvertently diverge, resulting in findings or non-conformities and thus additional work, time and cost during the technical documentation, change management or post-market assessment activities by the Notified Body and the manufacturer.

The Regulations introduced a fundamental shift by explicitly requiring that risk, benefit, and performance assessments be continually updated using data collected during the post-market phase. This means that the deliverables described above are subject to very frequent changes, as are the common components within them. As a result, manufacturers are faced with the continuous task of compiling and recompiling a very large and ever-shifting dataset into multiple fixed but overlapping reports for the purposes of audit by Notified Bodies and Competent Authorities. Likewise, Notified Bodies are tasked with reviewing these deliverables in many different formats from multiple manufacturers whilst keeping track of changes that may occur in the documentation during the course of the review. This is neither efficient nor desirable nor sustainable in the long term, given the number of devices on the EU market.

The limitations of this traditional approach are increasingly being acknowledged not only by medical devices and IVD manufacturers but also by Notified Bodies. An increasing number of commercial solutions are being offered to the industry to improve the efficiency of Technical Document management. However, these solutions are primarily focused on internal management, vary in approach and lack the standardisation needed for efficient data exchange with Notified Bodies and other stakeholders. These challenges are

intensified when the manufacturer collaborates with two or more Notified Bodies, each with its own reviewers following different approaches to documentation structures and assessment procedures.

Our Proposal

What is needed is recognition that Technical Documentation should be managed at a lower level of quantisation, with version control occurring at the level of the 'common components'. Such components are more technically termed as 'data artefacts' or shortly defined as 'items'. These could then be exchanged between stakeholders and built on demand into the deliverables required by a specific reviewer for a specific purpose, e.g. a PSUR, SS(C)P or potentially an electronic representation of labelling for the user. To achieve this, a standardised format for items is essential, along with a unified nomenclature to identify them, ensuring that they remain system-agnostic when shared between stakeholders.

The concept of managing documentation as individual and independent units of information is not novel but commonplace in other industries. The publishing industry and many actors in the health technology space use Component Content Management Systems (CCMS). Within CCMS, Component Content Authoring (CCA) focuses on creating, managing, and organising content as reusable components rather than static documents. These components can be stored, edited, and reused independently. The information is managed and owned by manufacturers. This approach allows them to efficiently handle version control, collaborate effectively, and streamline updates. It enhances consistency and simplifies the submission of technical documentation for external stakeholders, such as Notified Bodies or Competent Authorities. CCMS is often already used to manage websites, marketing collateral and labelling. However, it does not typically extend to Design History File (DHF) or Technical Documentation management, which usually follows the traditional approach of management and version control at the completed document level using tools such as Microsoft Word or Excel, often in conjunction with general-purpose document control system tools.

A more efficient approach to managing Technical Documentation would involve handling it at the item level, so items could be exchanged and assembled as needed for specific deliverables, such as PSURs, SS(C)Ps, or electronic labelling. This would require standardised formats and nomenclature to ensure system compatibility. MedTech Europe suggests exploring a transition to a harmonised model, separating content from form, to allow documents to be broken down into discrete, version-controlled items, and assembled into standardised deliverables.

This framework should be system-agnostic to ensure compatibility with the various IT tools used by the stakeholders involved. Importantly, such a standardised framework should be available to all stakeholders without financial cost to ensure that it does not represent a barrier to compliance for Small and Medium Size Enterprises (SMEs). Similarly, it should not preclude manufacturers from continuing to maintain Technical Documentation under their current model should they wish to do so.

Benefits of Change

There are several potential benefits for the European medical technologies industry in adopting a standardised CCA framework for Technical Documentation:

Internal efficiency

Implementing CCA has the potential to significantly reduce the manual burden of preparing and managing technical documentation, while at the same time reducing the levels of inconsistency and error. It would also substantially reduce the cost and time associated with creating and sustaining Technical Documentation, which is a particularly important consideration for SMEs. Adopting a standardised CCA framework would introduce a very high level of consistency in the Technical Documentation supplied by manufacturers and, in turn, promote consistency of review between Notified Bodies.

CCA also could potentially facilitate a simplified review of similar or related changes impacting multiple products from a single manufacturer, not just a periodic review. In a CCA model, the Notified Body could record in its system the identity and version of each item reviewed and the date it was done, along with the identity and qualification of the reviewer. Thus, on subsequent reviews, the manufacturer could simply confirm in an exchange file the item elements comprising the Technical Documentation listed by identifier and version number. This would enable a direct comparison of this data with the previous review, immediately identifying the elements that have changed. These, and only these elements, could then be exchanged between the manufacturer and the Notified Body, facilitating a very targeted and rapid review. Furthermore, if the reviewer needed to re-review unchanged elements of the documentation in light of changes elsewhere, they would always have full access to the complete current and historical versions of the Technical Documentation, which would be consistently indexed.

External efficiency

The use of a standardised framework for technical documentation would enable item-level data to be exchanged with Notified Bodies to facilitate both the initial review and ongoing sampling activities. Standardisation and version control at a granular level would assist the reviewer at the Notified Body to quickly navigate the Technical Documentation, immediately identifying changes that had occurred since the last review. CCA also could potentially facilitate a simplified review of similar or related changes impacting multiple products from a single manufacturer, not just a periodic review. This has the potential to significantly reduce the duration of reviews conducted by Notified Bodies, thus reducing regulatory lead times and the associated Notified Body costs.

Analytics and the performance of data items

Manufacturers could gain insights into the data items that have been most effectively reused across products and accepted by Notified Bodies. This analysis could highlight which items are revised most often and which align with content strategy goals, such as reducing translation costs, minimizing rework for errors, managing changes, or simplifying workflows. Similarly, with a standardised framework across manufacturers and Notified Bodies, it would be possible to deduce which data items are most frequently challenged at Notified Body review. This information could be used to further improve efficiency through targeted guidance for manufacturers and reviewers.

Use of further information technology solutions

Documents may need to be provided in the local language, such as the Summary of Safety and Clinical Performance, which can be managed effectively using automated translation tools. By employing a consistent data structure through CCA, duplication is minimised, making translations easier to maintain and enabling effective version control. This method can also support the leverage of AI technologies in the automation of other processes, contributing to the enhanced digitisation of various workflows, such as labelling, GSPR checklists, and others.

Conclusion and Objectives

Implementing a harmonised framework for Technical Documentation can alleviate the practical and cost burdens of compliance on manufacturers and other stakeholders, potentially reducing the impact of MDR and IVDR on EU patients' access to medical devices and IVDs.

- Recognise Benefits: Acknowledge the advantages of a standardised digital framework for Technical Documentation and engage with this evolving area.
- Develop Specifications: Collaborate with stakeholders to create a high-level specification for a digital Technical Documentation framework.
- Evaluate Solutions: Research and assess existing or proposed digital solutions to determine their suitability and utility against the developed specification without recommending any specific software system.
- Develop or Adopt Framework: Work with affected stakeholders to develop or adopt a digital framework model that meets the specification.
- Advocate Adoption: Promote the digital framework as a standardized model for managing and exchanging Technical Documentation.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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