

# Technical Documentation for MedTech companies - Future proof and save Time/Costs



Teams often use MS Word to produce a large percentage of their documents across multiple functions/departments since it is known by many people. Word is a good 'text processing' tool for writing simple business documents/reports, but inefficiencies are introduced when technical teams use it to create long and complex technical documents like technical documents (GSPR, DOC, STED, regulatory documents (TFs, FSCA/FSN, CER/PER, Annual reports like PSUR, SSCP, SSP, etc), user guides, and manuals with embedded data tables and graphics.

Companies are motivated to seek better solutions when they realize that the way they currently create technical documents is not able to keep up with growth in an enterprise's products and growth in life cycle changes (a small change in device description or a part number will lead to hundreds of documents changes and review/approval process instead of applying bulk updates), and growth in publishing formats beyond traditional print and PDF such as XML formats.

The choice for companies is to either increase technical documentation staffing (or required hours within the teams) staffing OR to increase the efficiency of how the documents are produced with modular and structured approach allowing for bulk updates in a controlled manner. Modular approach will also allow to Embed data from excels or databases directly into tables in documents eliminating the need of manual creation of tables and copy/paste scenarios.

## What drives the cost of technical document creation?

One of the largest cost factors in document creation is labor. The amount of labor performed by technical resources is based upon the volume of documents that must be written, the number of technical and regulatory writers available and their efficiency.

## Current trends that increase the volume of documents

A number of factors can increase the volume of documents that an enterprise must produce:

### ***Growth in products and markets***

As an enterprise increases the variety of products and markets it offers, additional technical documentation is needed.

### ***Global growth***

Customers around the world expect technical documentation to be translated to their language and culture.

### ***Interactivity***

Today's customer wants to give real-time feedback on digital content, such as reporting errors in documentation and contributing new content. This requires new in-built mechanisms. Also, users demand that content to be dynamic and interactive in nature, rather than static text and graphics.

### ***Electronic formats increasing***

The number of electronic document formats continues to expand beyond traditional formats like PDF files, and XML formats.

Single sourcing is a documentation methodology that enables you to reuse a modular chunk of information— also called an object - in multiple documents.

## Creating technical documents efficiently

The volume of documents that an enterprise is required to publish will continue to increase. Following that analogy into the documentation environment, we have three basic, inter-related concepts to implement before you can start to achieve 'document manufacturing' efficiencies:

- Data from databases or variables embedded directly into Documents (as part of tables)
- Reuse of content
- Specialization of tools to fit the 'role'

Reuse of content requires writers to think “modular” about how to repurpose content, and how to write reusable content modules.

## Using templates to implement document structure efficiencies

The requirement of reuse forces writers to think about structuring content within a single deliverable and across multiple deliverables.

Companies found that shrinking budgets and increased workloads are motivating content developers to look for ways to reduce development costs. One solution is to reduce the amount of time that authors, especially Subject Matter Experts (SMEs), spend formatting documents. SMEs waste a stunning 30% to 75% of their time formatting documents in non-structured (freestyle) authoring tools. By using structured authoring to enforce consistency, writers don't have to worry about formatting because the styles are applied automatically.

Structure may be thought of as a pattern. Following a pattern provided in structured authoring can speed the creation of content and provide consistent, reusable content.

The reality is that templates are difficult to enforce if authoring tools are not chosen carefully. For example, if templates are set up in Microsoft Word, writers and SMEs can still change the structure and the paragraph styles.

## Using Single Sourcing with Modular Content

Single sourcing is a documentation methodology that enables you to reuse a modular chunk of information also called an object - in multiple documents. First, you build objects such as procedures and tables and put them in source files. Then, you organize them into documents, such as technical documents (GSPR, DOC, IFU, others), and Annual reports (CER, PSUR, SSP, others). Finally, you link them together into cross references such as tables of contents and indexes.

If you change an object, it automatically changes in all the other documents that reference it. Compare this method to the traditional copy/paste, which can be a nightmare to maintain. There are several money-saving advantages to single sourcing:



- Reduced QC/Approval life cycle management costs since chunks of text are reused and therefore not required to go through document life cycle processes. This can be a major cost saving in enterprises that have more than one language to translate to
- Increased consistency of information presented
- Reduced development and maintenance costs and shorter time-to-market efficiencies
- Rapid reconfiguration since small content modules can be rearranged to create something new

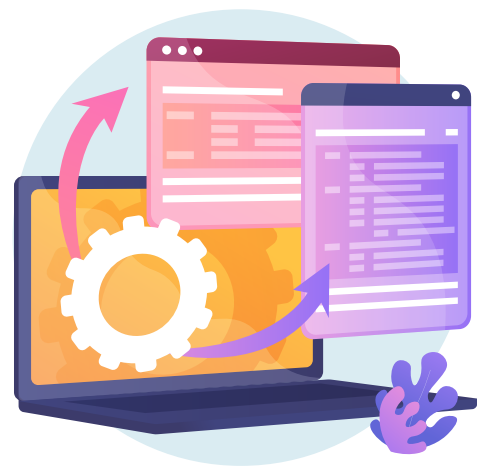
## Using Structured Authoring

Using structured authoring can be thought of as authoring with templates on steroids. The content rules are defined and are rigidly enforced and validated by the software the author is using. For example, content rules define what type of information should follow a heading 1, whether a minimum of two bullets in a list is required, and rules for images and if image captions are required.

With structured authoring, content is completely separated from format, so a writer can focus on writing and not on appearance. This separation allows multiple publishing audiences and delivery formats (PDF, DOC, XML) to be derived from a single source, and increases reuse of topics and modules across product lines.

The single most important reason why so many companies are considering structured authoring is the ability to ‘future-proof’ documents that need to be delivered HA/NB and other agencies.

A good CMS keeps structured content up to date and makes it easy to locate content for reuse and publishing, such as filtering for publishing into different formats.



## Using a Content Management System

Many organizations find that a Content Management System (CMS) can help them manage large amounts of content productively. A good CMS keeps structured content up to date and makes it easy to locate content for reuse and publishing, such as filtering for publishing into different formats.

There are different types of CMSs, but unless you need a specialized type, a component CMS would be a good choice since it manages content at a granular level, as compared to the document or page level that most others use. In authoring, the ability to customize the authoring tool to match the role of each contributor cuts the learning curve and training costs dramatically.

## Using tools that support publishing and reviewing

In addition to the authoring issues we have examined, enterprises need powerful publishing and reviewing capabilities. This is where many tools fall short. The tools must be able to publish to all the required outputs, such as print, PDF documents, online and XML outputs. The tools must also support a full reviewing cycle, where documents can easily be sent to reviewers, reviewers can easily make changes, and their comments can be easily incorporated.

## Using dependable tools

Enterprises demand high levels of dependability in the tools that they use for authoring and publishing technical documentation, regardless of the size of the document, the amount of content it contains or the type of content. Service and support are essential in large enterprises and a large pool of certified professionals for training, writing, consulting and template design needs to be available.

## Conclusion

Word wasn't built to handle the methodologies that enterprises need for efficient creation of technical documentation.

Some organizations have tried to force Word into enterprise-level methodologies by adding plug-ins and proprietary macros. Just as a trucking company would never try to turn a car into a truck because they were designed for fundamentally different purposes, eventually enterprises realize that - no matter how much it is modified—Word was never intended to meet demanding, high-volume technical documentation methodology requirements on an enterprise scale.

Microsoft created Word as a mass market, easy-to-use text processing product for everyday business use. That market is huge in comparison to the market for technical document authoring and publishing tools. The hard truth is that Microsoft isn't focused on your enterprise's technical documentation productivity issues because that market is comparatively so small.

Companies need a professional set of tools specifically designed for efficient technical documentation authoring and publishing.

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