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NAVIGATING THE COMPLEXITIES OF DOCUMENTS IN CMC DOSSIERS

THE POWER OF STRUCTURED DOCUMENTATION

Whitepaper

A study published in the Journal of Pharmaceutical Sciences offers a compelling outlook on the future of CMC regulatory submissions. Researchers predict a shift from traditional documentation to structured content and data management (SCDM) for dossiers. This strategic transition is anticipated to significantly streamline the process of CMC regulatory submissions.

In this white paper, we will explore the challenges organizations encounter with traditional documents, and how adopting SCDM for CMC authoring can result in substantial benefits across various business operations.

DASSAULT SYSTEMES

UNDERSTANDING TRADITIONAL AND STRUCTURED DOCUMENTS

To understand why structured documents are key to CMC authoring, it's essential to first comprehend the definitions and differences between traditional and structured documents. These differences play a pivotal role for those involved in the creation of CMC dossiers or any other CMC-related content.

Figure 1. Classic vs. structured document

Traditional documents

Also called classic documents, have a longstanding history in CMC authoring. Dossiers are often created in traditional document formats such as Microsoft Word documents or PDFs. These documents lack a specific form and freely flow across pages, with formatting cues providing insights into the type of information being presented. For instance, a larger font at the top of a page indicates a title. The entire document is managed as a single entity.

Structured Documents

Rather than being a single monolithic file like traditional documents, a structured document is composed of individual parts. Structured documents in CMC dossier authoring refer to those that adhere to specific formatting and metadata standards. In a structured document, the type of information determines the formatting, rather than the other way around. These documents are machine-readable and designed to enable easy data reuse, extraction, analysis, and comparison.

BREAKING DOWN THE ANATOMY OF A STRUCTURED DOCUMENT

Structured documents are composed of content templates and content types, each serving a specific purpose to maintain material organization. Some common types of content you see in a structured document include:

- **Topics:** These are pieces of reusable content.
- **Data topics:** These topics are generated through data queries.
- **Data tables:** These tables store data and are designed to organize numbers and other characters.
- **Topic elements:** Within each topic are topic elements. Topic elements are blocks of content to which specific formatting rules are applied.
- **Document map:** A document map is an assembly of all topics into sequence and hierarchy. This also makes the document easier for people and machines to read and navigate.

In addition to these elements, structured documents can be published to PDF, Microsoft Word, HTML, etc., depending on their intended use. The rendition will use a publishing style to automatically format the document, eliminating the need for shifting margins or changing fonts when the document is converted into different formats.

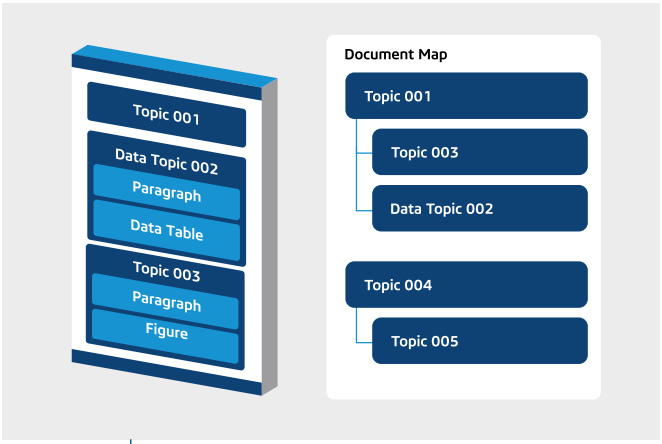

Figure 2. Document map assembles topics into sequence and heirarchy

BIOPHARMA'S CHALLENGE WITH TRADITIONAL DOCUMENTS

Having explored the concepts of traditional and structured documents, it's crucial to recognize the challenges and constraints that the biopharma industry encounters with traditional documents.

Traditional documents are typically produced with tools such as Microsoft Word, which often requires team members to manually update data copies within the document. When multiple people create documents, users have to repeatedly enter the same data in different documents. This often leads to data errors and a lack of consistency.

Formatting is another challenge associated with traditional documents. The effort required to write the document is significant enough; adding to the task of formatting and layout increases the burden. The more you focus on the layout, the less energy and effort you have to put into the content itself. Furthermore, when standards change frequently, formatting becomes even more complex. Updates to standards can impact document structures—such as headings, section markers, and bullet points—making the document difficult to read and disrupting the placement of images and tables. This issue goes beyond aesthetics; it can make the document difficult to understand.

Managing versions and routing processes also pose challenges. In traditional documents, users can only apply versioning and approval to the entire document, not to individual sections or the different documents in which the content is used. Approvals, edits, and other collaborations in document preparation have to be processed in a serial manner, which is a time-consuming method to ensure everyone approves the material. This process also relies heavily on specific client applications for editing and managing documents.

Once the document is finalized, distribution presents another hurdle. When a company distributes documents to its value network, it often results in document duplication and outdated content circulating on the Internet and within customers' storage.

NAVIGATING THE CHALLENGES OF TRADITIONAL DOCUMENT AUTHORING

In addition to the issues associated with traditional documents, the process of creating these documents also has its own set of challenges. Here are some problems that authors often face when crafting dossiers and other types of documents in standard formats:

- Managing the need to repeatedly verify the same data when the narrative around the data changes on a subsequent version.
- Adhering to the stringent quality standards set by health authorities and adapting to new initiatives such as the FDA's KASA drug review program.
- Managing data that is used in multiple areas for filing (e.g., in a stability summary and related sections of the dossier), which can complicate data traceability and control.
- Addressing the issue of disconnection between documents, which can result in valuable data being inaccessible.
- Controlling multiple data sources for documents, a situation that can result in data duplication, overlooked data, or common errors associated with manual input.
- Contending with several factors that increase document complexity such as:
  - The demand for quicker cycle times
  - The introduction of new modalities, like the complexity of new molecules or biologics
  - The inclusion of additional dosage forms, like pediatric dosages
  - The need to make submissions in new territories
  - Changes in suppliers
  - The constant increase in the volume of data
  - Deviations from standard formats and layouts due to ongoing changes

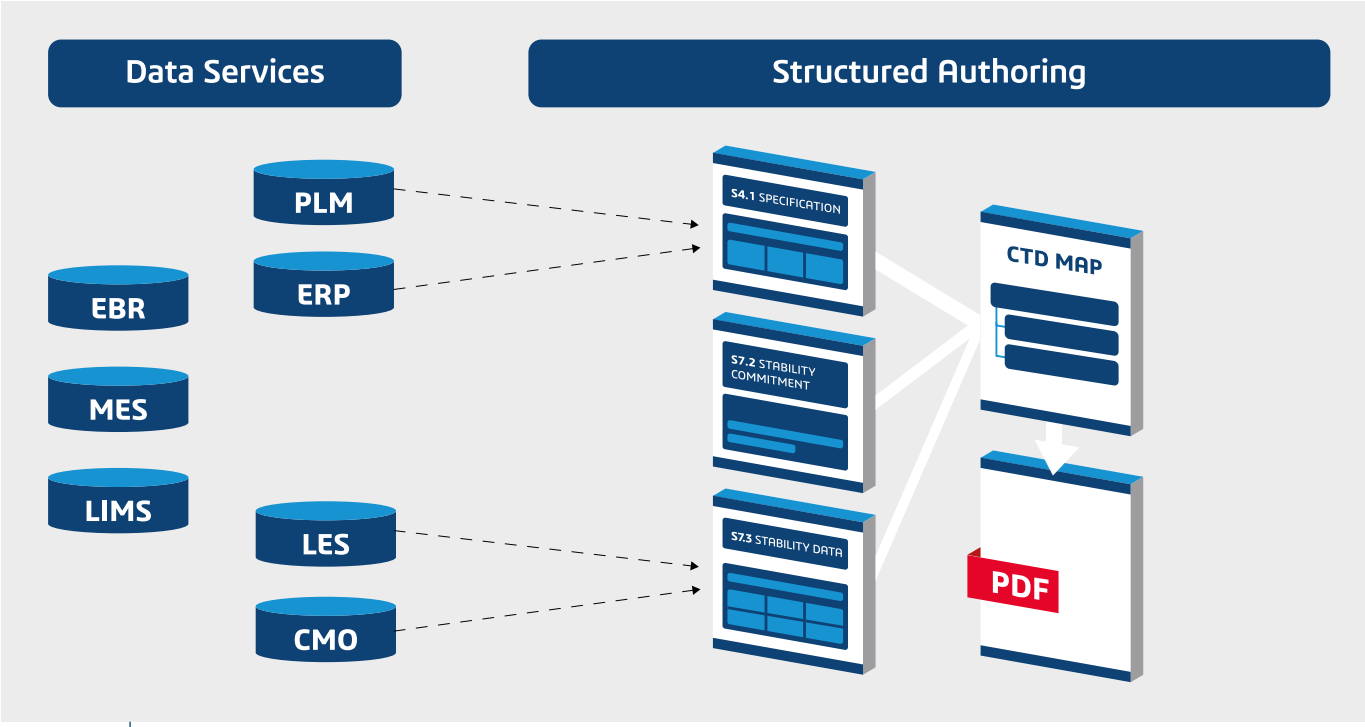

Figure 3. From data to document: What needs to happen

SIMPLIFYING CONTENT AUTHORING WITH STRUCTURED DOCUMENTS

Given the difficulties associated with traditional documents, structured documents have to address the needs of authors. An effective solution must tackle data verification, content re-use, digitalization, and automation in order to be a viable product for CMC content authoring.

Adopting structured documents has many advantages. By moving to an automated approach to authoring CMC dossiers with structured documents, organizations will see benefits in the following areas:

- Minimized review time because structured documents render data re-verification unnecessary.
- Simplified data connection: Either with a direct connection to the data in a data fabric or by importing data from external systems directly into a document table using ETL.
- Accelerated data aggregation: Structured documents include a harmonization layer, like a data lake, to ensure data quality through a unified data model.
- Data centricity, compilation, and traceability.
- Enhanced document quality with improved compliance to regulatory standards.
- Reduced time and cost in document creation—plus decreased time and cost due to simpler edits and reviews with individual modules compared to an entire document.
- Improved collaboration among authors.
- Reduced document duplication and centralized document versioning history.
- Facilitated data and content reuse, which is perfect for internal reports as well as regulatory dossiers in different markets.

Through our research on assisting life sciences companies in enhancing their operations, we've determined the substantial business advantages that most organizations witness when they switch from traditional documents to our structured document solution. Most organizations experience:

- A +$2M cost savings* per dossier. A significant portion of the savings come from reduced time spent authoring documents and particularly the savings in avoiding reverification of data. With structured document authoring, it's much easier to import rich data directly.
- An 80%-time reduction* for stability, batch analyses, and specifications sections.
- A 50% time saving* across the CMC section.
- Right-first-time submissions.

CONCLUSION

Structured documents greatly automate the CMC dossier authoring process, leading to a better experience for authors and significant cost savings. They offer a more standardized and organized approach to presenting information, which can aid regulatory agencies in their review process and facilitate electronic data exchange. Given the multitude of advantages that come with adopting a structured document authoring solution, it's unsurprising that the intelligent document processing market is expected to hit $7.4 billion by 2031.

To learn more about how your organization can benefit from implementing a structured document solution, watch this webinar on how structured documents make CMC authoring easier.

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