BIOVIA

3DEXPERIENCE®

STRUCTURED DOCUMENT MANAGER
TRANSFORMING DOCUMENT AUTHORING FOR CMC SUBMISSIONS
Datasheet

Chemistry, Manufacturing and Controls (CMC) is an integral part of any pharmaceutical product application to the FDA or any other regulatory authority and it is critical to attaining a successful registration filing. A CMC dossier is complex and its preparation requires significant efforts. The information included defines not only the manufacturing process itself but also analytical procedures and specifications for release and stability of the product together with the primary packaging and manufacturing facility and all of its support utilities.

DASSAULT SYSTEMES

THE TRADITIONAL APPROACH

Typically, the information to be included in the dossiers is coming from unstructured data residing in many different systems and applications, and even in paper lab notebooks. The access to this data and information is difficult and time-consuming. Manual transcription for document creation via copy-and-paste is error-prone and leads to inconsistencies and a lack of traceability. It requires (manual!) verification for every single data point to ensure reliability of data.

Document creation is not a one time off. It is an ongoing process. For example, development reports supporting the initial submission of a Marketing Authorization Application are produced over the ten to fifteen years of product development time and still updated post submission. Typically, thousands of pages of documents are created in the context of these reports. For example, the generation of eCTD Module 3 of the CMC submissions that includes product quality related information takes over 7000 hours on average.

Creating a complex CMC dossier requires multiple experts to work on the different parts of the same document. With traditional systems, reports and documents are sent via email, stored on SharePoint or a network drive, or use Google Docs, or Dropbox for sharing. The correct version of the document can be lost or the incorrect version of key documents might be used. For highly sensitive information, this approach is also not secure enough opening the doors for intellectual property theft.

The efforts to create CMC dossiers for New Drug Applications (NDA) or Marketing Authorization Applications (MAA) are so high and include so many non-value adding activities that many organizations have outsourced their creation to specialized consulting firms, which is generating additional costs.

STRUCTURED, AUTOMATED AND COLLABORATIVE

BIOVIA offers a radically new approach to CMC document creation moving away from static documents to a data-centric automated dossier creation. Within BIOVIA Structured Document Manager, documents are represented using a combination of content and data. All data, results and conclusions of the CMC dossier are already included in other systems and can be consolidated in data lakes. CMC documents can be compiled by pulling the data into the authoring tool, reviewing and finalizing it and reusing it in one or more documents.

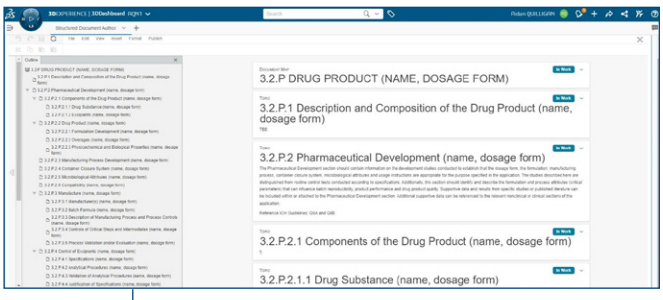


Figure 1: View of a structured document with different topics that different users can edit, freeze or release independently.

Users can now concentrate on content instead on the document preparation. The resulting documents are consistent, accurately structured and of improved quality. This allows users to omit any time consuming and cumbersome reverification of data. Document creation and review becomes substantially more efficient.

Organizations can ensure that new submissions will always include the most up to date content. As the same time it is easy to access any prior versions of data so a version of the dossier that was submitted and approved by the Health Authorities can always be accessed at any point in time.

Structured Document Manager allows online authoring, sharing, editing and live referencing of documents. Users within an organisation and across the value network can create, version and approve documents in an intuitive, collaborative way. The rich web-based authoring experience allows for a truly collaborative development of technical documents.

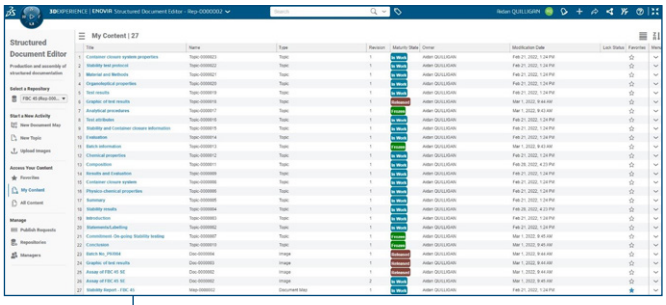


Figure 2: Structured overview of document sections, showing the revision and maturity state, owner, modification date and lock status. This allows easy collaboration and status overview at a glimpse.

Capabilities:

- Author and share documents across a value network chain
- Standardize document content, format and layout
- Automatically update document content in response to events and new data
- Leverage multi-channel publishing to produce PDF, HTML, Microsoft Word, etc.
- Collaborate on document content securely and in a controlled manner
- Provide visibility on the impact of updating content and where content is used
- Standardize report format, layout and appearance
- Re-use common content driving accuracy & consistency
- Leverage flexible data representations with advanced table design & management

GAIN NDA/MAA APPROVALS EASIER AND FASTER

With automated document authoring, Biopharma organizations can create CMC dossiers faster and more accurately. Dossiers will include current and up to date data. The confidence of data quality and integrity allows companies to eliminate tedious manual verification, which provides them with 30 to 70% time savings. Users can easily collaborate in a secure environment where all critical IP is protected.

With BIOVIA Structured Document Manager, organizations can optimize the authoring and management of scientific and medical documents. This will speed obtaining the license approval for a drug product or substance from agency authorities (FDA, etc.), reduce costs and ultimately accelerate time to patient for critical medicines.

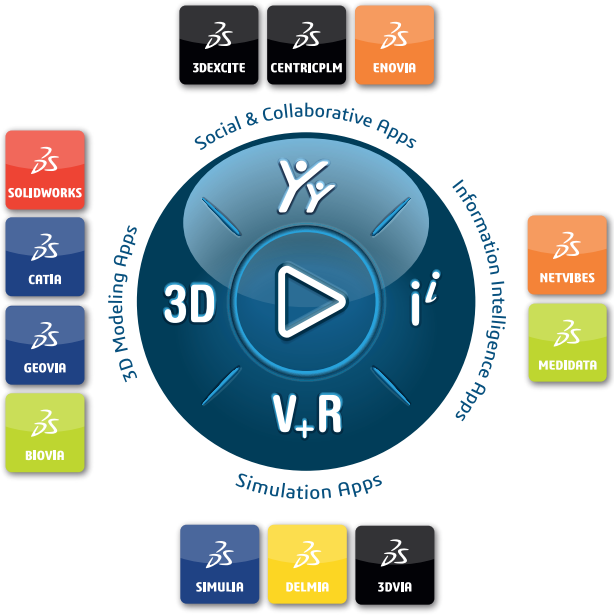
Value

- Accelerate document production by eliminating manual transfer (copy and paste)
- Reduce 80% of time for creating stability, batch analysis and specifications sections for dossiers
- Produce accurate reports through automated document generation
- Ensure current and up-to-date data in new submissions
- Save 30 – 70% of time by omitting manual data reverification
- Maximize transparency through traceability and direct access to source data
- Protect IP with a secure cloud-based collaborative environment
- Reduce time to market

Our **3D**EXPERIENCE® Platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3D**EXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production.

Dassault Systèmes' 20,000 employees are bringing value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit **www.3ds.com**.



DASSAULT SYSTEMES | The **3D**EXPERIENCE® Company

Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA