BIOVIA

3DEXPERIENCE®

QUALITY DOCUMENT AUTHOR

ENSURE REGULATORY COMPLIANCE WITH A ROBUST CONTROLLED DOCUMENT MANAGEMENT SYSTEM

Datasheet

Managing documents can be a complex undertaking, but with the help of a controlled document management system, it doesn't have to be. These systems are instrumental in collecting and safely storing large volumes of data, while also organizing, filtering, and recording permissions and revisions. The result is a robust hub that streamlines workflows, making it easier for regulatory compliance as well as internal processes.

DASSAULT SYSTEMES

The life sciences industry, in particular, benefits greatly from these systems as they help to ensure compliance with strict regulations and standards. With so many types of documents moving throughout an organization—from researchers and clinicians to quality and regulatory experts—it can be challenging to keep everything in order. However, a robust hub that streamlines workflows makes it much easier to maintain accuracy, helping organizations operate smoothly and efficiently.

CONTROLLED DOCUMENT MANAGEMENT CHALLENGES

Life science organizations generate a variety of documents—specifications, protocols, clinical trial data, test results, reports, labeling and more. Managing these diverse document types efficiently is a challenge. Moreover, it's critical to ensure that everyone across the organization works with the latest documents. This requires the controlled document management system to maintain revision control and traceability of changes. It's also necessary to control security to determine who can view, edit, or approve documents. Equally important is the need for everyone to understand document control procedures, which can be accomplished through regular training sessions.

In addition, regulatory requirements are becoming increasingly stringent, demanding more documentation related to permissions and approvals, thereby strictly enforcing regulatory compliance. Each department must present a comprehensive audit trail for both internal tracking and regulatory reviews. However, not all software can provide complete audit trails sufficient for these requirements.

SIMPLIFYING THE MANAGEMENT OF CONTROLLED DOCUMENTS

BIOVIA's Controlled Document Management System strikes a balance between robustness and simplicity, fostering collaboration within teams as well as with external organizations. It is a critical tool in life sciences for ensuring accuracy, compliance, efficiency and adaptability.

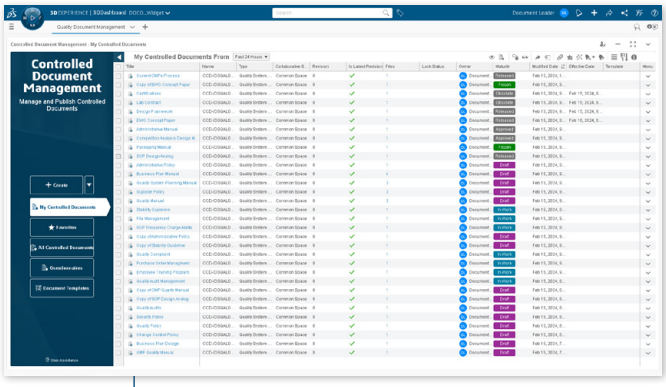

Figure 1: BIOVIA's Controlled Document Management System provides management and consumption of documents.

Designed with the customer in mind, **BIOVIA's Controlled Document Management System** aims to simplify interactions across the platform, while also aiding organizations in complying with applicable requirements and regulations. For example, the **BIOVIA Controlled Document Management System** can provide a record of how activities were performed as evidence of compliance.

Training management helps ensure that employees are familiar with the software and can use it comfortably. Periodic reviews ensure that all documents are kept up-to-date and also guarantee adherence to all necessary processes.

The availability of templates promotes standardization, ensuring that documents adhere to agreed formats and structures. BIOVIA is equipped to handle a diverse range of documents including electronic documentation, photographs, drawings, audio and video, product and defect samples, paint swatches for color matching, checklists, flow diagrams and even blank forms.

EMPOWERING AUTHORS

Controlled document management is just as much for the company as a whole as it is for individual authors. **BIOVIA's Controlled Document Management System** is built to empower authors and users to find the resources they need easily without disrupting workflows.

Authors can filter documents by using multiple criteria to find relevant content and they can access and manage their controlled documents easily using our 3D Dashboard. Whether users need to upload controlled documents or create new ones, the **BIOVIA Controlled Document Management System** helps enforce compliance requirements by managing maturity states and revisions. Change control processes can also be applied to manage the approval and release of controlled documents.

Capabilities

- Manage creation, lifecycle, review, and approval processes of controlled documents
- Achieve formal sharing of controlled documents across the **3D**EXPERIENCE® platform
- Access pre-defined workflows for document creation, review and approval, ensuring adherence to life science industry requirements
- Easily track and manage document revisions

TRUE COLLABORATION

Controlled document management is essential for maintaining compliance, ensuring document quality, secure collaboration and formal consumption and disposals adhering to quality and regulatory standards. The higher the level of transparency, the greater the understanding the team will have, thus enhancing performance and increasing quality.

When each person in an organization operates within their role with the right permissions, it allows organizations to safeguard information integrity, detect process bottlenecks, amplify productivity and endorse role autonomy.

It also ensures that teams are working from the latest accurate information. This fosters better collaboration with other teams and external entities. It also helps secure documents while allowing for signatures, approvals and ongoing training between teams. Using **BIOVIA's Controlled Document Management System**, audit trails can be maintained for all operations performed on controlled documents. This complete audit trail history captures user operations automatically and enables the demonstration of compliant processes to auditors and regulators. In addition, audit trail and eSignatures remain compliant with 21 CFR Part 11.

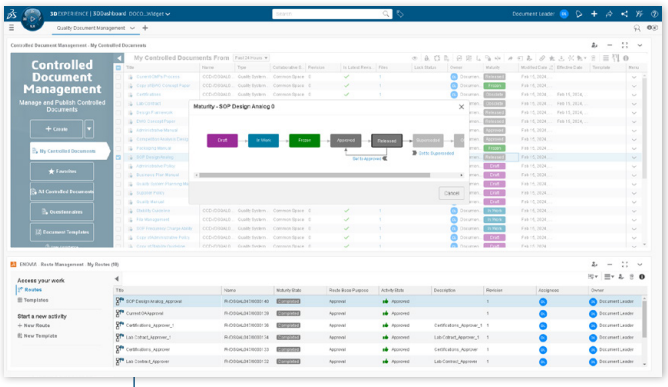

Figure 2: BIOVIA's Controlled Document Management Solution promotes collaboration and standardization.

Value

- Support quality and regulatory compliance with features like audit trails, lifecycle management, access control, and version control
- Ensure most up-to-date version of a document is available, accessible and consumable
- Ensure authorized users can access the documents
- Controlled management of the documents from creation to archiving and disposals that are in compliance with quality and regulatory standards
- Effectively manage document changes and record all operations in the audit trails that enable demonstration of compliant processes to auditors and regulators
- Ensure required individuals are trained formally in compliance with training guidelines
- Automatically update and notify training progress and status
- Minimize errors and enhance productivity by ensuring controlled distribution and consumption that only users with permission can use the document in production
- Ensure the controlled printing of the document usage is in compliance with policy and regulation

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**.

3DEXPERIENCE®

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

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

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