BIOVIA

3DEXPERIENCE®

CONTROLLED DOCUMENT MANAGEMENT

Whitepaper

DASSAULT SYSTEMES

Predicted to reach a market value of USD 44.72 billion by 2030, document control solutions undeniably play a crucial role in the pharma and biopharma industries[1].They manage fundamental operational processes that facilitate drug development, maintain regulatory compliance and ensure product quality.

In the pharmaceutical industry, document control systems provide a robust framework for managing and organizing critical documentation throughout the product lifecycle. These systems are designed to ensure compliance with regulatory standards such as good manufacturing practices (GMP) and good documentation practices (GDP). In the highly regulated sector, where precision and accuracy are paramount, document control systems help companies maintain version control, track changes and establish a secure and auditable repository for essential documents. By centralizing and streamlining document management processes, these systems foster collaboration, mitigate the risk of errors and expedite regulatory submissions. Ultimately, document control systems contribute to the integrity of pharmaceutical operations, supporting the industry's commitment to producing safe, high-quality products that meet stringent regulatory standards.

THE IMPORTANCE OF REGULATORY COMPLIANCE

Document control is essential for biopharma companies to stay compliant with various regulatory and legal requirements. According to research by Deloitte, pharma companies tend to be behind other industries when it comes to adopting technology for compliance, such as document control software[3].

Document control systems often include audit trails that record changes made to documents, detailing who made what changes and when. This transparency is crucial for demonstrating compliance during regulatory inspections and audits. It not only helps make regulatory audits efficient, but also helps build stronger relationships with regulatory bodies. To stay compliant with regulations, document control systems also incorporate archival systems that can be customized to meet retention rules.

Staying compliant is not merely about ticking off regulatory requirements—it is also beneficial for your organization. Beyond fulfilling obligations, regulatory compliance also offers your company advantages, such as:

- Future-proofing your company by staying in step with and even ahead of, legal and regulatory changes and updates.
- Accelerating progress and increasing efficiency and productivity as document control establishes standardized procedures for creating, reviewing, approving and updating documents. This consistent approach ensures that all documentation, including SOPs, protocols and reports, follow a uniform format and meet regulatory expectations.
- Reducing risks and cutting down on errors through appropriate access, required electronic signatures, and audit trails.

MAINTAINING PRODUCT QUALITY AND SAFEGUARDING PATIENT SAFETY

In 2023, manufacturing quality issues were the primary source of pharma supply chain disruptions and drug shortages in the United States[4]. It became evident that product quality doesn't just shape a company's reputation—it also directly impacts patient health. Moreover, such quality issues can set off a domino effect within the healthcare ecosystem, leading to backorders, product recalls and shortages, which ultimately delay patient care.

A key strategy for tackling these challenges is the adoption of a robust document control system. This system, which is central to biopharma companies, directly influences product quality. It includes establishing SOPs, product guidelines and GMP, all under a comprehensive review and approval process. When employees are well-trained in these protocols and adhere to them, the likelihood of errors dramatically decreases. By adhering to document control procedures, employees can contribute to the consistency, safety, efficacy and quality of the products they produce.

Should there be a mishap, features such as document history and versioning within the document control software can help pinpoint the root cause, enabling companies to prevent similar instances from happening in the future.

Interestingly, document control doesn't just enhance product quality; it's also a vital tool in safeguarding patient safety. Effective document control minimizes errors, which in turn reduces the production of poor-quality products and subsequent risks to patients. It aids in identifying product batches that might need to be recalled before reaching patients and ensures the necessary quality checks have been performed.

Furthermore, patient safety isn't limited to the physical product; it also encompasses privacy and data security. Document control systems maintain data integrity and confidentiality by restricting access to sensitive information, ensuring only authorized personnel can view or modify critical documents. This practice supports data privacy and meets regulatory requirements like HIPAA. Therefore, by integrating product quality maintenance and patient safety measures through document control, we can significantly mitigate supply chain disruptions and enhance patient safety simultaneously.

SUPPORTING DRUG DEVELOPMENT

For pharma and biopharma companies, an effective document control system is crucial throughout the entire process—from drug development to manufacturing and distribution. At every stage, employees are working with real-time data and using an approved set of documents. This not only safeguards information integrity but also fosters and streamlines collaboration for faster drug development. Electronic signatures and automated workflows further accelerate development processes for biopharmaceutical products.

Document control can also support drug development by providing insights into continuous improvement and change management. When each step of the manufacturing process is accurately recorded and approved with document control software, companies have the opportunity to improve their product and processes. They can identify process bottlenecks, pinpoint employees who may need additional training and speed up drug development.

A prime example of this is PTC Therapeutics, a pharmaceutical company specializing in the development of orally administered small molecule drugs and gene therapy. During its rapid expansion, the company encountered growing pains. One of their barriers to success was the large amount of time employees spent manually searching for key information in documents, submissions, reviews and company correspondence. This process delayed company responses and slowed critical decision making.

PTC Therapeutics worked with a consulting firm to implement a document control system[5]. As a result, the document control software helped PTC Therapeutics reduce processing time by 30–50%, as well as decreased IT costs for targeted programs by 35%. These gains helped employees better focus on drug development, rather than spending time going through emails to manually confirm approvals, reviews and process changes.

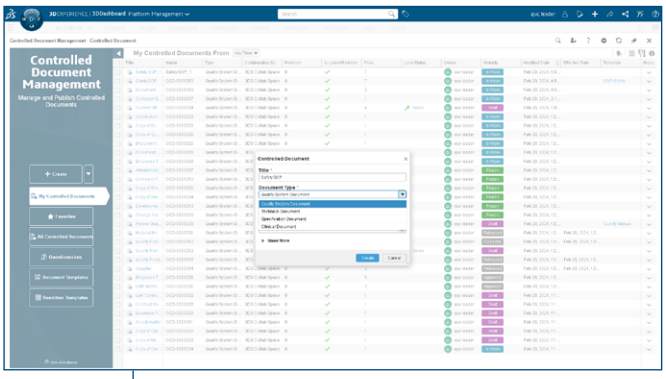

Figure 1: Create a new controlled document from the home page

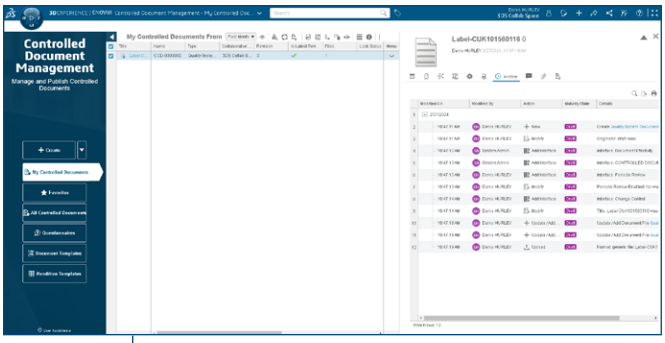

Figure 2: Display the audit trail of controlled documents

BIOVIA'S SOLUTION

BIOVIA understands that document control is essential for biopharmaceutical companies. Document control underpins product development, regulatory compliance, patient safety and product quality. That's why our solution was made specifically to help companies manage documents securely and provide the flexibility to meet your company's workflows and permissions.

Our document control solution includes benefits such as:

- Workflow management of controlled documents via process steps
- Flexibility with control – release/revise-controlled documents with enterprise or simplified change control
- on our **3D**EXPERIENCE Platform
- Electronic signature approval for relevant actions
- PDF rendering with a standalone monitoring service
- Periodic document reviews to routinely review for continued document validity
- Hardcopy management for paper documents
- Template-based document creation
- Robust and trackable change control process to release/revise controlled documents with Electronic Signatures
- Document and its metadata are made available in controlled readable mode
- Controlled access and contextualization based on permissions and classifications
- Controlled archival/disposal/recovery based on retention period rules

LEARN MORE

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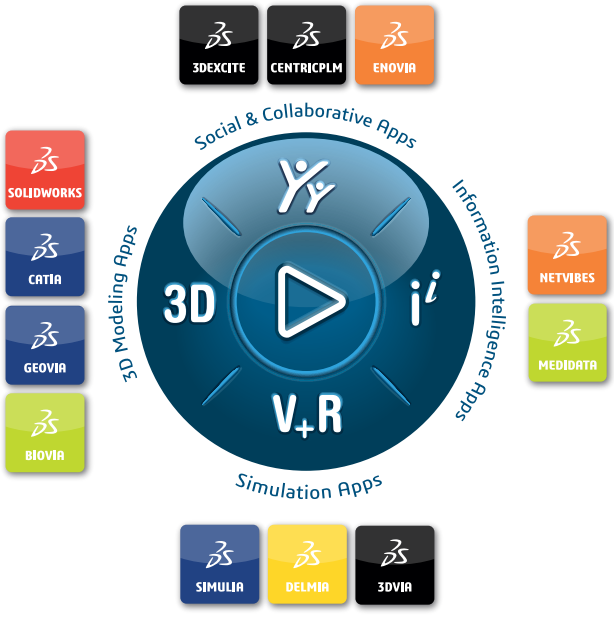

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