BIOVIA

3DEXPERIENCE®

ANNUAL PRODUCT QUALITY REVIEW REPORTING

UNLOCK THE HIDDEN POTENTIAL WITH STRUCTURED DOCUMENT AUTHORING

Datasheet

Navigating the regulatory landscape is a complex task for pharma companies, particularly when it comes to the mandatory Annual Product Quality Review (APQR). This process, which must be conducted at least once a year, is long and complex, requiring periodic updates focused on continuous improvement. It also calls for seamless collaboration between departments, which can exacerbate the potential for errors.

To streamline this critical yet arduous aspect of pharmaceutical production, BIOVIA has developed a solution. Our Structured Document Authoring – APQR solution accelerates document production and reduces the manual efforts required to meet compliance regulations. BIOVIA's approach also prioritizes content rather than document preparation, enhancing overall productivity.

DASSAULT SYSTEMES

CHALLENGES POSED BY APQR REQUIREMENTS

APQR reports often include a substantial amount of highly technical data from various sources. Interpreting these diverse data sets and trends requires collaboration across teams and input from experts who have a deep understanding of the multiple variables and subsequent implications. As a result, due to the depth and breadth of information, analyzing and interpreting content for APQRs may take several weeks or months to complete.

Further, collating information from diverse areas leads to larger document sizes. For example, APQRs can range from 100 MB to several gigabytes in size, which makes them cumbersome to handle, share, and store.

The cyclical nature of APQR review demands a quick turnaround, which can take significant effort. Pharma companies must establish and maintain reliable processes for year-round data collection, analysis, and documentation. In addition, continuous updates and revisions between annual reviews can demand monthly or quarterly attention.

INCREASE ACCURACY, COMPLIANCE, AND SPEED

BIOVIA's Structured Document Authoring – APQR solution addresses each of these challenges. This application optimizes regulatory compliance, reduces costs associated with APQR generation, and expedites time-to-market for pharmaceutical products.

Key features include automated data integration and standardized reporting formats. Users can produce high-quality documents that are accurate and aligned with regulatory standards.

The software also incorporates version control and access to previous revisions, providing increased transparency and traceability. These features can be crucial for audits, regulatory inspections, and maintaining a clear audit trail.

Moreover, the platform's collaborative authoring and referencing features foster efficient communication across departments. With enhanced collaboration, teams and relevant stakeholders can identify and address quality issues promptly.

With these and other features designed to improve operational efficiency, such as automated data integration and document preparation, users can streamline their APQR data compilation and review while minimizing errors.

VALUE

- Efficiency gains
- Faster regulatory compliance
- Improved data accuracy and consistency
- Enhanced collaboration
- Increased transparency and traceability
- Improved document quality
- Cost reduction
- Positive user feedback

CAPABILITIES

- Data-centric approach allows for the representation of documents using a combination of content and data
- Automatically update document content in response to events and new data
- Ability to standardize document content, format, and layout
- Enhanced collaboration with online authoring, sharing, editing, and live referencing of documents
- Support for version control and easy access to prior versions

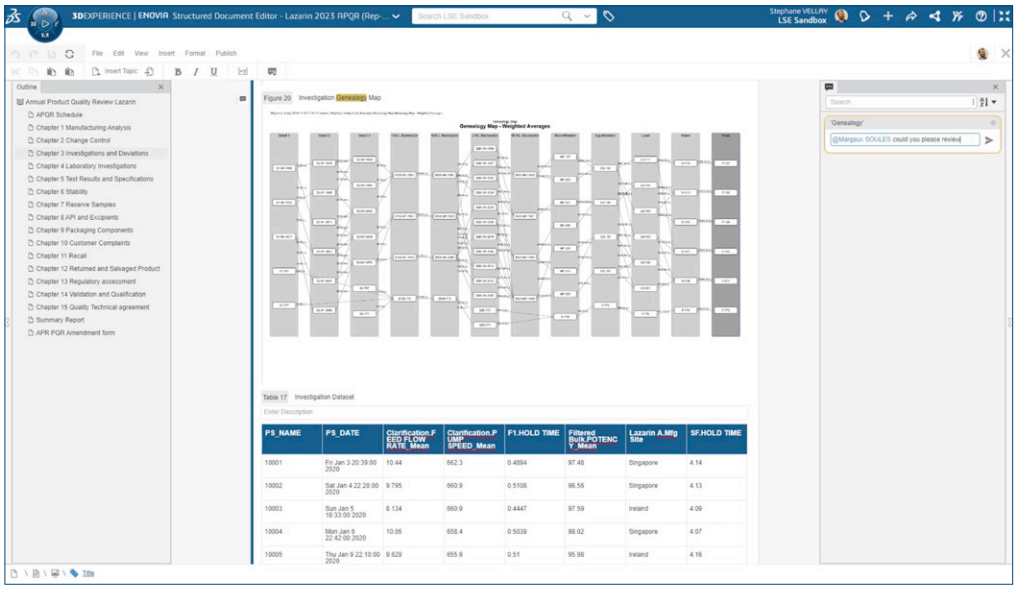

Figure 1: BIOVIA's Structured Document Authoring – APQR solution includes features such as online authoring, sharing, editing, and live referencing of documents to promote effective and timely collaboration between all stakeholders.

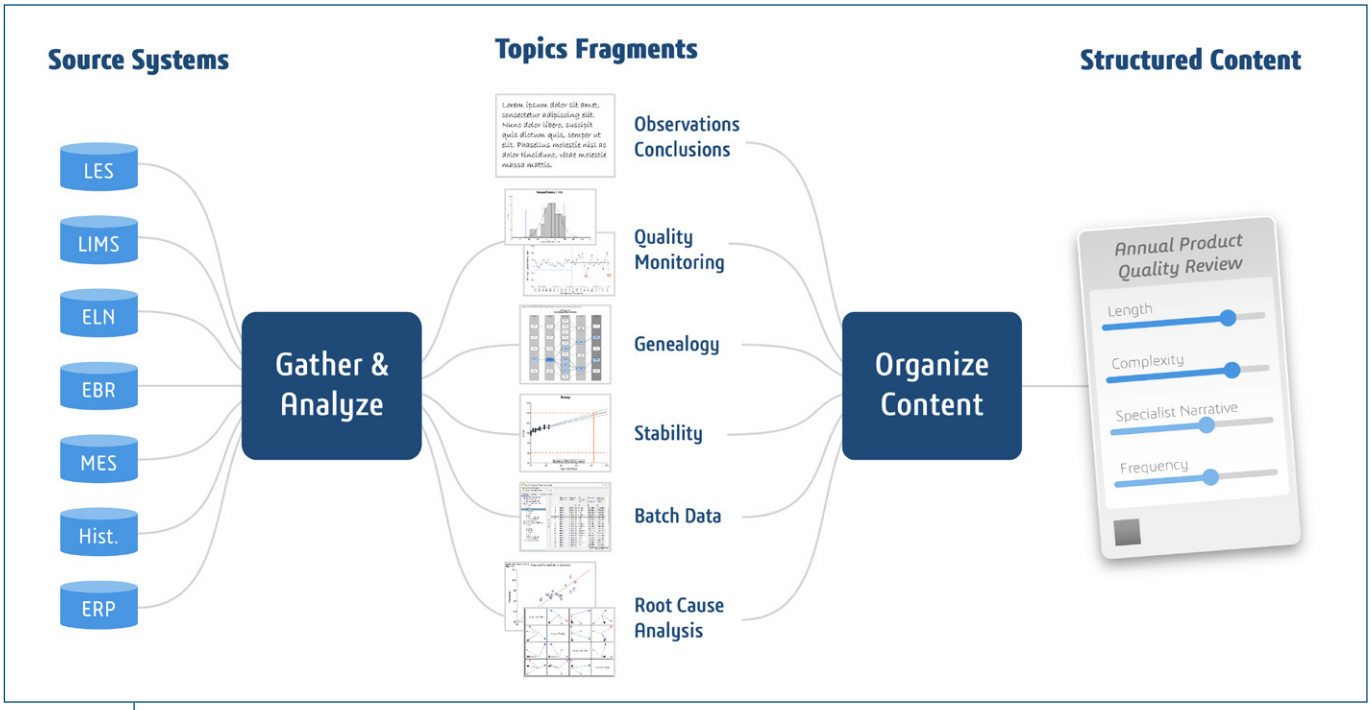

Figure 2: The Document Initialization tool makes it easy to search for and find data, thus reducing the costs associated with file organization

FOCUS ON CONTENT, NOT DOCUMENT PREPARATION

The APQR – Structured Document Authoring system supports a data-centric approach, facilitating the efficient creation of data-rich documents. It provides users with the tools to standardize the layout, format, and content of their documents.

Additionally, the BIOVIA solution allows users to expedite the initial setup and cut down on time spent organizing sections and data. The platform's versatility further enables users to utilize the modularity of document fragments and automatically update document content as events unfold and new data emerges.

Furthermore, all data is securely stored in a cloud-based environment. With all these features combined, BIOVIA's Structured Document Authoring – APQR stands out as an efficient and reliable solution for managing and standardizing document structures.

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