THE PLAYBOOK FOR STREAMLINED APQR GENERATION

A how-to guide for leveraging the power of artificial intelligence to optimize the creation of Annual Product Quality Report (APRQ) Generation.

STRUCTURED CONTENT AUTHORING REIMAGINED

In today's pharmaceutical industry, the practice of structured content authoring is becoming increasingly critical. This approach, which involves organizing content according to specific schemas or templates, is essential for companies as they prepare their Annual Product Quality Reviews (APQR) in compliance with regulatory guidelines. Unlike more conventional, unstructured methods of content creation, structured content ensures a consistent and standardized presentation across all documents, regardless of their complexity or size.

Structured content authoring organizes information into clear, distinct units, enhancing the ability to reuse, localize and adapt content across multiple platforms and channels. Using this approach, pharmaceutical companies can streamline their organizational processes, alleviate challenges such as miscommunication or errors and foster an environment of continuous improvement.

In this eBook, we'll uncover how pharmaceutical companies can unlock the full potential of machine learning in combination with transformative, data-centric structured content authoring solutions.

APQR FAST FACTS

From **100 MB to several gigabytes** in size

Average of **3 MONTHS** to prepare a manual APQR report[1]

Reports conducted **EVERY YEAR**[1]

SEAMLESS APQR GENERATION AND CONTENT MANAGEMENT

APQR plays a vital role in ensuring regulatory compliance within pharmaceutical production pipelines. These reports systematically evaluate quality, data and manufacturing processes to ensure consistency and reliability of pharmaceutical products throughout their development and market lifecycle.

APQR reports integrate data from multiple sources and require collaborative efforts across departments and input from experts well-versed in the subject matter. In addition, APQR content typically involves large volumes of data, with file sizes ranging from 100 MB to several gigabytes.

The extensive data contained within APQR reports means that their analysis and interpretation can take weeks or months. Given the annual requirement for these reports and the demand for quick turnaround times, organizations must establish streamlined processes for data analysis, documentation and compilation to manage updates and revisions effectively.

Integrating APQR into structured content management systems can enhance regulatory compliance, improve data integrity and streamline documentation processes. This efficient approach not only conserves resources but also promotes a culture of quality and compliance, accelerating the time-to-market for pharmaceutical products.

As Structured Content

- ✓ Easier to navigate
- ✓ Seamless integration of data sources
- ✓ Supports regulatory compliance
- ✓ Ensure timely completion

THE REALITY OF NON-COMPLIANT APQRS

In 2021, the FDA:

Issued **149 warning letters** across compliance programs

Delivered **101 facility inspection classification letters**

Issued recalls for **290 drug products** across classes[2]

COMPLIANCE, EFFICIENCY AND SPEED WITH MACHINE LEARNING

Creating high-quality scientific documents, such as APQRs, is complex and time-consuming. The traditional approach of manual data entry and collaboration among experts renders the process susceptible to errors and delays. **BIOVIA's Structured Content Authoring** tool introduces a shift in the way document creation is approached, by automating processes to ensure data consistency and integrity.[3]

This comprehensive tool simplifies every stage of the APQR process, from data gathering to meeting regulatory compliance. BIOVIA's Structured Content Authoring also improves the quality of documents, streamlines communication and fosters seamless collaboration among parties, making the document creation process more accessible.

THE VALUE OF BIOVIA DISCOVERANT

- Automated data aggregation and contextualization
- Large variety of data queries, analysis, and visualizations
- Self-service data access
- Cloud-based data exchange
- Automated report generation
- FDA compliant

AI: THE KEY TO FASTER, MORE EFFICIENT DRUG DISCOVERY AND DEVELOPMENT

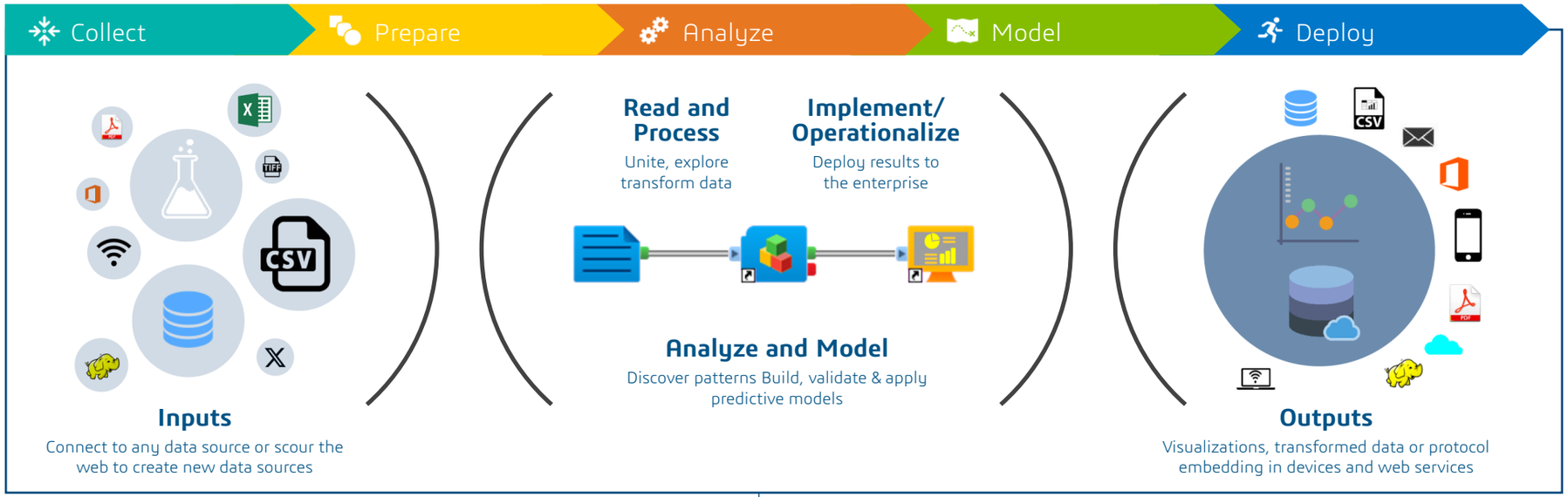
Artificial intelligence (AI) and machine learning can revolutionize drug discovery and development by integrating the **Structured Document Manager** with **BIOVIA Pipeline Pilot**, which deploys data-driven R&D operations to enable cross-functional collaboration.[4]

BIOVIA Pipeline Pilot is versatile, supporting existing data science workflows and introducing new, integrated solutions that enhance functionality. It simplifies generating documents from collected data, minimizing manual verification efforts.

Additionally, **BIOVIA Pipeline Pilot** automates the conversion of data and other content into standardized formats, which are categorized by information type. This approach can increase accuracy and improve consistency in reporting.

Integrating Structured Document Manager with **BIOVIA Discoverant** enables users to accelerate the delivery of therapeutic products while reducing costs.[5] **BIOVIA Discoverant** offers a robust platform for comprehensive analysis – whether descriptive, diagnostic or predictive – alongside plotting capabilities.

With BIOVIA's suite of products, all data is centralized within a shared and secure repository. Its cloud-based system automates the creation of documents based on data type, reducing manual data entry. What's more, it efficiently manages all stages of document development, from creation to release, ensuring accuracy and consistency throughout the research process. Users can adjust the data according to their specific methods, parameters and display preferences. **BIOVIA's Pipeline Pilot** takes user convenience one step further by filtering data based on parameters like product, study, conditions or timepoints.



BIOVIA Pipeline Pilot

INDUSTRY SPOTLIGHT

A mid-sized pharmaceutical company in Japan, which manufactures drug products for cardiovascular, oncology and neurology conditions, adopted BIOVIA's Structured Content Authoring and achieved superior results. Overall, this customer was able to:

- Reduce time creating dossiers by 80%[3]
- Reduce costs by $2M+ per dossier[4]
- Reduce root cause investigation process from 1 month to 1 hour[5]
- Save 30–70% of time creating reports and reverifying data[3]
- Maximize transparency and traceability[3]
- Speed time to market with 87% reduction in materials use during development[5]

CONCLUSION

BIOVIA's Structured Content Authoring tool effectively tackles the complexities and inefficiencies associated with traditional APQR processes. By offering features such as automated data integration, standardized reporting formats, version control for transparency and capabilities for both collaborative authoring and online editing, this application simplifies the demanding document production process. It achieves this through the use of standardization, modular fragments, automatic content updates and secure cloud-based storage.

When integrated with the AI-driven capabilities of **Discoverant** and **Pipeline Pilot** solutions, pharmaceutical companies can boost regulatory compliance, reduce costs associated with report generation and expedite time-to-market for their pharmaceutical products.

REFERENCES

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