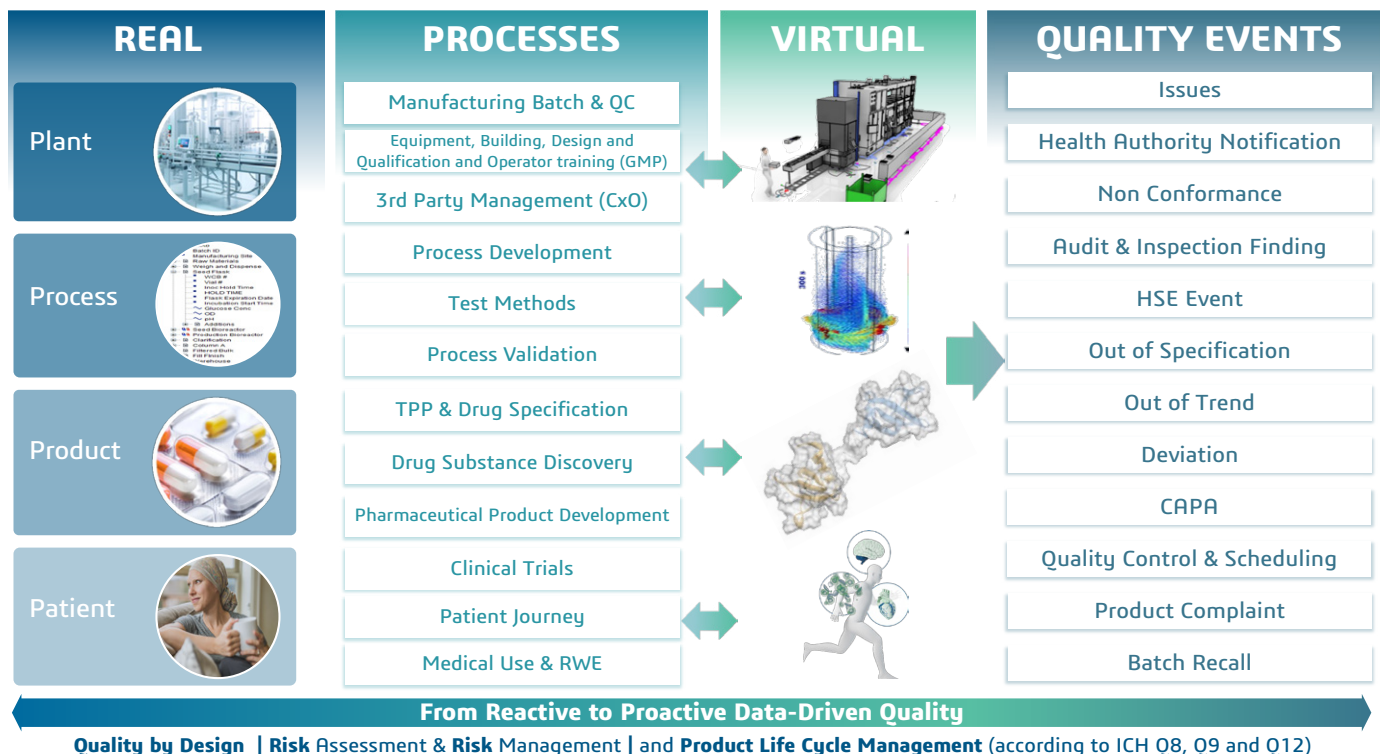


AI-POWERED BIOPHARMA QUALITY MANAGEMENT HARNESSING VIRTUAL TWINS FOR A COMPREHENSIVE END-TO-END SOLUTION

Datasheet



TOWARDS TOTAL QUALITY | VIRTUAL GUIDES AND INFORMS THE REAL



INTRODUCTION

In the fast-paced biopharmaceutical industry, maintaining product quality and safety is paramount amidst complex supply chains, strict regulatory requirements, and rapid market demands. Regulators require quality management processes for product approval, emphasizing predictability in manufacturing and frequent reviews to enhance yield and minimize errors. As products mature, data analysis often becomes cumbersome and error-prone.

BIOVIA's Biopharma Quality Management enables companies to efficiently manage quality across the enterprise. It generates accurate KPIs using reliable workflows, analyzes captured data insights, and auto-generates metric reports, thereby fostering GxP compliance. Moreover, BIOVIA's **3DEXPERIENCE®** platform seamlessly integrates the virtual twin experience of the Plant, Product, Process with real-world data.

LEVERAGING VIRTUAL TWINS FOR ENHANCED EFFICIENCY AND INNOVATION

New advancements in technology have revolutionized the way we approach critical operations such as manufacturing batch and QC process development, drug discovery, and clinical trials. The creation of virtual twins—digital replica of these processes—allows us to simulate real-world operations and identify areas for optimization. These simulations provide an unparalleled level of scrutiny that cannot be matched by traditional methods. They allow us to experiment with new ideas and identify potential

problems before they arise in the real world. By harnessing the power of these virtual simulations, we can optimize our processes to be more efficient, cost-effective, and innovative.

Understanding the virtual twin of a process enables users to shift from reactive to proactive quality management. It promotes Quality by Design (QbD) when developing the product and process (ICHQ8), advocates for a risk-based approach (ICHQ9), and streamlines change controls through seamless product lifecycle management (Q12).

BIOVIA's solution goes beyond managing quality events such as audits, CAPAs, and complaints. Leveraging the insights gained from the virtual twin experience in biopharma can predict and mitigate the frequency and severity of these events.

SIMPLIFIED, STANDARDIZED AND COLLABORATIVE ANALYSIS

BIOVIA's Biopharma Quality Management uses data to provide insights on patterns and potential trends. Unlike point solution quality management, we link the original issue to the solution, thus providing comprehensive reporting. This singular platform streamlines access to records, allowing users easy retrieval of details pertaining to impacted items, contributors, and change history of full reports.

With just a single click, users can filter and sort through "likely similar records," facilitating analysis of comparable instances.

Issues are interconnected across all processes, making it easier to trace the cause-and-effect relationship. The Analyst application is equipped to support custom packages of customer-specific process models. It conducts analysis across both current instances and historical data, feeding the output uniformly. This ensures seamless and efficient quality management.

WHY CHOOSE BIOVIA BIOPHARMA QUALITY MANAGEMENT

The Quality Management feature on **3DEXPERIENCE®** has unique capabilities including:

- **Comprehensive Quality Assurance:** It provides end-to-end quality management for clinical, manufacturing and medical devices, making it useful for hybrid biopharmaceutical companies.
- **Business Applications Integration:** It has the capability to link with line-of-business applications on **3DEXPERIENCE®**, promoting a digitally connected experience.
- **Connection to Execution Processes:** It can connect the actual execution process with the quality management system through a virtual comparative analysis.
- **Customization and Standard Processes:** It can utilize both out-of-the-box processes and customers own configurations, both treated equally.
- **Legacy Data Handling:** It has the ability to integrate legacy data and present it alongside new quality processes.
- **One Lab Integration for Lab Analysis Systems:** It can incorporate lab analysis systems for QC or Development Labs
- **Electronic Signature for Workflow Tasks:** It supports change approval and issue closure workflow tasks through the use of electronic signatures.

These capabilities allow customers to:

- Move from corrective to preventative actions
- Adopt a model-based approach to drive AI
- Leverage legacy processes to predict and prevent new issues
- Augment the decisions of the quality department with AI driven insights
- Mirror the real-world with a virtual twin that is quality focused

CONCLUSION

BIOVIA's Biopharma Quality Management offers a unique set of capabilities that enable companies to move from corrective to preventative actions, adopt a model-based approach to drive AI, leverage legacy processes to predict and prevent new issues, augment the decisions of the quality department with AI driven insights, and mirror the real-world with a virtual twin that is quality focused.

These capabilities are especially beneficial for hybrid biopharmaceutical companies, who need to manage the quality of their products and processes across a wide range of disciplines. By linking the Biopharma Quality Management feature to the line of business applications on **3DEXPERIENCE®**, companies can create a connected digital quality system that provides visibility and insights into all aspects of their operations.

This powerful solution can help companies to improve their product quality, reduce costs, and accelerate time to market.

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

Dassault Systèmes, the **3DEXPERIENCE** 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 **3DEXPERIENCE** 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™