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BIOVIA DISCOVERANT: THE ENGINE OF MANUFACTURING ANALYTICS

GLOBAL BIOPHARMA IMPROVES PRODUCT PURITY & REDUCES COSTS

Use Case

DASSAULT SYSTÈMES

Challenge:
Non-value-added activities of data compilation and contextualization; tedious risk assessment inhibiting cost containment; keeping treatment prices affordable for patients in need

Solution:
BIOVIA Discoverant as the engine of Manufacturing Analytics for the Predictive Plant

Results:
- Decrease non-value-added activities by 75%
- Reduce dashboard creation from four weeks to immediate, on-demand generation
- Compare data between sites and products
- Effectively monitor CMOs
- Spend more time on data interpretation, optimization and improvement
- Understand how to achieve the "Golden Batch"

CUSTOMER: A GLOBAL BIOPHARMACEUTICAL COMPANY

This multinational biopharmaceutical company is one of the 20 largest manufacturers of therapeutics, serving millions of people worldwide. Their goal is to serve the needs of patients wherever they are by leading in innovation and putting the patient at the center. The organization seeks to innovate through digital science while also leveraging partnerships and conducting its business in a sustainable way to help ensure people and product safety. They also focus on strengthening internal controls, providing rigorous compliance and risk management and establishing a structure that supports rapid and transparent decision-making.

CHALLENGE: NON-VALUE-ADDED WORK INHIBITING DEEP DATA INSIGHTS

Following several mergers and acquisitions, this customer must manage diverse brands, multiple facilities for different drugs and an increasing amount of data from disparate online and offline sources. In this environment, process monitoring and trending for Continued Process Verification (CPV) were extremely laborious tasks requiring manual data compilation and contextualization resulting in 80% non-value added activities (e.g., the continuous streaming of data from online sources with no batch context). As these data spanned long timeframes, it was very resource-intensive (time, people, money) to establish the relevant time window. Individuals were not able to spend their time on the interpretation of data and improvements required by the business.

Also, the dashboard creation for risk assessment was a time-consuming process. It required further manual compilation of data from multiple sources and calculations. The multiple transcriptions of data and information introduced high potential for error. These monthly and quarterly dashboards required over 100 tables and charts in Excel and PowerPoint. As all data were manually transcribed for each product, site and Critical Quality Attribute (CQA), it would take as long as a month to prepare a single dashboard.

These inefficiencies resulted in higher costs while also making it difficult to provide affordable treatments for patients in need.

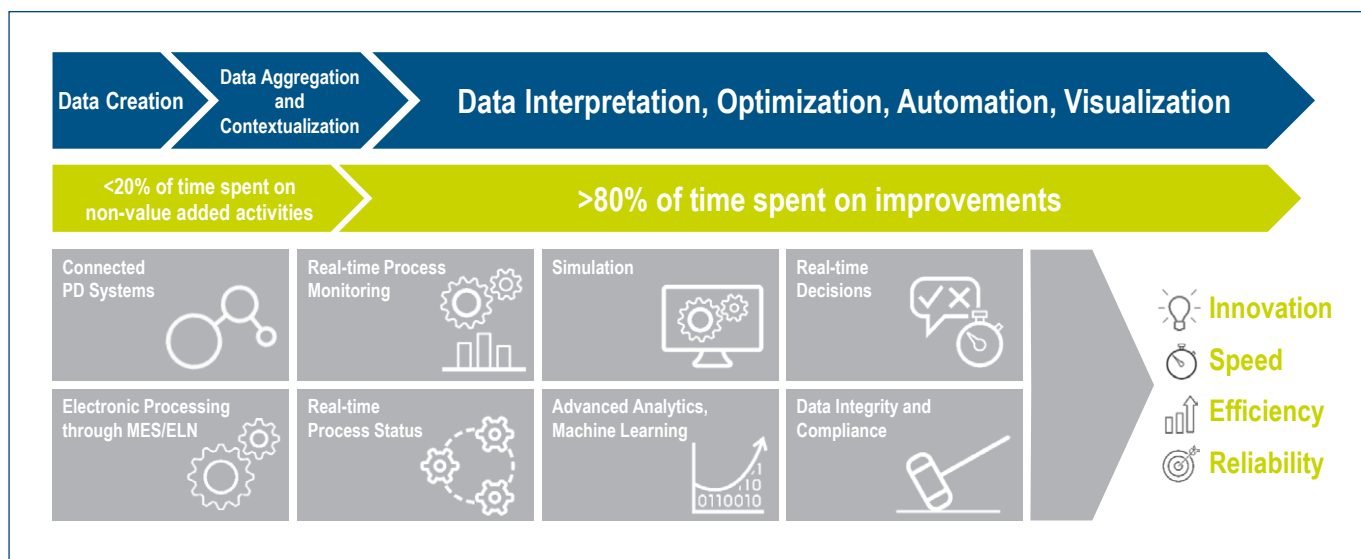## SOLUTION: BIOVIA DISCOVERANT AS THE ENGINE OF MANUFACTURING ANALYTICS

The customer implemented BIOVIA Discoverant to access data from online and offline sources and to feed other systems with data. Discoverant is the customer's automated manufacturing analytics tool for extracting and contextualizing data in support of the company's digital science and manufacturing informatics strategies.

Offline data consolidation includes data from the Quality Management System (QMS), Laboratory Information Management System (LIMS), Enterprise Resource Planning (ERP) System and the Manufacturing Execution System (MES). Discoverant also collects non-electronic data through compliant data entry facilitated by BIOVIA's Paper Record Input Manager (PRIMR). In addition, Discoverant amasses offline data from Contract Manufacturing Organizations (CMOs) and from the global marketplace. Online data flows from OSIsoft's PI system, which is connected to equipment on the manufacturing floor. Discoverant serves as a source system for Sartorius Stedim Biotech's SIMCA as well as Qlik's QlikView dashboarding platform. Both systems can leverage Discoverant's contextualization capabilities while also allowing access to critical metadata.

Another key aspect of the solution is more operational than technological: improved governance. Using Discoverant, the customer has been able to standardize fundamental terminology and calculations for manufacturing risk, yields, process efficiencies and other key performance indicators (KPIs).

Today, the company has created more than 60 Discoverant process or product hierarchies comprising over 45,000 parameters which allow them to trend critical parameters and react to adverse events before losing a product lot.

The company's goal to help patients in need requires minimizing cost increases for life-saving treatments with a view to keeping them affordable. They need to manufacture and monitor against the "Golden Batch" and drive down costs while increasing yield and purity. Therefore, the customer is also leveraging Artificial Intelligence (AI) to move from the "connected plant" to the "predictive plant" where proactive analytics across plants, multivariate analysis and AI with real-time data allow them to maximize innovation, speed, efficiency and reliability.

Data Creation	Data Aggregation and Contextualization	Data Interpretation, Optimization, Automation, Visualization
	<20% of time spent on non-value added activities	>80% of time spent on improvements

Connected PD Systems	Real-time Process Monitoring	Simulation	Real-time Decisions
Electronic Processing through MES/ELN	Real-time Process Status	Advanced Analytics, Machine Learning	Data Integrity and Compliance

- Innovation
- Speed
- Efficiency
- Reliability

A true data-driven enterprise will minimize non-value added activities. The ability to focus on data interpretation and optimization can improve innovation, speed, efficiency and reliability.

RESULT: IMPROVED PRODUCT PURITY AND YIELD WHILE MINIMIZING COSTS

With the implementation of BIOVIA Discoverant, the customer has been able to reduce non-value-added activities for data preparation. People now spend 80% less time locating, aggregating and manually contextualizing data, allowing more time for data interpretation, optimization and improvement. This savings means more time to learn from data and act on it while at the same time improving data integrity and compliance.

By combining BIOVIA Discoverant and QlikView, the customer has automated the creation of performance dashboards for over 15 products across numerous sites. Data are auto-extracted from Discoverant and Excel files, allowing the system to generate monthly and quarterly dashboards on demand.

With BIOVIA Discoverant, the customer can compare outcomes at different sites with different products and effectively monitor processes at CMOs through Discoverant hierarchies. BIOVIA Discoverant's structured, validated environment advances investigations and process improvements while also helping to assure compliance and data integrity.

OUTLOOK

The company's aim for 2022 and beyond is to achieve the "adaptive plant." In this scenario, self-controlling and adaptive manufacturing processes reduce the need for human data interpretation. Instead, AI helps to adapt manufacturing parameters automatically, thereby reducing reaction times and increasing yields.

"Launching BIOVIA Discoverant as a global application helped to usher in a new era. We have many Manufacturing Informatics tools but Discoverant is the heart for us."

— Manufacturing Informatics Specialist
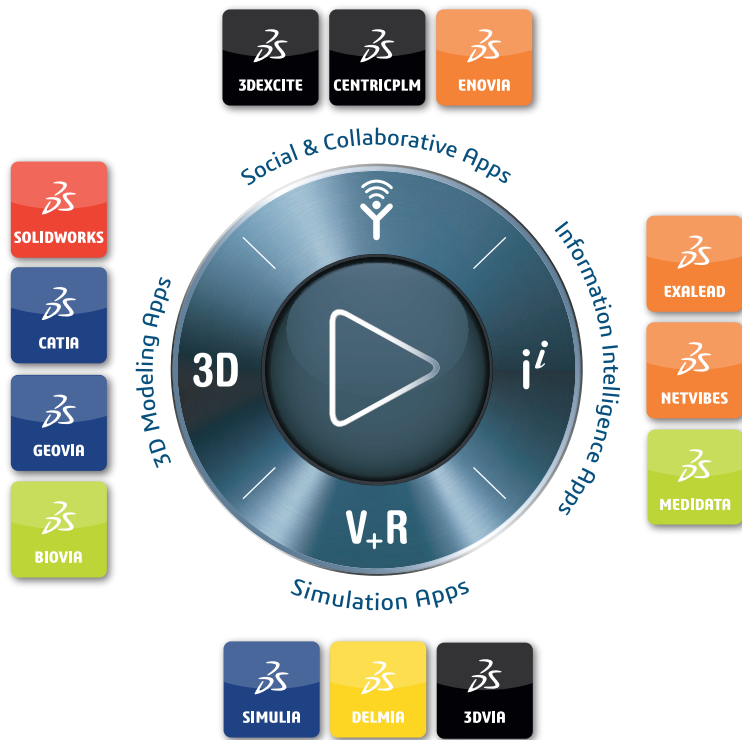
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DS-9905-0420