



3DEXPERIENCE®

# IMPLEMENTING A SCALABLE CPV SOLUTION

BIOVIA SOLUTION FOR CMOs



# QUALITY DATA MONITORING IN A DYNAMIC ENVIRONMENT

In today's dynamic, highly competitive biopharmaceutical industry environment, contract manufacturing organizations (CMOs) must meet specific data integrity, quality and compliance criteria to be considered for partnerships. Most importantly, Sponsor organizations and CMOs share responsibility for quality metrics and compliance reporting; both are equally accountable for establishing and maintaining a state of control in manufacturing processes.

- Are you a CMO provider struggling with timely and/or costly data aggregation, analysis and reporting procedures as you work with Sponsor organizations engaged in small and large molecule drug development or medical devices?
- Are you confident that your quality monitoring and regulatory compliance capabilities adhere to continued process verification (CPV) best practices?
- Is your company well positioned to add scale, diversify new value chain capabilities and expand your end-to-end service offerings as a global, comprehensive solution provider to the industry?

## BIOVIA SOLUTION FOR CMOs

The BIOVIA solution for CMOs is an industry-leading data monitoring and process improvement system for aggregating, contextualizing, analyzing and sharing manufacturing and quality data. With its automated alerts and reporting capabilities, the solution significantly decreases process and product variability, improving quality and compliance for CMOs and Sponsors alike.

The BIOVIA solution for CMOs is a scalable data quality monitoring system that can be quickly deployed and easily shared with Sponsor organizations that then gain secure and compliant access to real-time data and automated reporting dashboards.

**Organizations have realized the following benefits as a direct result of deploying the BIOVIA solution for CMOs**

**↓ 80-95%**  
Time  
Aggregating Data

**↓ 40-50%**  
Corrective Response Time  
to Out-Of-Spec/  
Out-Of-Trend Result

**↑ 30-50%**  
Data  
Accuracy

(BIOVIA benchmark metrics)





Factors that can motivate Sponsor companies to switch CMO provider include<sup>1</sup>:

- Better quality at competitor – 50% potential customers
- Improved logistics – 37% potential customers
- Lower error rate – 32% potential customers

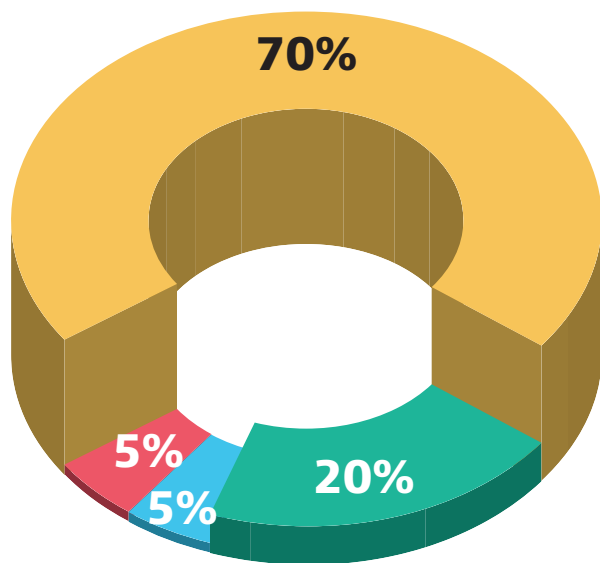
Adopting the BIOVIA solution for CMOs for process data analysis and reporting can help CMOs avoid dismissal scenarios such as these by harmonizing processes, simplifying Good Manufacturing Practice and regulatory compliance and enhancing decision making.

<sup>1</sup>Nice Insight 2016 Annual Survey Results, American Pharmaceutical Review, Jan. 2016

# QUALITY BEST PRACTICES FOR SCALABLE CPV

Continued process validation (CPV) and quality best practices have become mainstream activities in today's externalized biopharmaceutical industry. The BIOVIA solution for CMOs provides scalable CPV monitoring, manufacturing process optimization and improved regulatory compliance including data integrity in a validation-ready work environment.

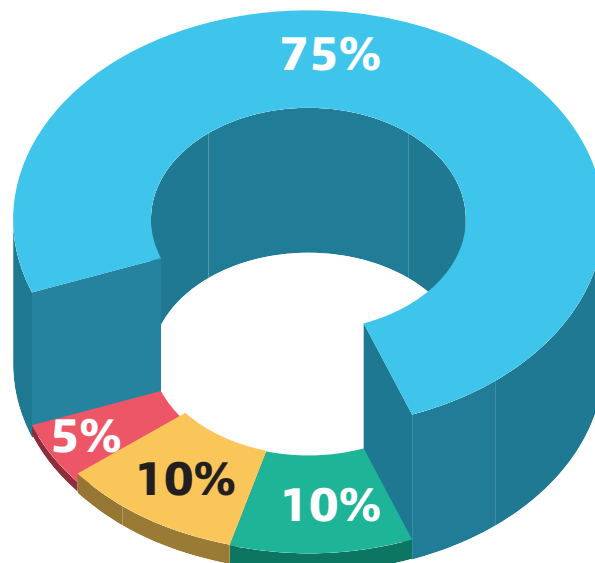
## TYPICAL CPV SYSTEM\*



● Data Aggregation

● Analysis (Investigations & Monitoring)

## BIOVIA CPV SYSTEM



● Data Cleaning

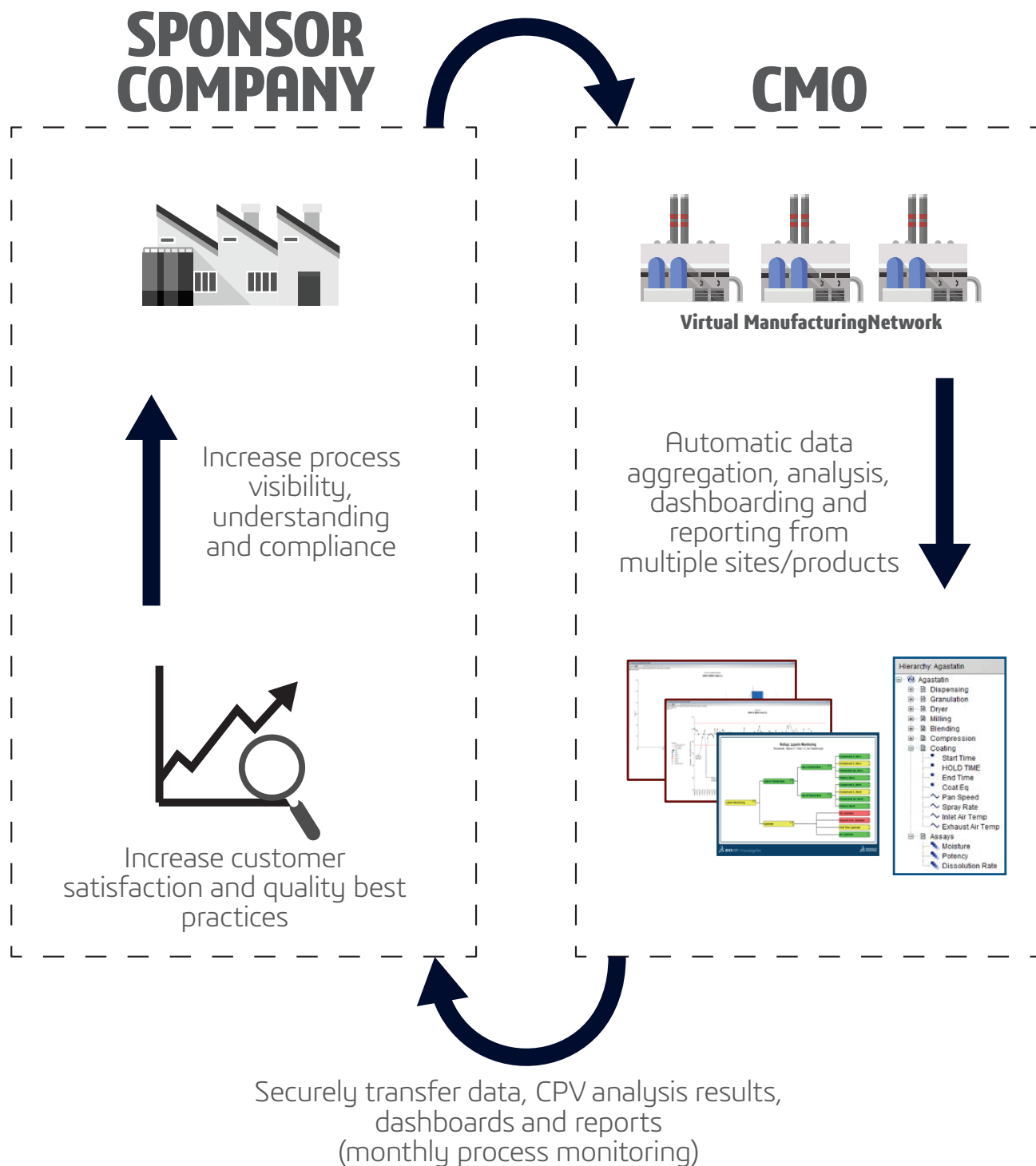
● Other

\*Assumes a typical CPV system is Excel-based with manual data aggregation.

Organizations using the BIOVIA solution for CMOs spend **70% more time on analysis and process optimization.**

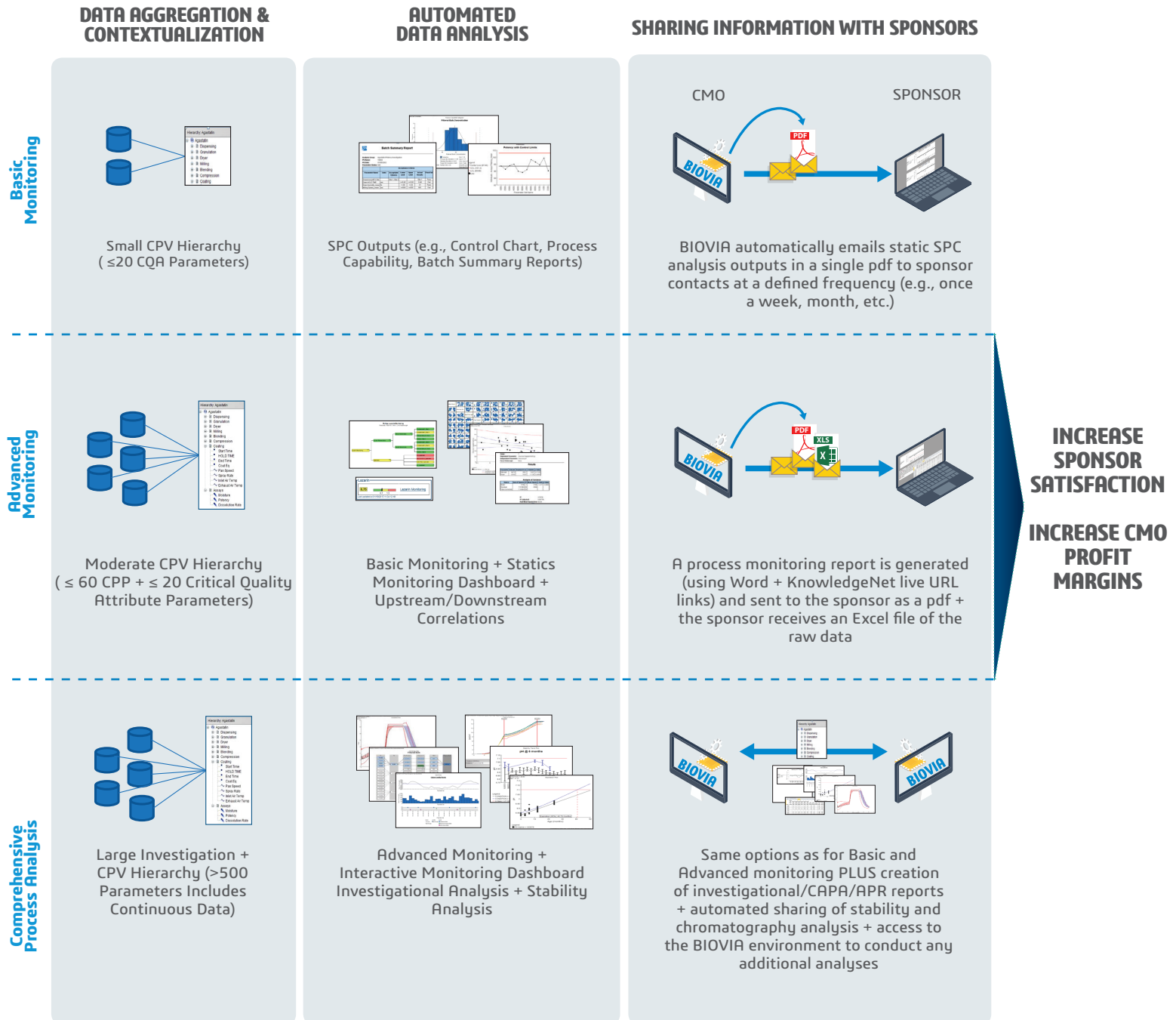
# COMPETITIVE VALUE-ADDED SERVICE OFFERINGS

Increased regulations impacting CPV monitoring and CMO quality procedures create the opportunity for CMOs to provide additional data and analysis offerings to Sponsors. The BIOVIA solution for CMOs provides a firm foundation for future manufacturing optimization tasks (e.g., investigational analysis, stability analysis, chromatography, etc.) that can increase margins, improve global supply chain visibility and strengthen collaboration and tech transfer with Sponsor organizations.

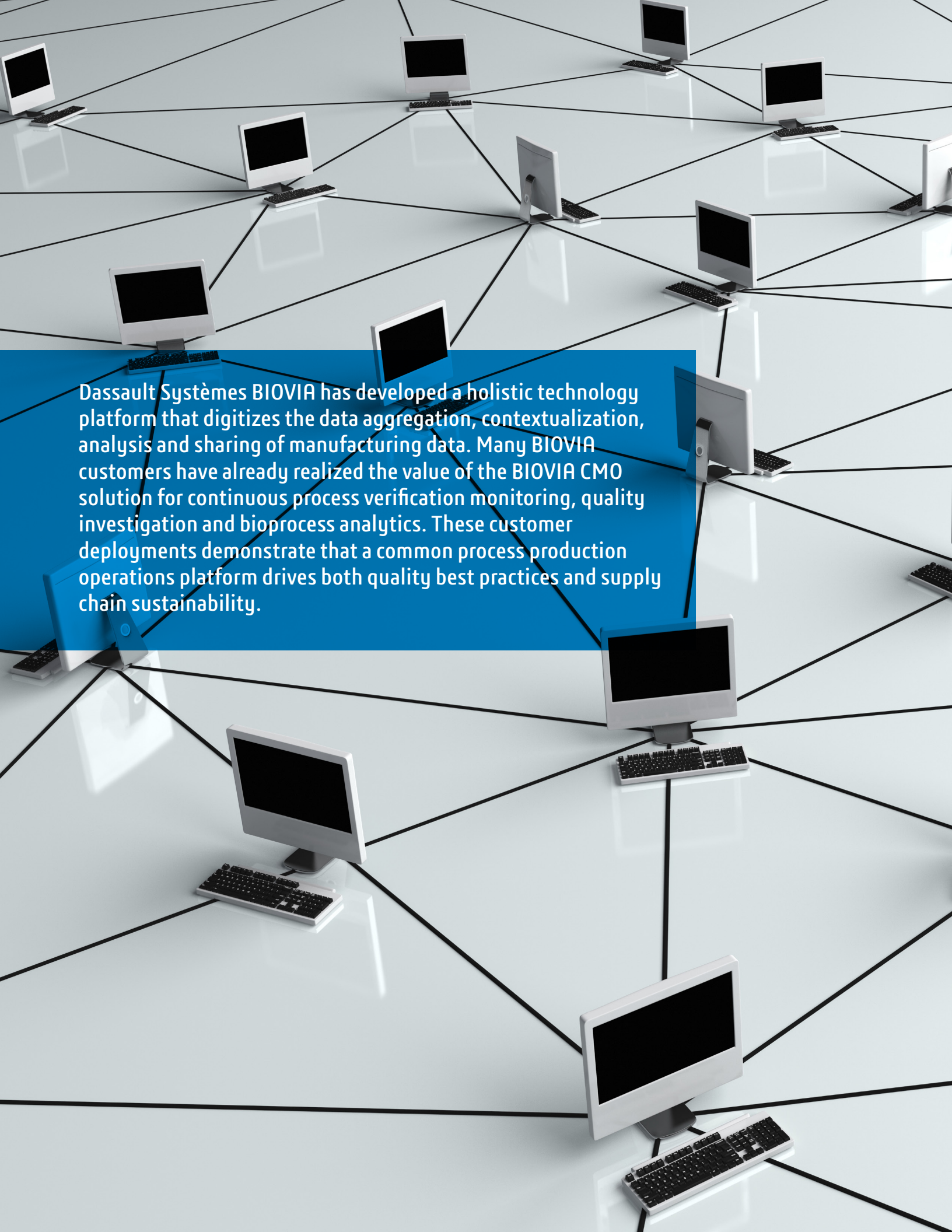


# VALUE-ADDED SERVICE OFFERINGS

CMOs can realize significant benefits by transforming critical business functions to improve regulatory compliance and increase margins. They can then make these capabilities available to Sponsor organizations as value-added services.



Deploy role- and product-specific dashboards for joint reviews with Sponsors. Share process information with multiple sponsors in a secure environment.

The background of the image is a conceptual illustration of a networked manufacturing environment. It features numerous computer monitors, each with a keyboard, arranged on a light-colored, reflective surface. These monitors are interconnected by a web of thin, dark lines that crisscross the scene, creating a sense of a distributed, interconnected system. The monitors are of various sizes and are positioned at different angles, some facing the viewer and others turned away. The overall aesthetic is clean, modern, and technological, emphasizing the theme of digitalization in manufacturing.

Dassault Systèmes BIOVIA has developed a holistic technology platform that digitizes the data aggregation, contextualization, analysis and sharing of manufacturing data. Many BIOVIA customers have already realized the value of the BIOVIA CMO solution for continuous process verification monitoring, quality investigation and bioprocess analytics. These customer deployments demonstrate that a common process production operations platform drives both quality best practices and supply chain sustainability.

# THE CASE FOR CHANGE

Both CMOs and Sponsor organizations can realize significant value from adopting the BIOVIA solution for CMOs as their standard process data aggregation, analysis and reporting technology. The CMO solution harmonizes processes and provides value-added services to CMOs and Sponsors alike.

## Strategic Benefits

- **Implement a single source of truth—from development to supply chain**
- **Enable quality best practices by leveraging data integrity efforts with an industry-standard CPV solution**
- **Increase customer satisfaction with value-added services**

## Economic Benefits

- **Reduce data aggregation, analysis and reporting efforts**
- **Improve accuracy and timeliness of CMO and Sponsor data sharing**
- **Streamline CMO collaboration activities for improved response times**
- **Reduce cost of compliance**

## Risk Mitigation

- **Simplify compliance with full traceability of all manufacturing activities**
- **Reduce product recalls, litigation and warnings**
- **Implement configuration-based, validation-ready, proven technology**
- **Reduce operational and compliance risk with greater visibility across operation**

## IT Impact

- **Simplify IT landscape and integration with single solution architecture**
- **Speed implementation and support with validation-ready solution**
- **Reduce administrative and maintenance efforts**
- **Simplify addition of future products with configurable solution leveraging existing practices and processes**

# THE VALUE OF PARTNERING WITH BIOVIA

Now more than ever, CMOs need a trusted, strategic partner that shares their vision and passion for what is possible in today's rapidly changing environment. Dassault Systèmes BIOVIA offers unparalleled experience and a strong track record in the biopharma industry to assist CMOs with their business and IT transformation journey.


As a brand of Dassault Systèmes, BIOVIA is part of a world-leading scientific company with over 210,000 enterprise customers across 12 industries in 140 countries supported by 12,600 partners. Partnering with BIOVIA puts these broad capabilities and global reach at the disposal of our customers, opening up new possibilities for transforming the world of scientific innovation.



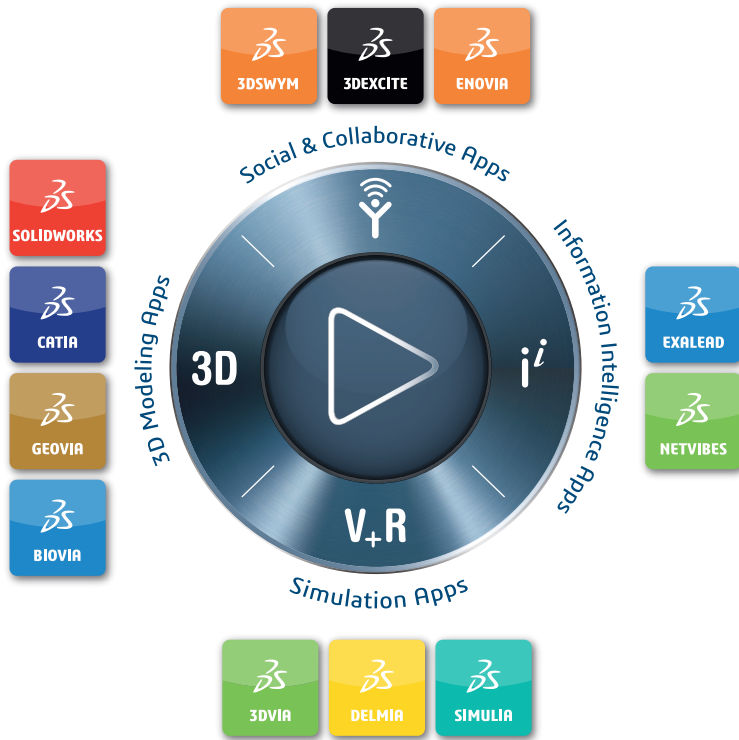
## The BIOVIA portfolio provides:

- A comprehensive solution addressing process production operations for CMO organizations
- Deep industry experience and broad customer base
- Excellent customer references with tangible results
- Framework for the 21<sup>st</sup> century: innovations to support your business model today and in the future

The **next step** is to develop a strategic business partnership with BIOVIA aimed at deploying a scalable CPV solution that harmonizes processes and improves quality and compliance for CMOs and Sponsor organizations alike.

A photograph of two women in professional attire. The woman on the left has short brown hair and is wearing a light-colored blazer over a patterned top. The woman on the right has dark hair pulled back and is wearing a light blue button-down shirt. They are both leaning over a table, looking at a large sheet of paper that appears to be a blueprint or a technical drawing. The background is a bright, modern office space with large windows and a grid-like pattern on the wall.

The BIOVIA solution for CMOs transforms the way CMOs conduct manufacturing and quality operations in support of their Sponsor organizations. Standardizing process data and reporting to align with regulatory guidelines is a common initiative of BIOVIA's top-performing customers. BIOVIA's extensive industry experience and deep expertise will provide your CMO team with the industry best practices and knowledge required to improve operational excellence and productivity across your customer ecosystem.



Our **3DEXPERIENCE®** platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE®** Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 210,000 customers of all sizes in all industries in more than 140 countries. For more information, visit [www.3ds.com](http://www.3ds.com).

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