DASSAULT SYSTEMES

BIOVIA

PROCESS MONITORING IN THE LIFE SCIENCE INDUSTRY

BIOVIA PROFESSIONAL SERVICES CPV/MONITORING SOLUTION

REGULATORY GUIDELINES

Regulatory guidelines require that companies monitor processes in addition to product specifications (e.g., FDA Guidance for Industry Process Validation-Stage 3; EMA Guidelines on Process Validation for Finished Products). Many companies, large and small, have embraced these regulatory guidelines, adopting monitoring techniques and quality best practices to proactively identify manufacturing trends that could become an issue and to remediate them before they create out-of-specification (OOS) situations.

Automated process monitoring systems are becoming industry-standard, mainstream activities in today's current Good Manufacturing Practices (cGMP) biopharmaceutical environment. The industry is leveraging automated process monitoring systems to traverse the Monitoring Maturity Model from initiation to full manufacturing intelligence.

This journey is often not sequential but recursive as new data is made available, guidelines are refactored and additional technologies are integrated into the IT landscape.

BIOVIA DISCOVERANT IS YOUR MONITORING SOLUTION

Process Monitoring Capabilities

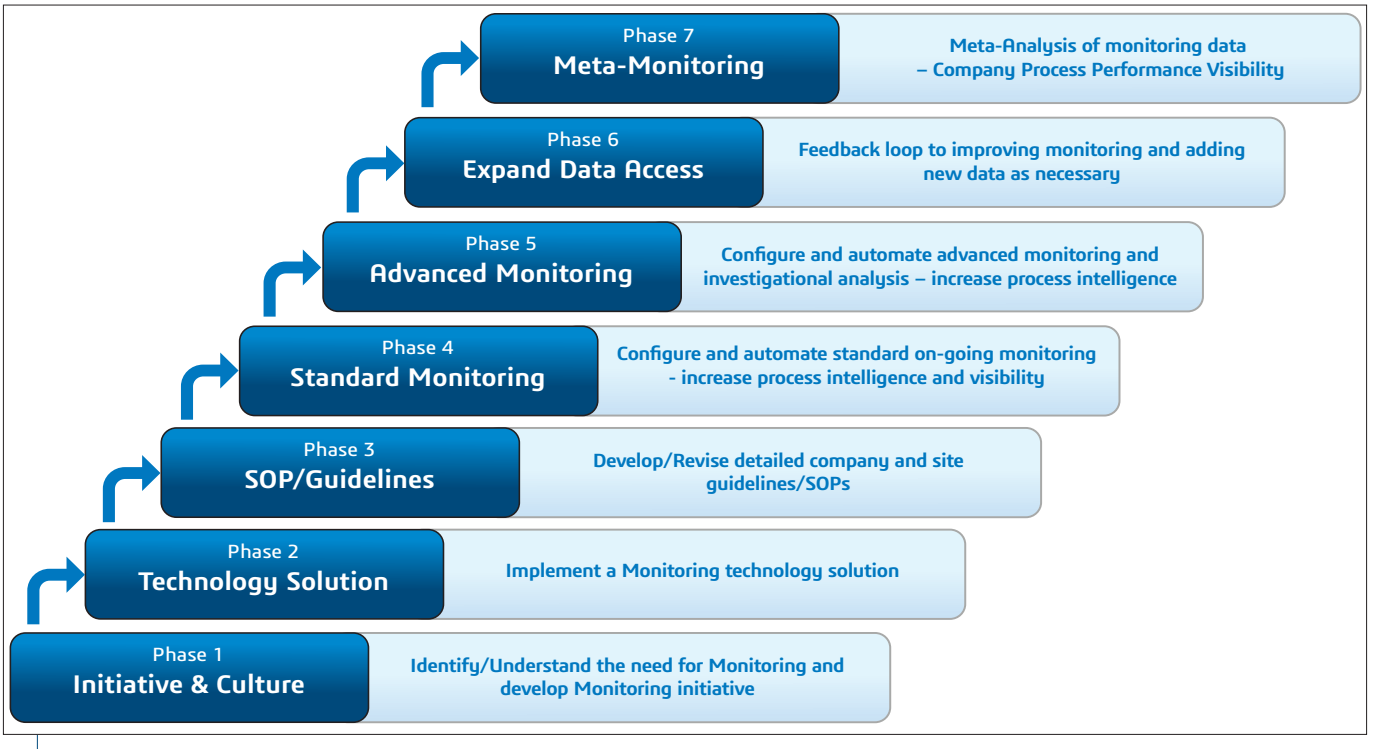
The BIOVIA Discoverant process production operations solution includes multiple components in a single, automated GMP environment including (1) data aggregation from source systems, (2) Statistical Process Control (SPC) and continuous monitoring outputs and (3) automated monitoring, dashboarding and reporting. The system aggregates information from 100s to 1000s of SPC outputs to provide a real-time overview of the enterprise, regions, product families, sites and products. In this way, BIOVIA Discoverant enables a "monitoring-by-exception" approach with email alerts and dashboards that rapidly identify and disseminate information about questionable trends. The system offers a validatable cGMP solution with SPC tools (e.g., control charts, process capability, assumption testing) and Life Sciences-specific continuous monitoring tools (e.g., golden batch analysis), with a validation kit, as well as easy extensibility to utilize third-party analysis and report tools. BIOVIA Discoverant supports Nelson and Western electric rules for alerts and provides the ability to send different alert levels to various groups (e.g., floor operators, tech ops/process Subject Matter Experts (SMEs), site leadership, quality, etc.). The software provides comprehensive reporting capabilities including control chart baseline tables summarizing target control limits and summary tables synopsizing quarterly and yearly out-of-tolerance (OOT) alerts.

As a leader in the Life Sciences industry, Dassault Systèmes BIOVIA has developed the BIOVIA Discoverant solution to meet all your monitoring needs for continued process verification, and to enable your organization to progress up the monitoring maturity model to full process understanding.

Process Monitoring Value

A few benefits from using the BIOVIA Discoverant Solution that our customers have reported:

- 80-95% less time aggregating data
- 40-50% reduction in correct response time to OOS/OOT conditions
- 10-15% improved productivity at manufacturing sites
- 40-50% reduction in FDA onsite inspection time
- 30-50% improvement in integrity of Contract Manufacturing Organization (CMO) data



The seven phases for monitoring maturity.

BIOVIA DISCOVERANT – IMPLEMENTATION SOLUTION

BIOVIA Professional Services supports complete solution implementations for small or large enterprise initiatives. For over 15 years our professional services team has been designing, developing and implementing proven, best-in-class data monitoring and process improvement systems for aggregating, contextualizing, analyzing and sharing manufacturing and quality data. Based upon successful system implementations at large biopharmas and small biotechs, we have honed efficient and effective implementation best practices supported by a dedicated team of product managers, product developers, engineers and industry leaders in manufacturing data integration. Our domain knowledge in life sciences and our statistical application expertise encompasses process monitoring software implementations, development of standard operating practices (SOPs) and communication/coordination with sponsors and CMOs.

Our Program model for new monitoring initiatives follows the Define, Execute, Enable and Extend phase cycles to take customers from project initiation through full process understanding. In each phase of this model, BIOVIA professional services employs the use of multiple workshops (onsite and remote), eLearnings, templates and deployment of domain and technical expert resources to complement customer teams. This proven approach speeds value realization, user adoption and regulatory compliance.

DEFINE

All programs/projects have business goals, monitoring programs are no different. Our program team aligns with customer stakeholders to document the business goals and then define measurable objectives. The team measures/baselines all objectives before the project begins, and then as key milestones are met periodically takes new measurements of objectives to ensure the business value is being realized. Additionally, during the Define Phase, our statistical and regulatory experts are available to either create or review monitoring guidance to ensure a balanced approach. Inefficient guidance can lead to larger technology investments, and lean guidance can leave manufacturing open to risk. Balanced monitoring guidance will maximize technology investment and reduce manufacturing risks.

EXECUTE

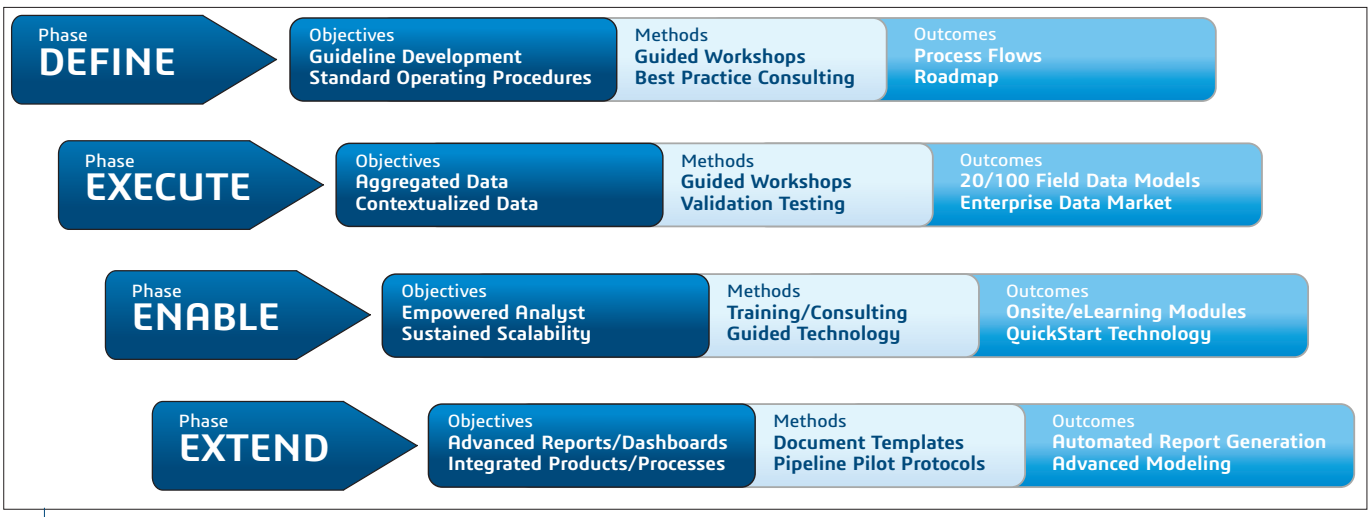
BIOVIA domain and product experts deploy the BIOVIA Discoverant Solution to aggregate and contextualize the manufacturing data. Validation experts test the solution and analytics experts setup the outputs required to support the monitoring guidance immediately upon promotion of the data maps to the production environment. BIOVIA delivers fully functional and validated solutions that can be immediately used for GMP decision making.

ENABLE

BIOVIA product and analytics experts deliver training and provide on-call and/or onsite support to ensure the user community ramps up quickly and realizes the value of the BIOVIA Discoverant solution. Training is supported by self-paced eLearning modules and instructional videos that can be utilized as reference materials. BIOVIA statisticians offer invaluable guidance for structure and use of data conforming to best practice in the Life Sciences industry. Our success is measured not by just delivering the solution, but by our customer's realization of value from the solution through its use and GMP decision making.

EXTEND

BIOVIA report experts automate report generation and create comprehensive dashboards utilizing data generated from BIOVIA Discoverant. Technical experts can add parameters to the data maps to create investigative and/or full process understanding data maps. The BIOVIA Discoverant architecture can be extended to additional sites, additional products and additional functionality as your data understanding grows. The data that BIOVIA Discoverant aggregates and contextualizes can be consumed by corporate data lakes for broader enterprise analytics. BIOVIA supports all facets of a customer's growth through the Monitoring Maturity Model to full process understanding.



The four stages of the BIOVIA Discoverant implementation solution.

NEXT STEPS

Contact your BIOVIA Account Manager to schedule a discussion with our monitoring experts and your Tech Ops and Quality representatives. BIOVIA can perform a no cost review of current monitoring guidelines and/or standard operating procedures to feedback industry best practices and alignment of solutions to your requirements.

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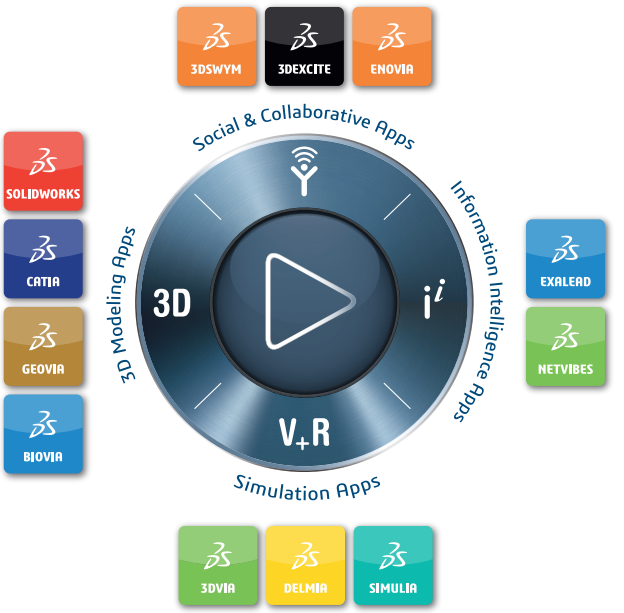

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DASSAULT SYSTEMES | The **3D**EXPERIENCE® Company

Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

DS-9201-0217