BIOVIA

3DEXPERIENCE®

BIOVIA DISCOVERANT FOR PROCESS DEVELOPMENT AND MANUFACTURING

Datasheet

BIOVIA Discoverant for process development and manufacturing is a validation-ready solution for process and quality data access, aggregation, contextualization, analysis and reporting. BIOVIA Discoverant empowers production operations in process industries, such as pharmaceuticals, biologics and specialty chemicals, to shorten time to market and maximize profitability. The solution does this by enabling understanding of critical process drivers that drive desired business results, monitoring variability for preemptive action and leveraging opportunities to maximize sustainability.

DASSAULT SYSTEMES

CHALLENGES

In today's process industries organizations need to ensure and defend market competitiveness as never before. One consequence is that they must maximize efficiency and reduce costs in their production processes. At the same time, they need to control product quality, variability and yield. Additionally, these parameters need to be continuously and reliably monitored with reports and results exchanged with other business areas and contractors for tech transfer and outsourced operations. This is challenging with traditional paper-based processes that rely on time-consuming and error-prone manual activities. Gathering and accessing the required data from disparate sources and paper records across the organization in order to make business decisions needs to be fast, but also must comply with regulations. Analyzing the aggregated data and generating reports is tedious, non-value-added work and error-prone if done manually with spreadsheets. Using un-validated data analysis adds compliance risks to the process. But Process Development, Manufacturing, and Quality depend on the reliable and timely accessibility of analyses and reports used for business-defining activities. Sticking to traditional processes will bear regulatory compliance risks and will cost organizations time, resources and money, ultimately jeopardizing their competitiveness.

SOLUTION

BIOVIA Discoverant provides Process Development, Manufacturing, and Quality users with self-service, on-demand access to process and quality data from disparate data sources and paper records. It automatically aggregates and contextualizes the data and enables ad hoc statistical investigations with automated validation-ready workflows. It provides browser-accessible outputs for teams of observational users across different organizations and geographies.

The solution supports three major areas that empower production operations, shorten time to market, and maximize profitability.

Process Design

Improve process design by understanding the critical process parameters

Process Control

Increase process performance by monitoring variability enabling preemptive action

Process Optimization

Enhance process improvement by understanding and control process and product variability

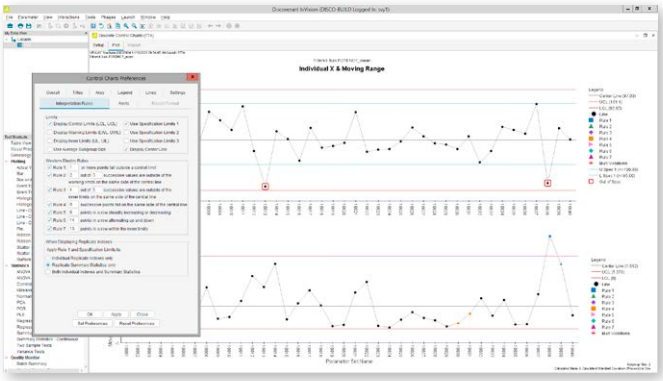


Figure 1: Control chart showing process trending with run rules and alerts for out of trend conditions

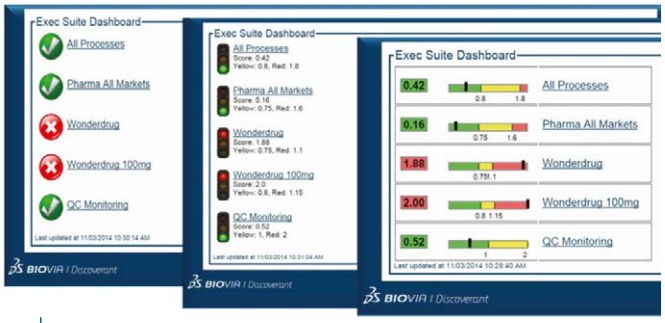


Figure 2: Three different types of signal monitoring display symbols are available with increasing levels of information content

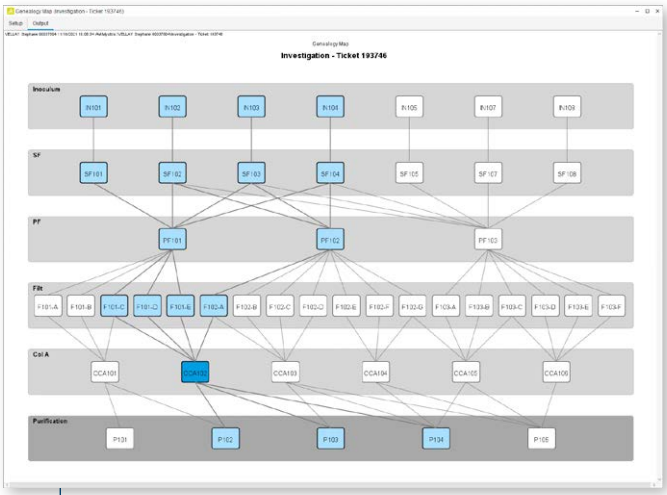


Figure 3: Interactive graphical process genealogy map showing all the ancestors and successors of a step late in the process.

CAPABILITIES

- Validation-ready solution for GMP decision-making without second person verification
- 21 CFR Part 11-compliant capture of paper record data
- Self-service point-and-click access to all process and quality data
- Ad hoc cause-and-effect analysis using all types of process and quality data
- Many statistical tools designed specifically for the pharmaceutical industry that include investigative and predictive capabilities
- Analysis of online and offline cell culture and chromatography data
- Automated data analysis and visualization outputs
- Monitoring of variability with automated alerts for review-by-exception (CPV)
- Genealogy Map for interactive graphical genealogy reporting allowing upstream/downstream traceability from a selected batch
- Stability analysis and expiration dating with automated Out-of-Trend (OOT) alerts
- Role-based Signal Monitoring Dashboards for process performance monitoring across internal and external (e.g. CMO) manufacturing networks
- Cloud-based exchange of data and automated analysis between sponsor and partners

BENEFITS

Process Design

BIOVIA Discoverant enables the design of robust GMP processes which will help to:

- Identify Critical Process Parameters (CPPs) and operating ranges required for sustainable production and (Critical Quality Attributes (CQAs) to verify and monitor high product quality at commercial scale
- Scale-up and transfer of a validatable processes with built-in quality (Quality by Design – QbD) for in-house or contractor operations
- Establish a culture of data for process knowledge sharing and collaboration
- Accelerate the preparation and approval of science based submissions to speed time to market

Process Control

BIOVIA Discoverant provides immediate visibility into process performance, quality and compliance risk which will:

- Ensure process robustness through ongoing verification of performance as designed (Continued Process Verification – CPV)
- Maximize productivity and minimize costs with automated alerts and monitoring-by-exception
- Establish a culture of ownership with visibility, communication and collaboration across internal and external organizations
- Reduce the time and cost of periodic reporting for review and compliance, such as Annual Product Review (US) or Product Quality Review (EU)

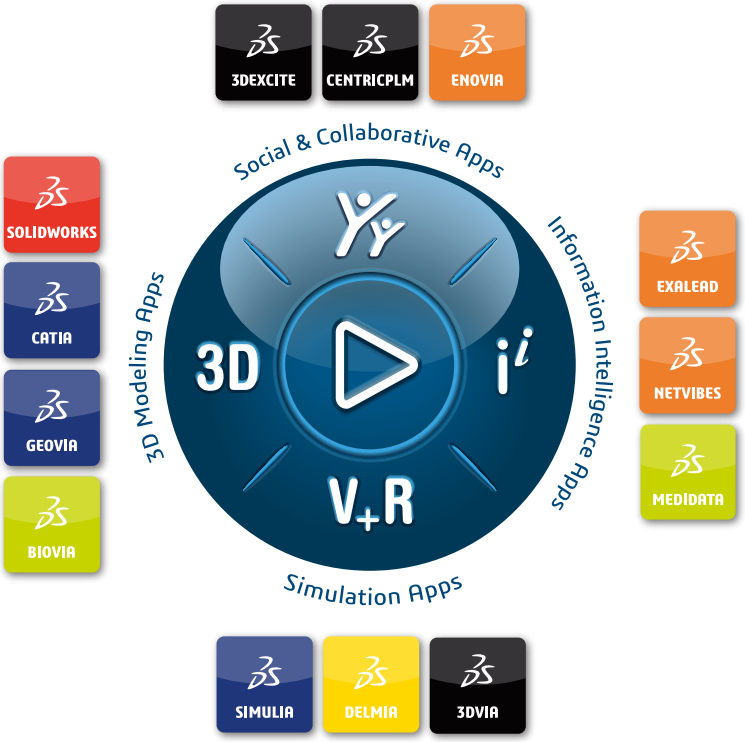
Process Optimization

BIOVIA Discoverant enables improved understanding and control process and product variability which will:

- Improve economics by identifying, reducing and controlling sources of variability and maximizing yield, quality, and sustainability
- Accelerate preparation and approval of ongoing science based submissions for Scale-Up and Post-Approval Changes (SUPAC)
- Reduce costs of deviations with near real-time data access and advanced analytics
- Establish a culture of excellence in production and compliance

Overall, "Manufacturing for Life" minimizes non-value-added manual tasks, reduces the risk of errors and compliance enforcement costs, and promotes process understanding and knowledge sharing to reduce process variability. Ultimately, it helps speed time to market and improve process economics and sustainability.

LEARN MORE



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

Dassault Systèmes, the **3D**EXPERIENCE 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 **3D**EXPERIENCE 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**.

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