BIOLOGICS MADE RIGHT FIRST TIME INDUSTRY PROCESS EXPERIENCE

DATASHEET

PROCESS DESIGN, PERFORMANCE AND IMPROVEMENT IN BIOLOGICS

Biologics manufacturers are challenged today with reducing variability and costs, as well as speeding time to market by collaborating across growing manufacturing networks with external and internal partners spread across the globe. As they strive to develop and improve process performance and quality to meet business, regulatory and patient needs, effective utilization of their process and quality data is critical to success. The Biologics Made Right First Time Industry Process Exerience enables understanding of critical bioprocess drivers, monitoring variability for preemptive action and leveraging opportunities to maximize sustainability and maximize profitability and shorten time to market.

BACKGROUND

Many pharmaceutical and biopharmaceutical organizations are shifting their activities away from small molecule toward biologics drug development. The biologics R&D workflow from discovery through development to manufacturing is similar to small molecule R&D at the highest level but demands unique processes required by the added complexity of biological systems.

To design and implement robust biologics processes, monitor their performance, and to troubleshoot and introduce improvements to them, businesses need to make scientifically-informed decisions. Bioprocess and quality professionals need self-service, on-demand access and aggregation of process and quality data from multiple sources (including paper records) in the right context for analysis, interpretation and action enabling them to collaborate across organizations and geographies to convert data into information and then into process knowledge that becomes available for access and dissemination across global manufacturing networks.

CHALLENGES

To design and implement robust biologics processes, monitor their performance, and troubleshoot and introduce improvements to them, businesses need to make scientifically-informed decisions. But process development, manufacturing and quality functions in biologics companies generate an abundance of data which needs to be readily available in a user-friendly, meaningfully organized (contextualized) form to provide process knowledge that supports operations. Traditional manual methods, such as spreadsheets, are error-prone, waste valuable time, and can incur large opportunity costs. As organizations generate more data through implementation of QbD (Quality by Design), PAT (Process Analytical Technology), PR (Process Robustness), and CPV (Continued Process Verification) initiatives along with new manufacturing and measurement technologies, they need better ways to access and use their data.

Barriers to achieving this include the following:

- Data is stored across multiple disparate sources (including paper based records). Aggregation is time consuming and non-value-adding.
- Organizing aggregated data for analysis and reports is tedious, non-value-added and error-prone when done manually.
- Using un-validated data analysis adds compliance risks to the business.
- Highly-trained technical staff are incurring substantial recurring costs resulting from error-prone, non-value adding tasks.
- Processes are highly complex with global manufacturing networks and Contract Manufacturing Organizations

SOLUTION

The Biologics Made Right First Time satisfies the needs of process development, manufacturing and quality users for validation-ready, self-service, on-demand access to process and quality data from disparate databases and paper records. It aggregates and contextualizes process and quality data automatically to enable ad hoc statistical investigations with automated workflows which provide browser-accessible outputs and role-based dashboards with updates and alters for widespread teams. This removes non-value-added manual data tasks, reduces the risk of errors, and promotes process understanding and knowledge sharing to reduce process variability, speed time to market, and improve process economics and sustainability. Critical process parameters in solution preparation, cell culture, fermentation, harvest, filtration, centrifugation, purification, formulation, filling and finishing operations can be more easily identified and monitored. Four closely integrated sets of capabilities, deliver value in the following ways:

- Self-service on-demand data access, aggregation and contextualization of data of different types from disparate data sources
- A simple, Part 11 compliant browser-interface for transforming paper-based data into compliant electronic records
- A Genealogy Map provides a visual representation of lot genealogy throughout the manufacturing process.
- Analytical and statistical tools allow users to trend and investigate process and quality data
- Reports and graphics that can be accessed and displayed though a browser, performance metrics can be shown in role-based dashboards with drill-down capabilities

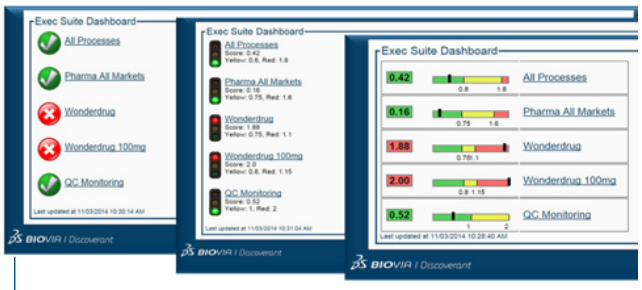

Figure 2: Signal Monitoring Dashboard that allows users to communicate process or product trends and status throughout the organization.

The Biologics Made Right First Time enables organizations to collaborate internally and externally and across geographies to convert data into information and then into process knowledge. This will enable the understanding of critical bioprocess drivers, monitoring variability for preemptive action and leveraging opportunities to maximize sustainability.

BUSINESS VALUE OF BIOVIA BIOLOGICS SOLUTION

Capabilities	Benefits
• Role-based dashboarding and signal monitoring • Integrated self-service, on-demand access to all process and quality data (including paper data)	Increased efficiency, easier decision making
• Advanced visual, numeric and statistical capabilities for ad hoc data analysis and reporting • Graphical display of lot genealogy with drill-down • Analysis of on-line chromatography and other multi-phase data	Improved process understanding, reduced process variability
• Validation-ready solution to make GMP decisions • Automated creation of APQR's and other templated reports	Improved compliance, reduced cost of quality
• Scalable enterprise solution for virtual deployment across multiple servers/ organizations/geographies	Improved collaboration

BIOVIA Biologics Solution helps to bring better products to market faster

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

BIOVIA Corporate Americas
BIOVIA
5005 Wateridge Vista Drive,
San Diego, CA
92121
USA

BIOVIA Corporate Europe
BIOVIA
334 Cambridge Science Park,
Cambridge CB4 0WN
England