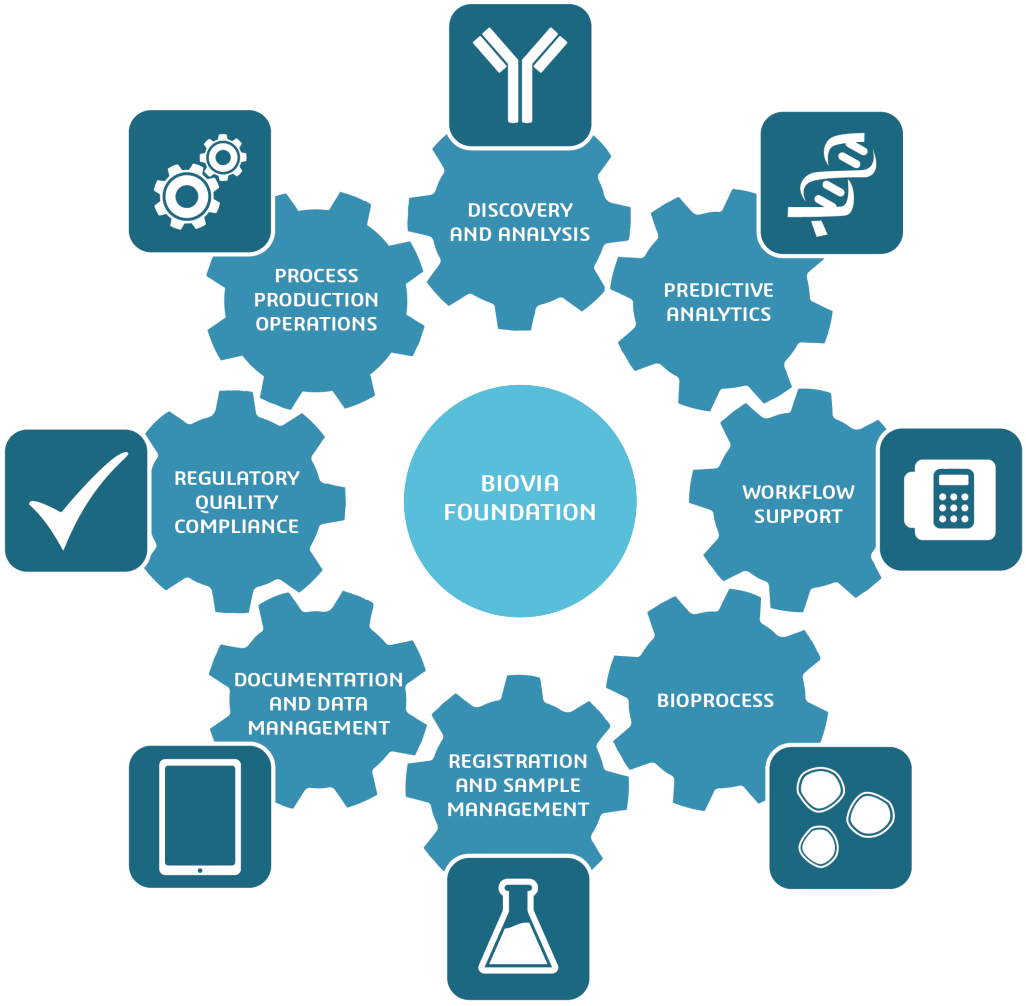
DASSAULT SYSTEMES

BIOVIA

BIOVIA BIOLOGICS
DATASHEET



HELPING TO BUILD BETTER BIOLOGICS, FASTER

Many research organizations are increasing their efforts in biotherapeutic discovery, development and manufacturing. The research and development workflow for biologics is similar to that of small molecule at the highest level, but requires more unique processes inherent in the added complexity of biological systems. The BIOVIA Biologics Solution is designed to meet the needs of the individuals and teams who are a part of these processes.

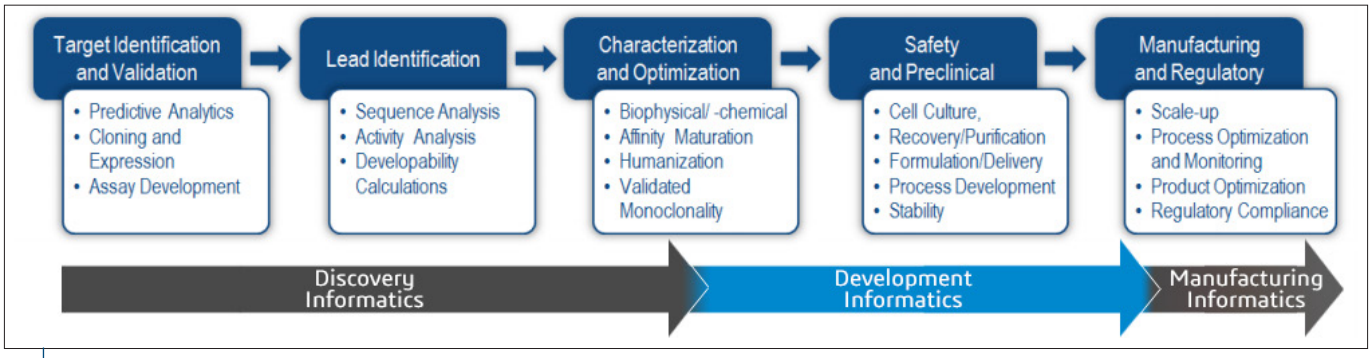


Figure 1: Biologics Research, development and manufacturing

WHAT IS THE BIOVIA BIOLOGICS SOLUTION?

The BIOVIA Biologics Solution is a suite of capabilities supported by a common platform, designed to help with the discovery and optimization of biotherapeutic candidates as well as the optimization of the overall workflow, including the development, manufacturing and compliance processes. It supports the documentation of experiments and the management and analysis of all scientific and quality data generated throughout the process.

Benefits

Our solution helps overcome barriers to innovation and process efficiency from early discovery research through development. It is the only solution of its kind. The BIOVIA Biologics Solution helps to overcome **innovation barriers** by providing tools to:

- process and understand high volume antibody sequence data
- manage high volumes of sequence and cell line data
- analyze sequence annotation and activity data together
- assess developability early in the process
- rapidly customize workflows

The BIOVIA Biologics Solution helps to overcome **process efficiency barriers** by enabling real time project tracking and collaboration with various groups involved in the process. The system is biologically aware and shares integrated or linked data models with:

- registration systems
- sample management systems
- electronic notebooks and corporate databases
- assay management systems
- process management and manufacturing systems
- regulatory and compliance systems

WHO BENEFITS

The BIOVIA Biologics Solution benefits numerous individuals in pharmaceutical and biotechnology organizations by removing barriers to innovation and process efficiency, while enabling regulatory compliance.

- **Leaders in Research and Development** will see higher quality biologic candidates moving faster towards manufacturing. Supported by: the automation of processes, a reduction in resource bottlenecks, improved technology transfer and the ability to share live content effectively.
- **Leaders in Manufacturing, Quality and Regulatory** will see improvements in efficiency and quality and reductions in compliance risk from maximizing and leveraging process knowledge and traceability.
- **Information Technology departments** will see decreasing costs by minimizing the number of disparate applications. The benefits of a unified approach include:
  - dramatically reduced implementation and setup time compared with rolling out separate or integrated systems
  - simpler maintenance and upgrades because all occur on a single platform
  - the ability of administrators and developers to focus on meeting user requirements rather than getting the various application components to work together in the first place
- **Teams** in biologic research, development and manufacturing will have added insight throughout the process allowing the benefit of live data sharing and more informed collaborative decision making for faster and better biologics innovation.

KEY CAPABILITIES

Discovery and Analysis

Unified informatics tools to simplify the analysis of biology data

Capabilities:

- Antibody Discovery – Annotation, alignment, clustering, activity data correlation, developability predictions
- Single Cell Validation and Cell Growth Detection – Automated Image analysis

Predictive Analytics

3D Protein Engineering and Biologics Design. Integrated platform for discovery from project conception to lead optimization

Capabilities:

- Protein engineering
- Predicative analytics – in silico cloning
- Antibody modeling
- Simulations
- Predictive ADME/Toxicology
- Data mining
- X-ray analysis

Bioinformatics Workflow Support

Pipeline Pilot is the industry's leading graphical scientific workflow authoring application with a large library of components to easily build science processes.

Capabilities:

- Create, test and publish scientific services
- Deploy and run scientific services
- Aggregate and get immediate access to volumes of disparate research data locked in silos
- Automate the scientific data analysis and rapidly explore, visualize and report results, sequence analysis, imaging, statistical modeling, documents and text
- Use value-added scientific services

Registration and Sample Management

Registration - Building and managing consistent, searchable and shareable corporate compound registries

Capabilities:

- Registration, search, mining and information analysis on biological entities and relationships

Sample Management -Lifecycle management of samples

Capabilities:

- Support of customer-specific processes and workflows
- Liquid and solid sample tracking

Bioprocess

A system to streamline capture, analysis and reporting of scientific information, registration and screening to enhance collaboration, accelerate decisions and improve the efficiency of bioprocesses.

Capabilities:

- Planning and execution of experiments
- Data analysis for powerful queries and visualization
- Configurable report templates
- Capturing of sample pedigree
- Data mining and knowledge generation

Documentation and Data Management

Multi-discipline application to document and manage the flow of information, tasks and materials within and between labs

Capabilities:

- Customizable document workflows
- Integrating scientists, instruments, solutions and information
- Cloning, templates and automated calculations
- Standard work practices and rapid reporting
- Automated data capture, cataloging and storage
- Improved data quality and integrity
- Secure document versioning, electronic signatures and audit trails
- Real-time project tracking
- Access and analyze data from different sources
- Enabled tech transfer

Process Production Operations

Biologics process and quality data access, aggregation, contextualization, analysis and reporting. The solution enables design of robust GMP processes and immediate visibility into process performance, quality and compliance risk, as well as improved understanding and control of process and product variability.

Capabilities:

- CFR21 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
- Automated data analyses and visualization outputs
- Graphical display of process genealogy for lot traceability
- Automated trending and alerts for review-by-exception (CPV)
- Role-based Signal Monitoring Dashboards for visibility across in-house and contractor operations
- Stability analysis with automated Out-of-Trend (OOT alerts
- Analysis of on-line and off-line multi-phase cell culture and chromatography data

Regulatory, Quality and Compliance

Regulatory, Quality, and Compliance Management solution for controlling data, content and processes for quality assurance and regulatory compliance. Delivers performance excellence in complex research and manufacturing environments.

Capabilities:

- Regulatory: eCTD submissions, clinical TMF
- Quality: Document and content, deviation and CAPA, change control, complaints, audit
- Compliance: Policy and procedure management, marketing materials, corporate ethics and compliance, reporting and dashboarding, cGxP, EU Annex 11, FDA 21 CFR Part 11 Compliance
- Third-party collaboration and oversight

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