

ONE BIOLOGICS DEVELOPMENT LAB INDUSTRY PROCESS EXPERIENCE

DATASHEET

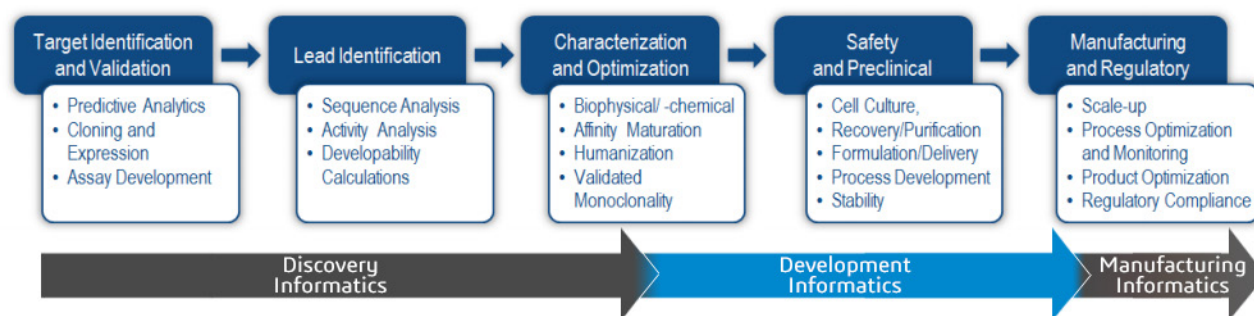


Figure 1: Information Management across the Biologics Development Lifecycle

AN END-TO-END SOLUTION FOR BIOLOGICS DEVELOPMENT

The growth of biologics drug development and the challenges of managing and leveraging biologics data, especially in development, demand an improved informatics environment supporting the efficient and compliant management of biologics data. BIOVIA's ONE Biologics Development Lab Industry Process Experience provides such an integrated environment accelerating innovation, reducing cycle times and ultimately enabling customers to bring better products to market faster.

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. Biologics Development activities extend from characterization through formulation and process development to optimization and tech transfer with a large amount and variety of data involved at every step. For example, a biotherapeutic agent typically requires around 250 in-process tests (compared with around 50 tests for small molecules) to ensure safety, efficacy and safe, reliable production of therapies. An informatics system for Biologics Development has to capture a large amount of complex, diverse data and information along with their context, and the system must accommodate evolving workflows.

CHALLENGES

Disjointed systems and paper-based processes—often in combination with Excel and PowerPoint—are still predominant in Biologics Development, leading to inefficiency, reduced insight into experimental results and less innovation. To make sound decisions early (e.g., about media to be used or about cell lines), scientists need easy access to meaningful, fully contextualized and linked data including trends extracted

from different sources. Achieving this with a traditional set-up is almost impossible because of the many different analytical techniques scientists use such as chromatography, spectroscopy, electrophoresis, thermal and particle analysis and ELISA (Enzyme Linked Immunosorbent Assay). In addition, scientists must work with the specialized analysis software for curve fitting and point systems for handling protein purification, inventory management, balances, etc. If this technology is not integrated, scientists must transcribe data and results manually—a tedious and error-prone process resulting in long analysis and reporting times. The inability to track links between entities impedes information transfer and slows product development. Rerunning experiments further hinders productivity and increases compliance risk.

Traditional systems do not provide the necessary management monitoring of the diverse tasks and complex projects involved in Biologics Development. Poor data management practices negatively impact data quality and security in addition to efficiency-extending development cycle times and impacting time to market.

SOLUTION

To address these informatics challenges, BIOVIA provides a fully integrated Biologics Development solution supporting the management of all data related to the characterization of substances, the development of formulations, manufacturing processes and related testing. The BIOVIA Foundation provides the underlying technology framework for integrating equipment, data systems, applications, analysis tools and other business or laboratory informatics systems. As a result, ONE Biologics Development Lab functions as an integration hub improving efficiency and compliance along the entire Biologics Development value chain. To set up and document an experiment, scientists use out-of-the-box templates that define the structure of the data entry and enable scientists to create new experiments quickly and easily by cloning previous experiments. Data about the biologic lead substance is integrated from a central biologics registry. Direct access

to substance inventory data (e.g., for media) ensures timely availability, prevents use of expired substances, minimizes inventory and avoids unnecessary spoilage.

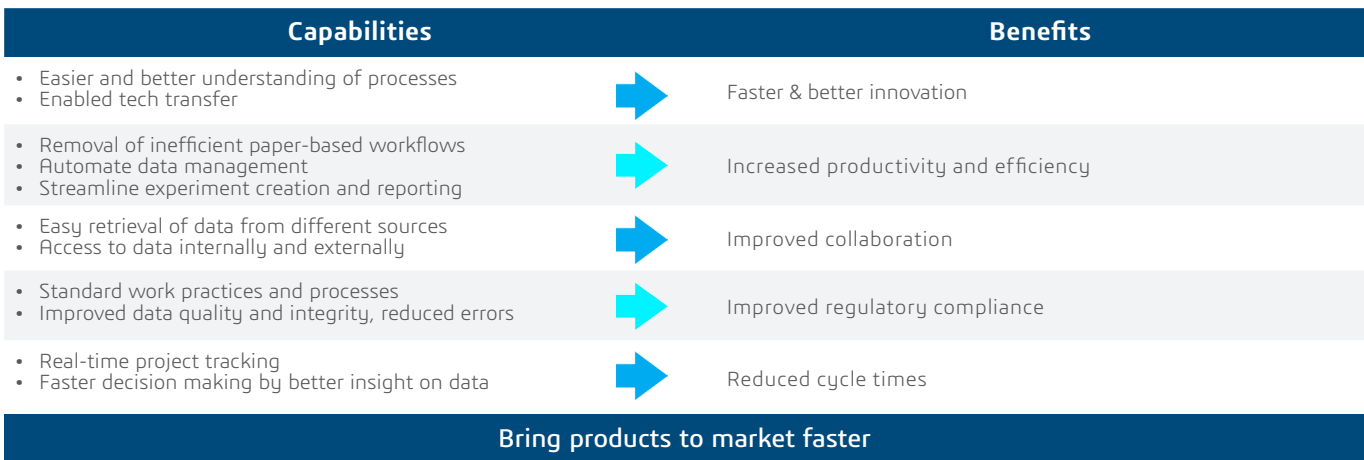
Once an experiment is set up, ONE Biologics Development Lab enables easy entry of observations and results. Scientists just drag and drop files and images into the experiment or enter observations and data directly into the system, for example, using mobile devices. The data to be entered can be unstructured (microscopy, gel images, blots, etc.) or structured (spreadsheets, graphs, etc.). Instrument integration enables the automatic capture and transfer of analytical data and results and data exchange with thirdparty applications. Scientists can then leverage specific inherent spreadsheet capabilities for data analysis and processing of biology experimentation including automated calculations, curve fitting, data pivoting, graphical visualization, etc. Error-prone and nonvalue added steps are removed from the data entry/transfer process, so that the scientists can focus on science.

Experiment parameters, conditions and quantities can easily be changed and adapted for scale-up and related values are automatically updated. Scientists can track relationships and query and report on a variety of biological entities such as antibodies, hybridomas, immortalized cell lines, etc. to fully understand their lineage and origin. All entries are organized and catalogued for easy access and sharing. Advanced search capabilities allow collaborating scientists to retrieve and access relevant experiment data for reuse in other applications and systems. Most importantly, new results and insights can be transferred back into the system. This capability is essential to support the organization and management of large amounts of highly complex and dispersed biologics data. The capability improves collaboration, innovation and tech transfer within development, with other departments and with outside collaborators.

ONE Biologics Development Lab gives managers in Biologics Development a comprehensive overview of the progress of ongoing projects with real-time dashboards identifying trends quickly. Data stored in other databases and applications are also accessible for analysis, eliminating the need for tedious and costly data consolidation into a single system. ONE Biologics Development Lab can be extended upstream to Biologics Discovery and Research - capturing biologics, target identification/validation, assay development, screening, drug metabolism/pharmacokinetics (DMPK), toxicology and bioanalytical experimentation. Overall, ONE Biologics Development Lab enhances productivity, efficiency and collaboration while reducing compliance risk. It helps scientists make better decisions more quickly, driving innovation and reducing cycle times in bringing compliant products to market faster.

Result Summary									
Name	Test ID	Test Name	Method Name	Method ID	Result Name	Working Flag	Result Value	Result Units	Test Date
* Inoculum									
Name	Lot #	Manufacturer	VCD	Volume	% Viability		Titer Conc		
1 ACCL 2704 - Initial Inoculum		Accutry	3.0 ES cells/mL	1.52 L	84.5 %		3.9 mg/mL		
2 ACCL 2704 - Target Inoculum		Accutry	8.3 ES cells/mL	76 L			8.9 mg/mL		
3 ACCL 2704 - Actual Inoculum	8124-017-A	Accutry	7.1 ES cells/mL	14.8 L	87.3 %		8.3 mg/mL		
* Samples									
1845 Sample ID	Name	Sample ID	Process Step	Sample Type	Storage Condition	Container	Plan Amount	Act Amount	
1110055	Day 1 Sample	8124-017-003	Daily Bioreactor(3)	IPC	2 to 8 C	Polypropylene	5 mL		
1120603	Day 2 Sample	8124-017-004	Daily Bioreactor(3)	IPC	2 to 8 C	Polypropylene	5 mL		
1130057	Day 2 Sample	8124-017-005	Daily Bioreactor(3)	IPC	2 to 8 C	Polypropylene	5 mL		
1130459	Day 3 Sample	8124-017-006	Daily Bioreactor(3)	IPC	2 to 8 C	Polypropylene	5 mL		

Figure 2: Document experiments by “cloning” prior work based on the templates created and their associated properties to capture the full context of a biology experiment.



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