



# Case Study

## Pfizer Builds on the Genedata Biopharma E2E Workflow Platform

»Pfizer is pleased to have gained full access to this system for antibody discovery and protein engineering, which is now an integral part of Pfizer's large-molecule discovery engine«

Dr. Will Somers, VP Global Biotherapeutic Technologies, Pfizer



### Summary

Top global pharmaceutical company Pfizer has transformed itself into a leading biotherapeutics company by leveraging its significant disease expertise and implementing the best large-molecule R&D technologies to deliver innovative treatments that benefit patients worldwide.

### Industry

Biopharma

### Key Challenges

Pfizer's diverse and growing biopharma R&D operations required a central system to share data and align large-molecule R&D processes across different teams and geographies.

### Results

Fully integrated, end-to-end (E2E) workflow platform implemented, increasing Pfizer's biopharma R&D operational efficiency

### Solution

Genedata Biologics® and Genedata Bioprocess®

## Background & Challenges

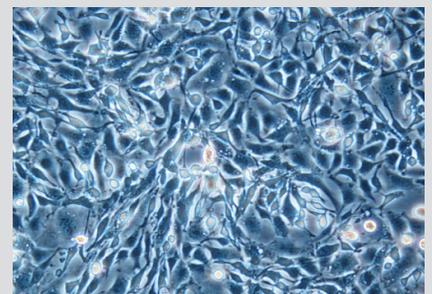
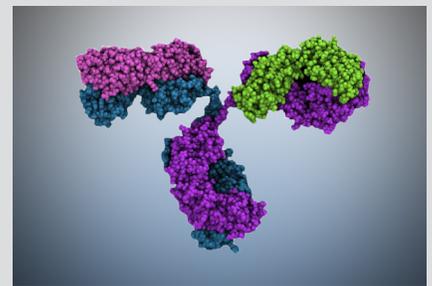
Pfizer, the world's largest pharmaceutical company, is a research-based organization with significant R&D investment. Key research areas include inflammation and immunology, internal medicine, oncology, rare disease, and vaccines. Biotherapeutic discovery and development within Pfizer is centralized in the Biomedicine Design and Biotherapeutic PharmSci departments.

With R&D teams spread across the globe, vast amounts of data were being collected in silos, making it difficult for teams to share information. This impeded collaboration and led to process inefficiencies. The challenge Pfizer faced was the alignment of workflows and the centralization of data for more than 200 Pfizer scientists located at 6 sites around the world.

After an aborted attempt with a develop-as-you-go approach, Pfizer decided to evaluate the market in search of a commercial enterprise data management system for their large-molecule R&D groups. The desired system would need to act as a backbone platform and central repository for Pfizer's biological R&D workflows and include tools able to capture specific instrumental data, workflows, analyses, and each group's unique contribution to the overall biological drug discovery process at Pfizer.

## Solution: Genedata Biologics

After conducting a thorough market evaluation to identify an off-the-shelf enterprise system for large-molecule discovery,



### Digitalization Requirements in Biopharma R&D:

The identification of large-molecule therapeutics, such as monoclonal antibodies (above), is based on sophisticated R&D technologies that produce vast amounts of data that need to be captured, processed, stored, analyzed, and interpreted in order to identify suitable drug candidates. Biopharma R&D organizations, such as Pfizer, require a workflow management platform tailored to biopharma requirements to streamline the full R&D process and identify the next-generation of biopharmaceutical drugs.

Pfizer decided to implement Genedata Biologics® as their central repository for their biologics discovery data, including screening, molecular biology, engineering, expression, purification, and analytics. Since the platform works out of the box and includes unique and comprehensive built-in business logic for all major discovery technologies, such as phage and yeast display, hybridoma, or B-cell-based approaches, Pfizer was able to get up and running quickly. In addition, the platform's open architecture made it possible for Pfizer to integrate it into their existing R&D and IT environment and to develop highly integrated custom tools on top.

»We had a vision when we brought in Genedata and it quickly became clear that

Genedata provides an excellent structure to the data and a great foundation to build upon«

“One of the reasons we chose Genedata Biologics was the platform’s process coverage. We required that the full diversity of Pfizer’s large-molecule processes and technologies be supported by one integrated system,” said Dr. Sergio Rotstein, Director, Research Business Technology, Pfizer.

The overarching reason Pfizer chose

the Genedata platform, however, was its ability to serve as a central data backbone and application environment upon which they could build tools to flexibly address Pfizer-specific requirements and to drive innovation using the system’s ability to onboard specialized R&D groups, which employ novel and proprietary discovery technologies.

After only four years, the system is now used by more than 250 people in 15 groups located at 6 Pfizer R&D sites around the globe and supports 200+ distinct discovery projects

### Efficiency Gains & Cost Savings

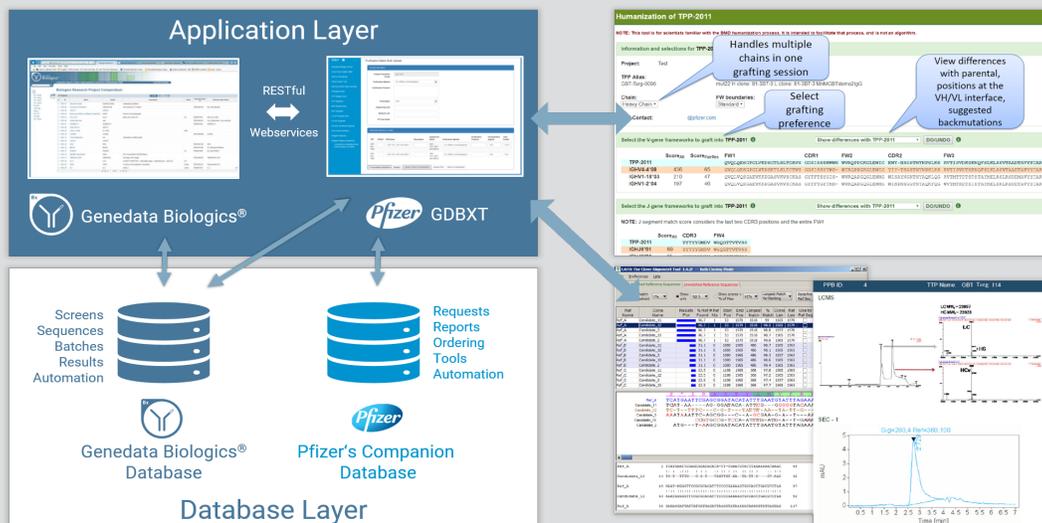
As a commercial off-the-shelf (COTS) product, Genedata Biologics went into operation for the first R&D user groups in just a few weeks, followed by adoption across the entire Pfizer Biomedicine Design discovery organization. The figures speak for themselves: after only four years, the system is now used by more than 250 people in 15 groups located at 6 Pfizer R&D sites around the globe and supports 200+ distinct discovery projects, including more than 900,000 clones, 28,000 lead

molecules, 900 cell lines, and tens of thousands of protein batches and their respective analytics and QC results.

For all these groups, Genedata Biologics enabled a high-throughput protein production workflow that was instrumental in dramatically increasing project throughput, with Pfizer reporting an increase, by a factor of as much as 10, in antibodies converted to full IgG per project. Furthermore, the system has helped to improve quality of results by eliminating errors resulting from passing spreadsheets and other ad hoc data exchange. Finally, the system has helped to standardize workflows and requests and allows specialized groups to work and operate more efficiently in a division-of-labor organization.

»Genedata Biologics’ flexibility allows Pfizer to configure the system to address both proprietary discovery processes as well as Pfizer-specific business processes and nomenclature«

“Pfizer is pleased to have gained full access to this system for antibody discovery and protein engineering, which is now an integral part of Pfizer’s large-molecule discovery engine,” said Dr. Will Somers,



**Solid foundation to build upon:** Genedata Biologics serves as a central and shared data backbone on top of which Pfizer is developing new applications addressing Pfizer-specific workflow and technology requirements (left). These new applications interact in a bi-directional way via RESTful Webservices (arrows) and make use of Genedata Biologics’ full business logic. (Right) Example of Pfizer applications built on top of Genedata Biologics: (1) Pfizer’s proprietary humanization tool, directly interacting with Genedata Biologics, (2) clone alignment tool employing a Pfizer-specific scoring logic, and (3) report generator producing laboratory documentation according to Pfizer-specific formats and standards.



and innovative technologies that require custom workflows, additional metadata, or integration with robotics and automation equipment. By having the Genedata enterprise platform as our central data backbone, we can build our own in-house solutions around it and keep all the information secure, stable, and accessible in one central place," said Dr. Joel Bard, Associate Research Fellow, BioMedicine Design, Pfizer.

Another key decision criterion behind adoption was the system's data interoperability and system integration capabilities. Even in a complex, multi-vendor environment, Genedata Biologics can seamlessly interact with diverse instruments and IT environments. Comprehensive Application Programming Interfaces (APIs), based on RESTful web services, enable multifaceted – yet easy to maintain – integrations.

Finally, information security and IP protection capabilities were central to Pfizer's decision to move forward with Genedata. The system's fine-grained user and access control, together with its easy integration with Pfizer's corporate authentication systems, were additional reasons behind their choice.

## Expanding Scope: Genedata Bioprocess

Three years after the deployment of Genedata Biologics, Pfizer decided to expand beyond discovery and implemented Genedata Bioprocess® to support their large-molecule pharmaceutical development.

"After conducting a pilot project to determine if Genedata Bioprocess had the potential to meet our requirements,

we decided to move forward with its implementation," said Dr. Sergio Rotstein, Director, Research Business Technology, Pfizer.

The integration of Genedata Bioprocess with Pfizer's existing Genedata Biologics platform has created a centralized, shared data repository that can be accessed by both research and development units. Improved data tracking and analysis via integrated data collection and enhanced data association has helped Pfizer to streamline data-focused biopharma development processes.

»Now that we have a central data backbone in place where all information can be accessed and shared, our R&D groups can spend their time on critical scientific tasks, instead of manual data reporting and management«

Pfizer decided to operate the Genedata platforms in one instance to facilitate maintenance and integration. As such, fundamental data for development candidates can now be handed over seamlessly from the Biomedicine Design discovery group to the cell line development team in charge of developing high-titer, stably expression cell lines.

## Future

The Genedata platform has become a vital part of Pfizer's R&D organization and is used at every stage of their large-molecule research operations. Pfizer is now looking to further expand the platform to new fields and applications and usage of the platform

is being extended in two directions.

First, Pfizer is working towards expansion of the use of Genedata Biologics for research on novel therapeutic modalities and further downstream in the development process.

Second, Pfizer has started to use Genedata Biologics as the foundation for artificial intelligence (AI) and machine learning approaches to lead optimization. The availability of all experimental assay and analytics data for all molecules and samples, including historical data, in a highly structured database, enables Pfizer to systematically mine data across projects. By applying deep learning algorithms, Pfizer can identify correlations between drug-like properties and molecule characterization data. For example, machine learning algorithms can make predictions about the risk profile of any given drug candidate.

"We have come a long way since we decided to deploy Genedata Biologics at Pfizer. We are committed to continue working closely with Genedata and we are very pleased with the knowledgeable and engaged support we get from the Genedata team," said Dr. Joel Bard, Associate Research Fellow, BioMedicine Design, Pfizer. "Now that we have a central data backbone in place where all information can be accessed and shared, our R&D groups can spend their time on critical scientific tasks, instead of manual data reporting and management."

Learn more about Genedata Biologics® and Genedata Bioprocess® at [www.genedata.com/biologics](http://www.genedata.com/biologics) [www.genedata.com/bioprocess](http://www.genedata.com/bioprocess)



Genedata Biologics® and Genedata Bioprocess® are part of the Genedata portfolio of advanced software solutions that serve the evolving needs of drug discovery, industrial biotechnology, and other life sciences.

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