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> **Will Somers**, Ph.D., VP Global Biotherapeutic Technologies, Pfizer

Pfizer Builds on the Genedata Biopharma E2E Workflow Platform

INDUSTRY
Biopharmaceuticals

GENEDATA CUSTOMER SINCE
2015

ABOUT PFIZER
Top global biopharma giant Pfizer delivers biotherapeutic treatments that benefit patients worldwide.

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.

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

GENEDATA SOLUTIONS

BIOLOGICS

BIOPROCESS

Biotherapeutic Discovery and Development

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, 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.

"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 Sergio Rotstein, Ph.D., Director, Research Business Technology, Pfizer.

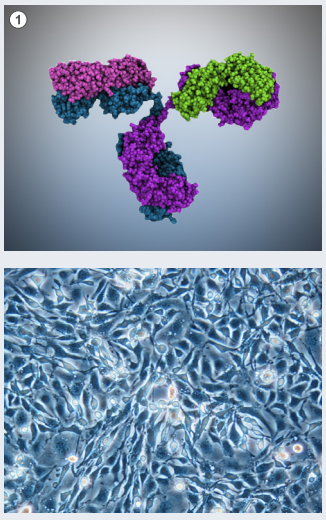
The overarching reason Pfizer chose the Genedata platform, however, was its ability to serve as a central data backbone and application environment upon which they could build tools to flexibly address Pfizer-specific requirements and to drive innovation using the system's ability to onboard specialized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

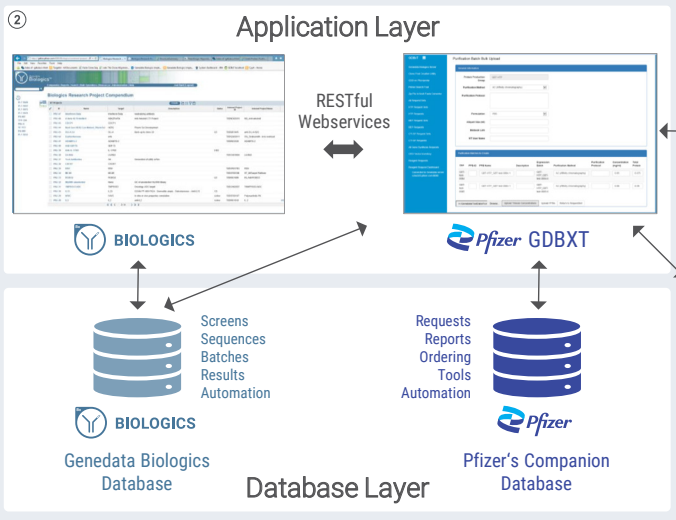
Efficiency Gains & Cost Savings

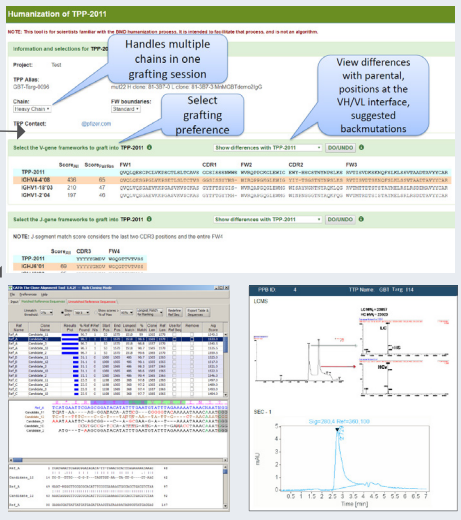
As a commercial off-the-shelf (COTS) product, Genedata Biologics went into operation for the first R&D user groups in just a few weeks, followed by adoption across the entire Pfizer Biomedicine Design discovery organization. The figures speak for themselves: after only four years, the system is now used 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







① ***Digitalization Requirements in Biopharma R&D:*** *The identification of large-molecule therapeutics, such as monoclonal antibodies, 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.*

② ***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.*

workflows and requests and allows specialized groups to work and operate more efficiently in a division-of-labor organization. "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 Will Somers, Ph.D., VP Global Biotherapeutic Technologies, Pfizer.

Having central access to relevant R&D information has revolutionized how Pfizer discovery groups work today. In the past, information was scattered across groups and geographies and people needed to spend an inordinate amount of time trying to find and interpret key data. Now, every group has immediate access to critical information, such as protein and DNA sequences and measures of developability and manufacturability, which enables informed decision-making and saves tremendous time and, ultimately, money along the R&D process.

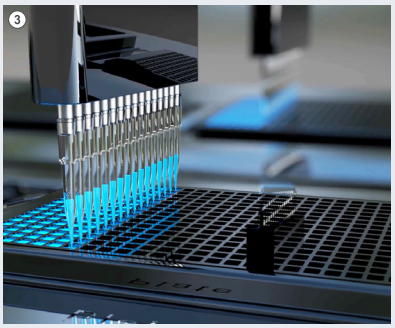
Having a shared central system also means that creation of manual batch reports is a thing of the past for many research groups. Since all the data is registered into the system during daily operations, information on every lead is updated in real-time after each step along the R&D workflow. This means collected data can be tracked and verified all the way back to the beginning of the R&D workflow, providing a crucial historical record.

Building on a Solid Foundation

Besides the immediate functional benefits witnessed after implementing Genedata Biologics, Pfizer chose the system as their large-molecule R&D data backbone for infrastructural and architectural reasons. Pfizer wanted simplified and harmonized R&D operations. At the same time, they wanted a platform that could flexibly address Pfizer-specific requirements, such as Pfizer-proprietary antibody molecule formats (e.g., bispecific antibodies), and that was extendible, so that Pfizer's informatics and IT teams could build new functionalities on top of it. The flexibility and openness of the Genedata system was a key criterion behind Pfizer's choice.

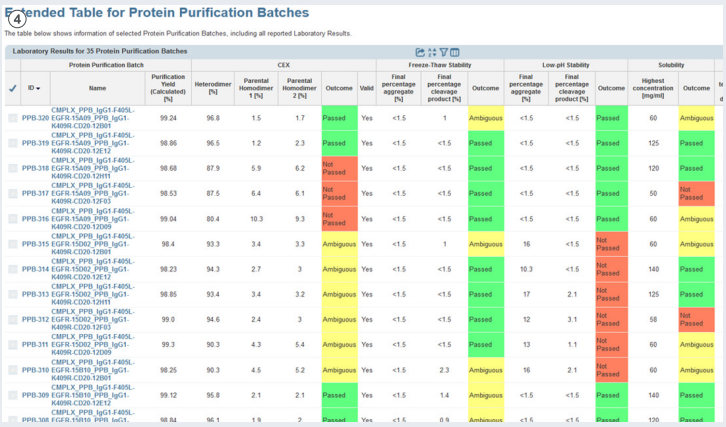
"Genedata Biologics' flexibility allows Pfizer to configure the system to address both proprietary discovery processes as well as Pfizer-specific business processes and nomenclature," said Sergio Rotstein, Ph.D. Director, Research Business Technology, Pfizer.

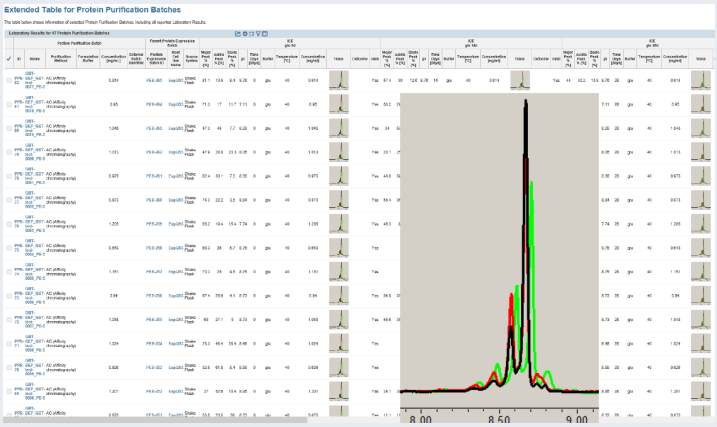
Genedata Biologics is an open system based on an industry-standard three-tier architecture. Pfizer can easily extend the system to support future changes in technology or functionality – which is what clearly differentiates Genedata Biologics from many other options. The initial deployment, as well as ongoing extensions and adjustments, demonstrate a maximum ability for configuration and customization.



③ ***Increasing automation & throughput:*** *The direct integration of the Genedata platform with Pfizer's automation equipment and laboratory robotics has enabled Pfizer to dramatically increase throughput of the large-molecule R&D process, such as sample handling and testing. The Genedata platform allows users to automatically control and manage pipetting and sample handling by liquid handling robotics stations and assay readers, enabling true high-throughput biopharma screening, engineering, and production processes.*

④ ***Central Data Cockpit:*** *Examples of Genedata Biologics dashboards in use at Pfizer that integrate molecule, sample, and assay & analytics data. (Left) Intuitive traffic light system to assess a drug candidate's suitability by integrating multiple parameters, such as developability and manufacturability criteria. (Right) Purification batch dashboard integrating Pfizer's lead molecule information with respective expression and purification data, allowing drill down to all relevant QC testing information (e.g., aggregation or endotoxin levels). A panel of therapeutic antibody lead candidates is shown, including respective analytics information, such as Inorganic Trace Analytics (ICE) information.*





"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. Antibody drug discovery is an extremely dynamic field, and our teams constantly bring in new science 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 Joel Bard, Ph.D., 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, multivendor 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 Sergio Rotstein, Ph.D., 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. 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 Joel Bard, Ph.D., 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."