



We needed a central platform to capture and process data across our global R&D teams, while ensuring full data integrity and traceability, and Genedata was the only solution that ticked all the boxes right from the start.

Björn Hock, Ph.D., VP Biologics Technologies and Development, Ferring

Industry
Biopharma

Customer Since
2020

About
Ferring Pharmaceuticals is a global biopharmaceutical company developing innovative treatments in the areas of reproductive medicine, maternal health, gastroenterology, urology, as well as ground-breaking microbiome-based therapeutics and gene therapies.

Key Challenges
Ferring required a state-of-the-art data infrastructure to integrate biologics development workflows across bioprocess and analytical development and to be scalable and future-proof to serve multiple international R&D sites.

Results
Genedata Bioprocess was swiftly deployed for various modalities across multiple locations to allow Ferring to derive business value and scientific insight from its diverse R&D data sources.

Genedata Solution
 **BIOPROCESS**

From mAbs to Therapeutic Microbiomes

Ferring Establishes a Global Bioprocess Development Data Framework

Background & Challenges

Ferring Pharmaceuticals is a research-driven specialty pharmaceutical group developing treatments for reproductive health, urology, gastroenterology, and endocrinology. Since pioneering work establishing industrial production of synthetic peptide hormones in the 1950s, Ferring has grown into a global organization with more than 7000 employees worldwide. Ferring’s commitment to innovation is exemplified by a diversified pipeline and product portfolio including the first gene-therapy for bladder cancer ADSTILADRIN® and the first microbiome replacement therapy REBYOTA™, both of which were FDA-approved in December 2022.

In April 2021, Ferring looked for an end-to-end data management system for the newly established Ferring Biologics Innovation Centre (FBIC), based at the Biopôle innovation campus in Lausanne, Switzerland. The solution had to serve CLD, USP, DSP, and analytics groups and be scalable to work within an international, multisite development organization with established R&D and manufacturing sites in Israel, Germany, Switzerland, Denmark, and the USA. Ferring wanted to gain value from all of their global sources of biologics data and improve data quality and development efficiency.

The data management systems already in use at Ferring included a mix of internally developed software tools and a commercial electronic lab notebook (ELN). Almost all transfer of information between process steps or groups involved time-consuming and manual processes. The captured data was not sufficiently structured and interoperable, which made it impossible to mine the data and get long-term value and utility. Ferring envisioned a solution that would facilitate robust and rapid handover of data between teams and R&D sites, break down data silos, enable new insights, and accelerate

development projects. Ferring needed an integrated workflow management system that could:

- Register diverse product lead candidates across multiple biologic modalities.
- Capture structured data from diverse instruments and manufacturers (bioreactors, LC-MS, flow cytometers, imagers, AKTA chromatography systems etc.).
- Integrate and exchange information with their existing ELN.
- Provide a central platform for integrating data, e.g., during scale-up from Ambr microreactors to production-scale bioreactors.

was opened and Genedata Bioprocess was implemented across the CLD, USP, DSP, and analytical development groups (Figure 1). The deployment process was completed within 3 months thanks to the off-the-shelf nature



Without having to embark on a lengthy and costly customization project, Ferring was able to take advantage of Genedata's off-the-shelf platform and immediately start using the software across all our R&D sites. The Genedata platform also supports our quality and compliance requirements, functionality completely missing in the other solutions we looked at.

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VP Biologics Technologies and Development, Ferring

Solution

Ferring embarked on a comprehensive procurement process. However, it was clear early on that Genedata Bioprocess was the only off-the-shelf solution available that could comprehensively cover Ferring's end-to-end process requirements, while also providing a scalable, structured data infrastructure that was already compatible with many of their facilities and instrumentation. In the initial project phase, the newly established FBIC facility

of Genedata Bioprocess, and its robust pre-existing integration capabilities. System setup and user training through Genedata's Hypercare program was conducted both online and in-person by Genedata consultants.

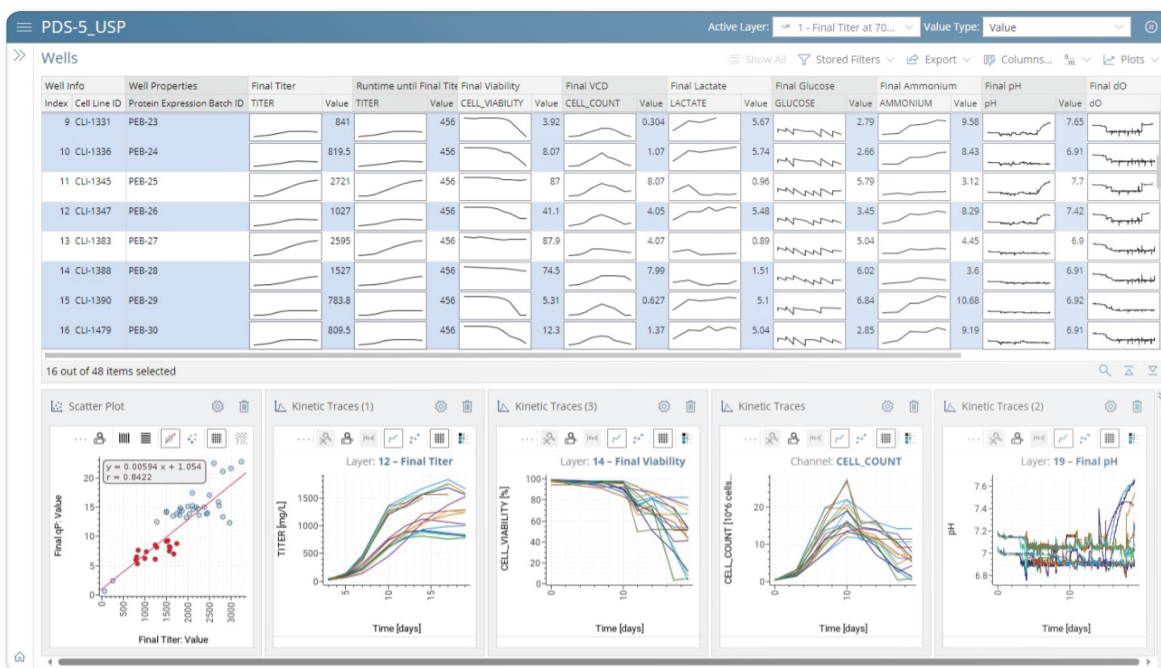


Figure 1: Ferring's process development data management system, built on Genedata Bioprocess, enables complete end-to-end capture of critical information and includes comprehensive data integration capabilities off-the-shelf. This screenshot shows an upstream-process data dashboard where time-course online and offline data can be easily integrated and explored.

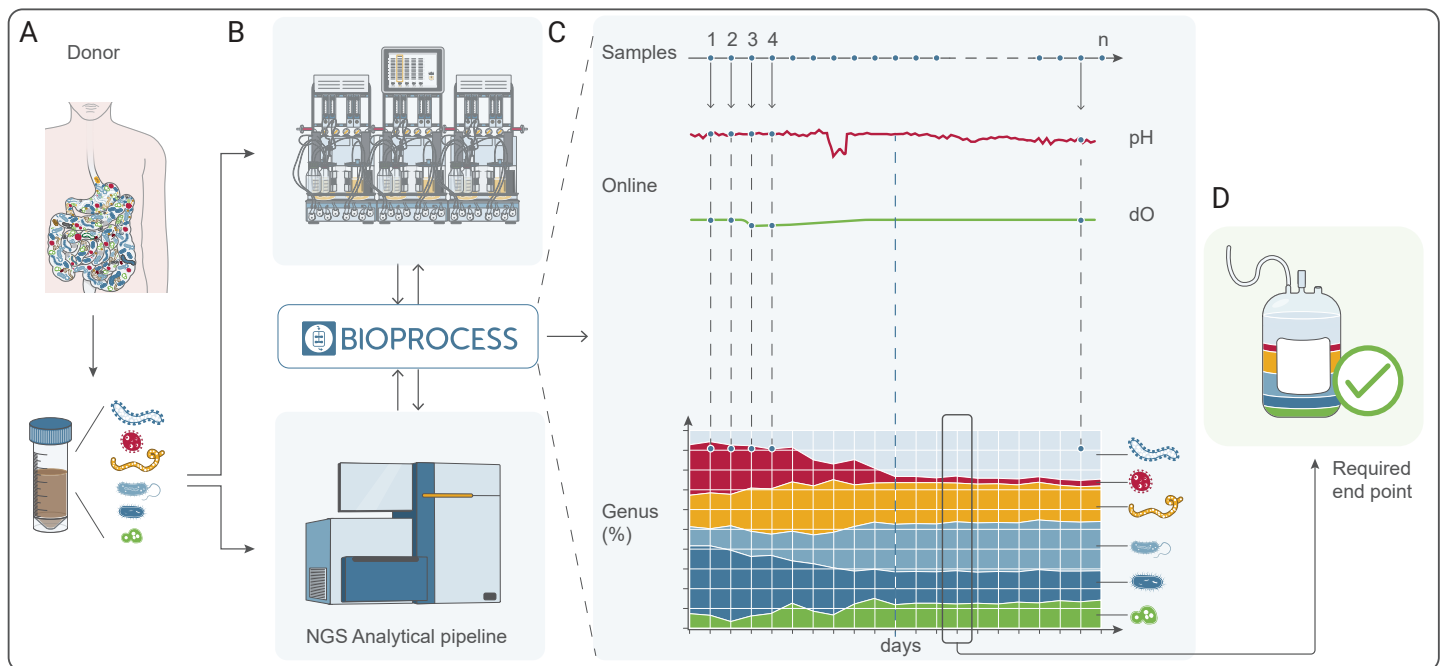


Figure 2: Ferring's pioneering Microbiome Replacement Therapy Rebyota is used for the treatment of recurrent *C. difficile* infections. In MRT, the microbiome is collected from healthy donors, and microbial consortia are determined via next-generation sequencing (A). To facilitate the further development of MRTs into safe and scalable treatments, Genedata Bioprocess captures and links all batch/donor information and online/offline process parameters (DO, pH, etc.) in one structured system. This data is integrated via APIs and RESTful webservices with Ferring's in-house NGS-based microbiome data science pipeline (B) This enables Ferring to comprehensively and automatically quantify the relationship between particular process parameters and microbiome consortia diversity (C) so that Ferring can optimize scalable, consistent production of microbiome replacement products with specified microbial composition for therapeutic benefit (D).

Building on the successes of the FBIC deployment, Ferring subsequently rolled out Genedata Bioprocess to other international sites where diverse biotherapeutics are under development, including gene therapies, protein-based therapeutics, and state-of-the-art microbiome replacement therapies. With its unique bioregistration engine and open architecture, Genedata Bioprocess could be easily configured to support these novel therapeutic modalities. A highlight is the use of Genedata Bioprocess to support microbiome replacement therapy development, which comes with entirely new bioprocess development requirements.

"We were delighted to realize that we could use the pre-existing integration and data analysis capabilities of Genedata Bioprocess to integrate data from our NGS-based microbiome data analysis workflows and our bioreactor experiment data," said Andre Ferreira, Ph.D., Senior Application and Data Engineer, Ferring.

Microbiome replacement therapy (MRT) is a highly effective treatment paradigm (Figure 2) where microbiota from healthy donors are collected and processed into a

standardized form, before being transferred to patients suffering recurrent *C. difficile* infections. Every batch is extensively screened and subject to characterization at the microbiome level by next-generation sequencing (NGS) to verify that it meets approved standards (i.e., accepted microbiota composition).

"Genedata Bioprocess has enabled us to build an efficient data analysis pipeline to comprehensively characterize the relationship between bioreactor process parameters and microbiome consortia, enabling us to develop standardized microbiome replacement therapies at scale," continued Ferreira.

Efficiency Gains and Cost Savings

Genedata Bioprocess now captures structured data along Ferring's bioprocess workflows and gives scientists and engineers access to powerful tools to streamline their daily operations (Figure 3). It helps handover of data between teams by capturing full production history and associated data for each batch. Ferring also uses Genedata Bioprocess to help manage inventory, such as tracking aliquots and raw materials or even storing daily instrument

Query mAb stock for a project
(e.g., how much is left for DSP)

< 10 Seconds



Find a certificate
(e.g., mycoplasma of a cell bank)

< 1 Minute



Compare 4 data series of 6 batches, from 3 experiments
(e.g., Viable Cell Density, viability, Dissolved Oxygen, lactate)

< 3 Minutes

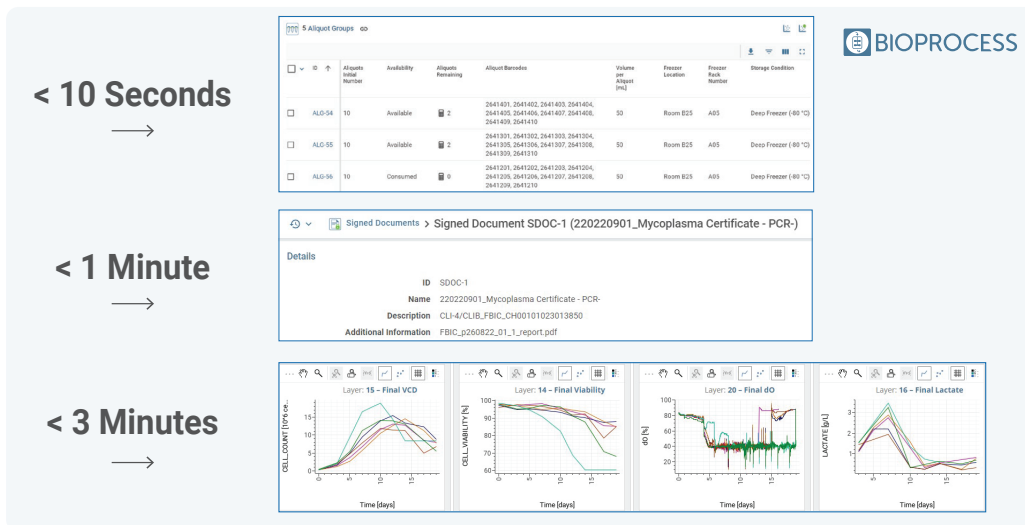


Figure 3: Examples of how the system's structured data generates operational value for USP and DSP groups at Ferring. Critical information, such as stock levels or an analysis certificate, can be checked in a matter of seconds. As Genedata Bioprocess captures all online and offline time-course data from bioreactor runs in an easily explorable analytics layer, comparing experimental parameters across batches can be completed in minutes (bottom).

calibration logs. A key business value comes from being able to attach the complete raw material history to each batch, as well as easily connecting this information to characterization data, so that quality issues for any batch can be rapidly identified and corrected.

Investing into Genedata Bioprocess has helped Ferring to build efficiency and scalability into the organization. Ferring had to decide how to best structure and standardize workflows, which has increased alignment between groups and increased data quality. Ferring could easily connect laboratory tablets and barcoding systems to the new system and devised internal data quality standards for efficient protocols. Now they can retrieve critical information with a click, such as checking an analysis certificate of a cell bank. They can compare data series from multiple bioreactor runs from separate historical experiments in a couple of minutes. Tedious manual data collation tasks have been eliminated, which not only increases the quality of data and records collected, but also saves significant working time in day-to-day operations.

“Using Genedata, we have a single source of high-quality data from all our international biologics development

activities, giving our development scientists and engineers access to all the information they need. It is faster and easier to track projects, which we now complete in a far more efficient manner,” summarized Ferreira. Since the data entered in the system is stored in a single unified and structured database, high-level analysis of the scientific and business parameters across the whole organization is now possible. The integration and comprehensive data capture makes the assembly of data for compliance and regulatory purposes much easier and gives the organization the most up-to-date information to guide informed decision making.

Outlook

Ferring continues to expand its usage of Genedata Bioprocess to additional groups working on diverse novel modalities and locations across their international organization. In addition to serving new groups, Ferring is increasing its use of the system's automation capabilities to capture and process data from instruments, so they have more time to focus on innovation and delivering novel treatments to patients faster.