



Eat Well, Live Well.



Genedata allows us to accelerate cell culture media development so that our biopharma partners can develop novel innovative treatments and vaccines faster and at a lower cost.

Hiroyuki Mise, General Manager of Ajinomoto's Biopharma Solutions Group

Industry
Biopharma

Customer Since
2021

About Ajinomoto

Ajinomoto is a global biotechnology company developing high-performance cell culture media and offering contract development and manufacturing services (CDMO) to the biopharmaceutical industry.

Key Challenges

Efficient cell culture media development requires an advanced digital solution for integrating and analyzing R&D data across different functions that are distributed across different development and manufacturing teams in Asia.

Results

Using Genedata Bioprocess as their central enterprise workflow platform enabled Ajinomoto to increase the efficiency and quality of their cell culture media development operations.

Genedata Solution



Ajinomoto Speeds Up Cell Culture Media Development Using Genedata Bioprocess

Background & Challenges

Ajinomoto is a multinational food and biotechnology company headquartered in Tokyo, Japan, with leading capabilities in the development and manufacturing of amino acids and specialized animal origin-free cell culture media. Ajinomoto's well-known cell culture media products CELLiST™ and StemFit® are used to develop and manufacture diverse innovative immunotherapies, viral vector vaccines, induced pluripotent stem cell (iPSCs), and other novel biologic modalities. Ajinomoto also offers custom media optimization services as well as CDMO services to the pharmaceutical industry, allowing customers to benefit from Ajinomoto's advanced media for their own drug development and manufacturing.

Optimized growth media are critical for ensuring drug product quality and play a crucial role in increasing biological product yield to reduce long-term production costs. However, defined cell culture media are extremely complex and expensive to develop and manufacture, with strict requirements to ensure media quality. To achieve this, Ajinomoto performs intensive characterization of cell culture media during development by comprehensively evaluating dozens of components. Important performance data including product titer, product quality, cell viability, and metabolites in the media are monitored over time, which requires high fidelity capture and analysis of experimental, process, and product analytics data (e.g., mass spectrometry data).

Due to the large number of media components that must be carefully evaluated during media optimization, the experimental design space is vast (Figure 1). The combinatorial complexity

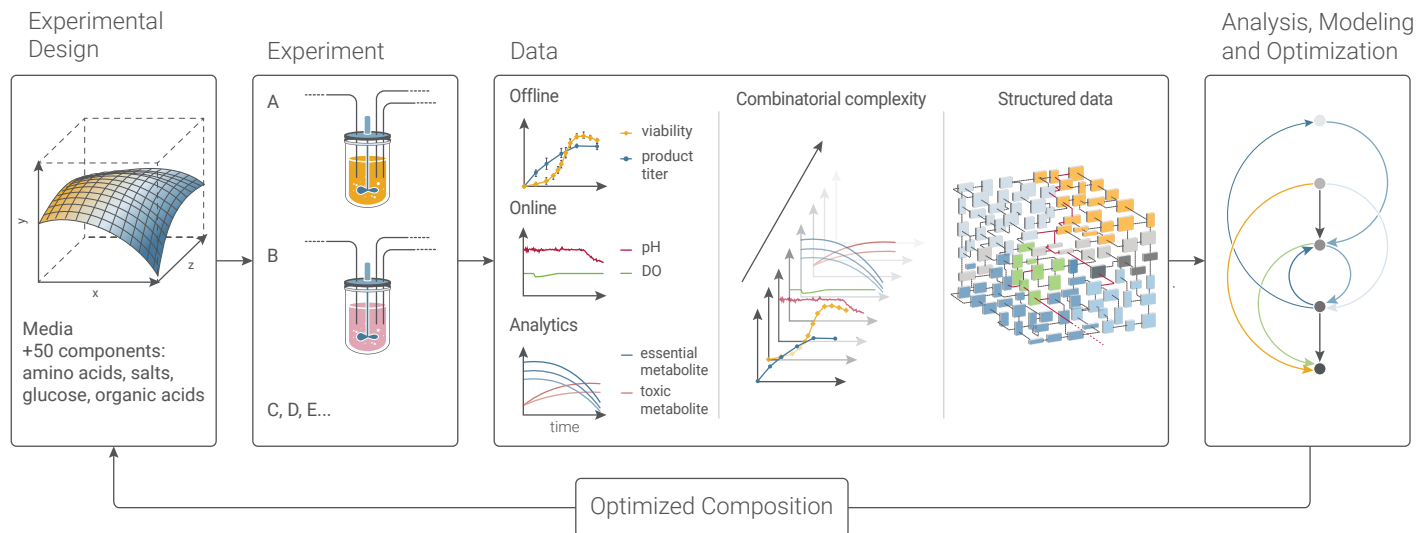


Figure 1: Cell culture media optimization workflow: The experimental design workflow for media optimization experiments poses specific requirements for data capture and analysis. Typically, for each experiment there are dozens of input parameters (media components, but also process parameters) and dozens of online and offline readouts (e.g., pH, DO, titer, VCD), as well as product analytics (e.g., glycan analytics, metabolites, etc.). A structured data capture is required for systematic cross-experiment and cross-campaign analyses, including novel AI/ML approaches. Besides the workflow automation and data capture requirements, the digital platform needs to be able to integrate with existing IT and software ecosystems at Ajinomoto (e.g., DoE) via integration interfaces for seamless data exchange.

of media optimization experiments requires that all data is captured and made available in structured form for systematic analysis. This challenge, combined with the need for full traceability of each experimental procedure and media component, means that cell media development requires a sophisticated workflow management solution that can handle complex cell culture time course data, together with all relevant process and product quality data.

As part of its global digitalization initiative, Ajinomoto sought a digital platform to capture and integrate all data from media optimization sites in Korea, India, China, and Japan. They aimed to find a workflow management system that would integrate all data to increase the efficiency of laboratory operations. As part of this initiative, Ajinomoto wanted to fully capitalize on the value of its large historical data sets from hundreds of media optimization projects, meticulously gathered over a period of 15+ years. Their historical data was spread out and fragmented in different legacy software systems and Excel files, limiting accessibility for analysis of these data sets in an integrated fashion. The file-based storage of data made it laborious to compare different experiments due to heterogeneous vocabulary, inconsistent metadata, and limited data integration. Data science operations were limited by the prohibitive effort required to wrangle the data.

Thus, Ajinomoto looked for a single digital solution that could:

- Track raw materials, samples, batches, process parameters, and cell growth characteristics.
- Capture complex media compositions.
- Integrate experimental data from diverse laboratory instruments including bioreactors (e.g., Ambr-15), assay platforms (e.g., CeDex Bio HT), cell counters (e.g., Vi-CELL XR, Vi-CELL BLU), LC-MS.
- Provide a centralized structured data source to facilitate comprehensive statistical analyses of media optimization data and other modeling, data science, and AI/ML approaches.
- Make all data centrally available in real-time, for all relevant groups to automate reporting and eliminate error-prone manual data transfer steps.

Solution & Benefits

After an extensive market assessment, Ajinomoto chose Genedata Bioprocess because it fulfilled most of their needs out-of-the-box and the platform could be easily configured to address Ajinomoto-specific requirements (e.g., Ajinomoto-specific sample naming, or instrument integrations).

“We chose Genedata Bioprocess after carefully looking at the market for a solution that could best cover all of our needs. With Genedata Bioprocess, Ajinomoto has been able to digitalize

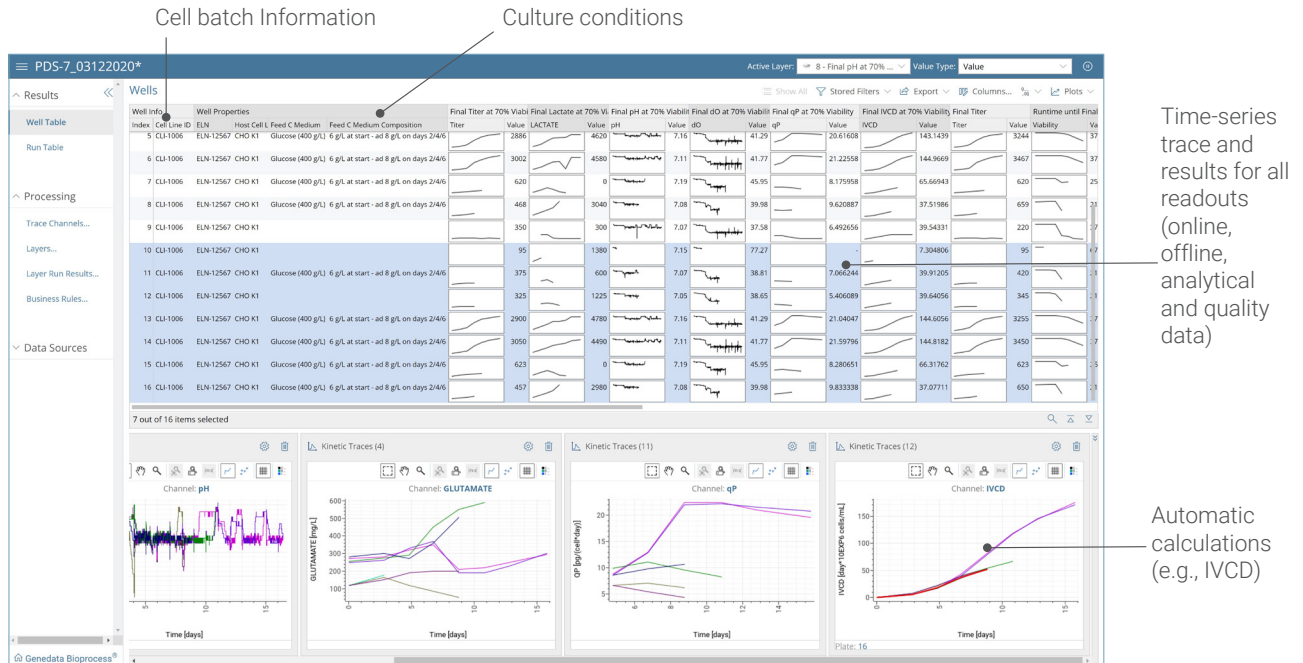


Figure 2: Genedata Bioprocess dashboard for cell culture medium development. Genedata Bioprocess enables massively parallel experimentation, structured data capture for advanced data mining and analytics, and end-to-end tracking of the media development process. This screenshot shows a panel of cell lines cultured in individual bioreactor vessels, with each row representing a transfected cell line cultivated with a different feeding regimen. The columns display both online bioreactor data and offline data integrated in time-resolved plots. The system performs analyses and calculations on the data automatically and enables integrated data-driven decision-making to identify optimum cell culture media for specific cell types and conditions.

Genedata Bioprocess connects data capture, analysis, and reporting across all our media development operations and helps us to better integrate our development and manufacturing teams in Japan and Korea, which leads to our shorter development timeline and significantly increased productivity.

Masaru Takayanagi, Ph.D.
Executive Officer of Ajinomoto.

its cell culture media development and optimization workflows across its international sites, using one central system for all cell culture media data management,” said Masaru Takayanagi, Ph.D., Executive Officer of Ajinomoto.

Today, Ajinomoto starts to use Genedata Bioprocess across all its media development R&D teams in multiple global sites. Genedata Bioprocess enables the comparison of multi-dimensional time-course data from different media formulations (Figure 2). By integrating media composition data, process parameters and measurements obtained from hundreds of experiments, Genedata Bioprocess provides a comprehensive dataset on the influence of the different media components on cell growth, productivity, and product quality. Programmatic access to all data is available via web services and APIs, which is critical for new data science approaches applied at Ajinomoto. It is now possible to easily compare historical experiments generated at different sites or interrogate differences between batches and access the value embedded in their legacy data.

To streamline the execution and analysis of complex experiments, where 60+ different amino acid compositions are evaluated per run, Genedata Bioprocess directly imports data from a variety of instruments including Ambr-15 microbioreactors, Vi-CELL BLU, LC-MS etc., (Figure 3). “The platform integrates with our existing laboratory instrumentation, allowing us to evaluate huge volumes of cell culture media development data at a level

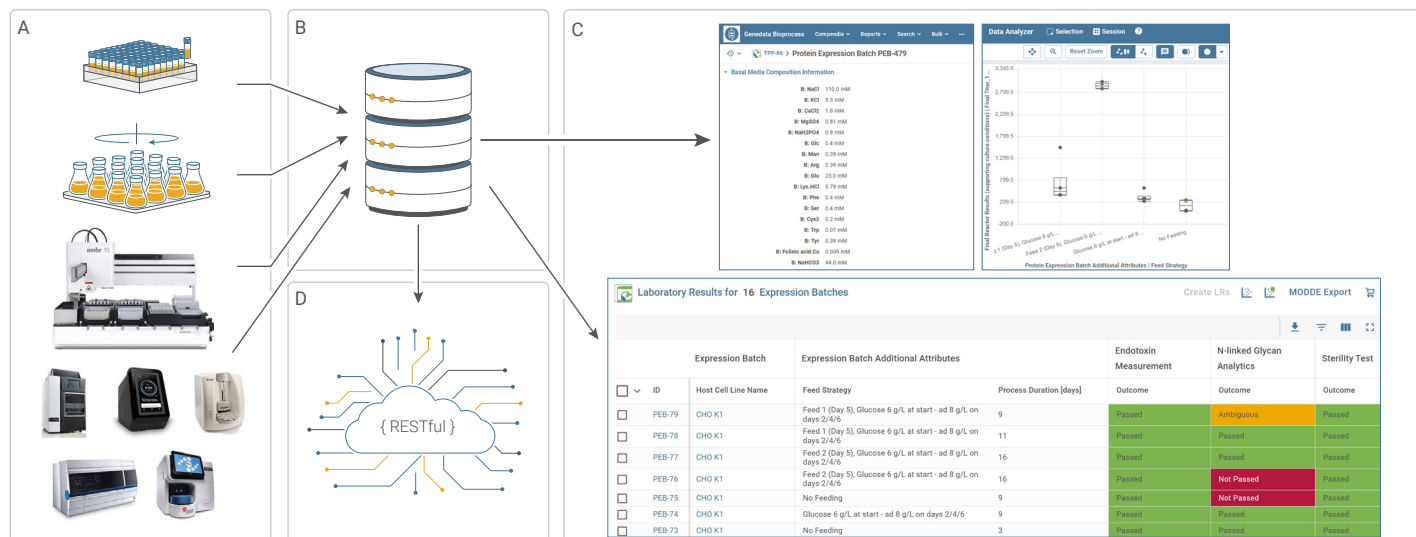


Figure 3: The Genedata Bioprocess system used by Ajinomoto’s cell culture media development teams consists of a four-level architecture, covering data input (A), structured data storage (B), an in-built data analytics layer (C) and open integration interfaces (D). With the new system, Ajinomoto’s scientists and process engineers can explore and compare high-quality time-course data from diverse sources, using in-built analysis tools such as configurable dashboards, hit selection tables, as well as external statistical tools and AI/ML applications that are integrated via Genedata’s APIs (e.g., RESTful webservices).

of complexity that was previously unimaginable,” said Hiroyuki Mise, General Manager of Ajinomoto’s Biopharma Solutions Group. Important calculated time series statistics such as IVCD, specific productivity (Qp), and metabolite concentrations are automatically calculated by the system. Furthermore, the in-built data analysis tools empower media development scientists and process engineers at Ajinomoto to make data-driven decisions, increasing efficiency and resulting in more performant cell culture media. This information is available in customizable dashboards, which allow scientists and process engineers to make fast decisions based on reliable information.

Using Genedata Bioprocess as a central enterprise system has the potential to deliver major business benefits through increased alignment and standardization of experimental data, streamlining cooperation and efficiency. As a result, it is expected that the speed at which projects can be completed increases. “With Genedata Bioprocess we are able to streamline and speed up our media development processes for both standard and customized cell culture media,” said Masaru Takayanagi, Ph.D., Executive Officer of Ajinomoto. This could bring big benefits to Ajinomoto’s process efficiency.

Outlook

Today, Genedata Bioprocess is a key component of Ajinomoto’s business growth strategy for its expanding cell culture media business around the world. All information across Ajinomoto’s groups in Korea and Japan can now be traced and related in one central platform that ensures data integrity and compliance. “After the successful deployment in Japan, we have now expanded the use of Genedata Bioprocess to our Korea-based teams to facilitate cross-site projects, resulting in significantly more efficient operations in our joint projects. At the same time, we are preparing for further expansion to our development site in China,” said Hiroyuki Mise, General Manager of Ajinomoto’s Biopharma Solutions Group.

As Genedata Bioprocess is fully scalable, this has the unique benefit that all data can be captured and integrated across new R&D sites as needed. “The value of Genedata’s system will further increase when our new customer service centers begin operation,” said Masaru Takayanagi, Ph.D., Executive Officer of Ajinomoto. Genedata Bioprocess is now an integral part of Ajinomoto’s digitalization strategy, which continues to utilize automation, AI/ML, and Genedata’s advanced data infrastructure to maximize business value for custom media development projects and CDMO services.