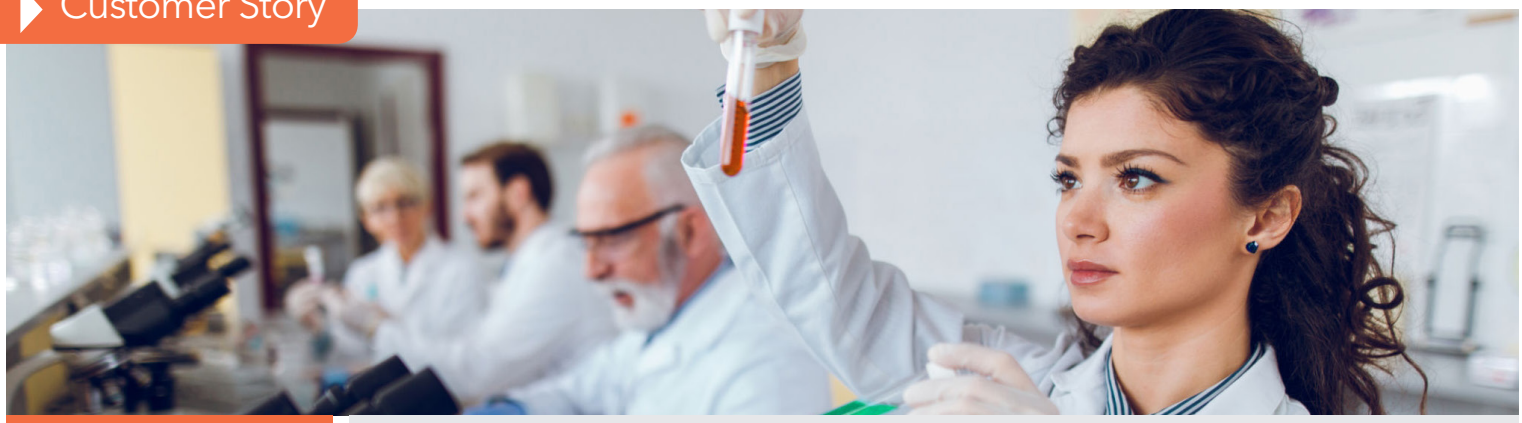
Customer Story



Fujifilm Diosynth Biotechnologies

Challenge

In an industry where design decisions have a significant impact on cost, scientists need more efficient approaches with which to optimize biopharmaceutical process development.

Statistical solutions for high-throughput science

Scientists at Fujifilm Diosynth Biotechnologies build process knowledge by optimizing experimentation at the development stage

In the highly competitive biopharmaceutical and biotechnology marketplace, rapid innovation cycles and adherence to a high quality standard are critical. Design decisions have a significant impact on cost, as manufacturing aims to make consistent and correct batches of product with no rework.

Recognizing that customers and health care providers have come to expect products that are both high-quality and cost-effective, contract development and manufacturing organization Fujifilm Diosynth Biotechnologies (FDB) is now providing its scientists a suite of state-of-the-art statistical and data science tools that aid in decision making, leading to both more efficiency overall and more replicable science. This move constitutes a recognition of scientists' growing need for statistical capability in the lab.

With locations in the UK, US and Denmark, FDB is a leading provider of contract biologics, gene therapy and vaccine process development and GMP manufacturing services. The company works in close partnership with customers around the world, offering extensive scientific expertise in cell culture, recombinant proteins, viral vaccines, microbial fermentation and gene therapies. It develops full life cycle manufacturing processes – including process characterization and process validation – for biopharmaceutical products from concept to commercial release and ongoing supply.

Innovation in high-throughput technology elevates experimentation

FDB has pioneered the use of high-throughput experimental approaches in addition to embracing automation and other equipment upgrades that aim to save time, increase process understanding, and enable integrated data workflows streamlining staff hours on individual tasks. These new technologies have played an outsize role in increasing throughput for FDB elevating its lab systems beyond the industry standard. These new technologies and approaches are increasingly being adopted by other players in this sector.

"High-throughput technology has had a significant impact on timeline development in biologics programs," says FDB Staff Scientist Somaieh Mohammadi. "For instance, ambr® [technology] in cell culture and fermentation established enhanced capability including using it as a suitable scale-down model, to deliver trustworthy evaluation and characterization of process performance and product quality from small scale to large scale."

As part of FDB's Data Science group, Mohammadi who has expertise in Statistics and Computational Engineering and her colleague Gwen Ninon – also a Staff Scientist in Data Science – work with internal clients to help establish new data science proficiencies. Through formalized training, individual ad hoc consulting and the deployment of longer-term strategic development workflows, Mohammadi and Ninon and their data science associates aim to equip FDB colleagues to better utilize high-throughput technologies like mini and micro ambr® bioreactor banks and automated liquid handling and analysis systems which can generate reams of data in very little time. To promote process innovation, it is their role to envision and implement new statistical and data science approaches that will inspire better performance in the lab by facilitating knowledgeable decision making.

One of the areas where Mohammadi and Ninon have made major strides is in Computational Fluid Dynamics (CFD). At FDB, CFD techniques designed to predict and optimize performance have become more prevalent in recent years. The diversity of choices for input parameters in this process, however, had become a bottleneck for scientists who were finding they needed to run more simulations to account for the abundance in factors. Mohammadi and Ninon were called in to help.

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Somaieh Mohammadi, Staff Scientist

"Due to the high complexity in our processes, we needed a better tool to assess the impact of physical forces such as fluid and gas flow in addition to consideration of more conventional parameters, which would include feed rate, cell density, etc.," Mohammadi explains. In search of a tool that could help them constrain input variables – and optimize experimentation with a design of experiments approach – she and Ninon turned to JMP® Pro.

Design of experiments helps optimize experimentation and shorten development times

One of the key features of JMP – and its sister configuration JMP Pro – is the software's tailor-made design of experiments (DOE) platform, which supports advanced DOE methods like custom design and definitive screening designs. DOE methods are today playing an increasing role in pharmaceutical and biopharmaceutical labs around the world, where statistical methods help research scientists to reduce the number of experimental runs that must be performed in a given test, thereby shortening development cycles. Though it is not the only software with in-built DOE capabilities, Ninon explains, JMP Pro was an essential tool for creating a DOE-based workflow that could be applied to CFD.

"DOE-based CFD modeling helped us to make better design decisions that will at the end of the day result in process understanding and product reproducibility," says Mohammadi. The key benefit of a DOE approach, Ninon adds, is that scientists can plan experiments in advance, separating those factors that are important from those that are just noise.

"From a statistics point of view, we get to run experiments without worrying about lurking factors or randomization," Ninon says. "Being able to test a range of conditions quickly at small scale in a proven model is key to getting through characterization and validation faster and with less risk."

Functional Data Explorer is a key feature in preparing data for analyses

JMP Pro also offers a multi-utility platform known as Functional Data Explorer (FDE), which is in essence a data transformation tool that helps scientists to prepare data for analysis – including DOE. FDE comes in particularly handy in biologics development where much of the data – sensor data, transactional data or chemical spectra for example – is presented as a function. As Mohammadi and Ninon might attest, the challenge of working with functional data is that often, scientists don't want to analyze the functional data directly; rather, they want to work with the underlying functions which produce the observed data.

FDE transforms that data into a form that can more easily be analyzed. As such, it is a crucial tool for pre-processing data for exploratory analysis, creating surrogate models or reducing dimensions. And FDE outputs can be easily shifted into another JMP platform with just the click of a button.

"The very easy-to-use ML platform is also great," Ninon adds, "and the fact that you can save dashboards in HTML to share with non-users." The in-built shareability of JMP analyses is as important for scientists working collaboratively on development projects as it is for those like Mohammadi and Ninon who work in an advisory capacity providing ad hoc support.

Today, scientists at FDB have many tools to choose from. But, says Ninon – who learned Minitab in graduate school and has also used open source software extensively – JMP is their first choice for certain types of analyses. The visualization and data imputation qualities in JMP, in addition to its specialty platforms like FDE, are huge factors. "Although we could have done [all these things] in R, we would not have thought of it without prompts and it would have been very difficult and time consuming to get it done," she adds.

"Although there are a lot of complicated calculations and coding going on in the background," says Mohammadi, "the very user-friendly platform in JMP makes it quite easy to use." These efficiencies all ultimately contribute to the speeding of development cycles and, in turn, both profitability and scientific innovation.

Solution

JMP® Pro is helping scientists at Fujifilm Diosynth Biotechnologies (FDB) to establish new data science proficiencies in support of the company's broader business goals. From exploratory data analysis and dimension reduction with the tool's Functional Data Explorer platform to design of experiments and visualization, JMP provides a strategic, cost-effective means for scientists to grow process knowledge in less time.

Results

By broadening their statistical and data science toolkit, FDB's scientists are making biopharmaceutical development and manufacturing processes more robust and replicable. The streamlining of early phase development has led to a shorter development and production time scales.

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