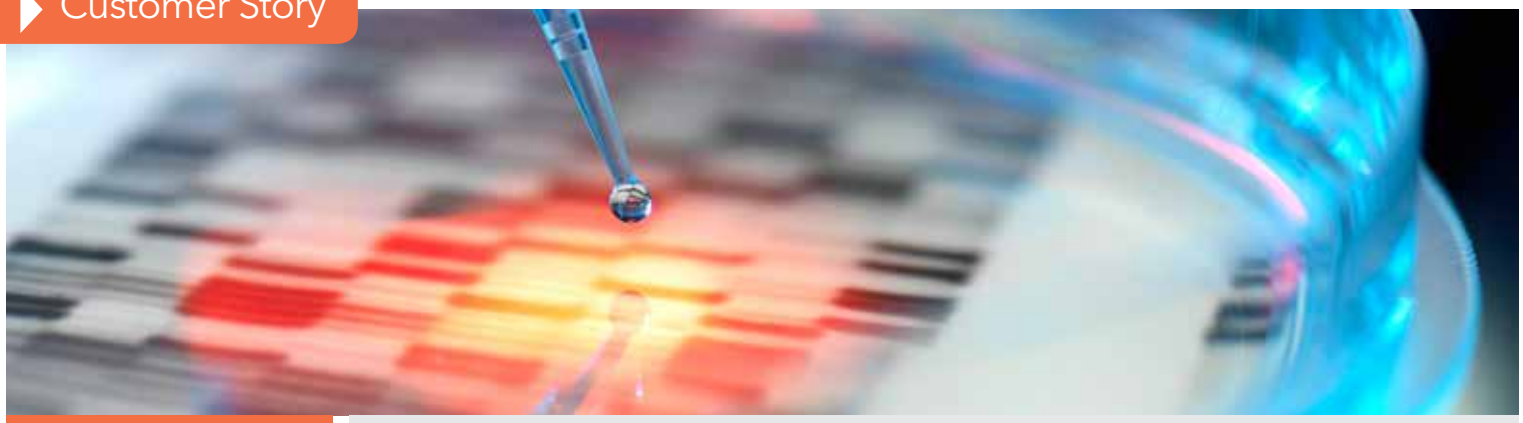
Customer Story



Daewoong Pharmaceutical

Challenge

High medical costs have increased global demand for novel treatments, and there is intense competition among pharmaceutical companies to be first to market.

QbD accelerates the move toward ever more innovative areas of research in pharmaceuticals

Daewoong Pharmaceutical, one of Korea's largest pharmaceutical companies, uses big data to develop new biologics drugs in a competitive global market

It's no surprise to anyone that medical costs continue to rise, putting important treatments out of reach for many patients around the world. Inexpensive new treatments that don't compromise quality are a holy grail to pharmaceutical companies, with both patients and health providers eager for options. To meet this demand, pharmaceutical companies are pursuing innovative areas of research that capitalize on the availability of increasingly large amounts of medical data, such as personalized medicine and biologics. Despite fierce competition and high research costs, the massive untapped global marketplace for these products makes the potential payoff irresistible.

Rising to the challenge of this competitive landscape, Daewoong Pharmaceutical has invested heavily in research and development, particularly in biologics, or drugs made from living cells. Kyoung-Yun Kim leads the NABOTA Research Team at Daewoong, where he works on biologics research and development. Like other large pharmaceutical companies, Daewoong's R&D program targets treatments whose original patents are on the cusp of expiration, to capture the market ahead of their competitors.

Timing is critical to allowing a company to have a successful product launch, and regulatory bodies wield significant power over this process. Although the NABOTA Research Team's biologics are different drugs than their biosimilar predecessors, regulators demand that these products meet specifications equal to or surpassing the original formulations – a requirement that ultimately increases the time to market. Thus, researchers, and subsequently also manufacturers, have to develop stringent processes and demonstrate consistent quality and efficacy to meet regulatory requirements and limit delays. "To do this, you have to perform many analyses that even the original company didn't perform," says Kim.

Communicating the value of statistics companywide

Kim's team of researchers works on NABOTA, a botulinum toxin formulation that has exploded on the market since its launch in 2014. Ongoing research has increased the labeled indicants, expanding NABOTA use globally; with this success and continued investment in R&D, Daewoong aims to expand its NABOTA branch globally to become the highest-valued company by 2023.

Considerable amounts of data are required to conduct this ongoing research and manage global production, however. Regulatory bodies mandate stringent quality standards, and production facilities must collect significant amounts of data to monitor the purity of their products and ensure compliance, especially as they scale up production. From research to production, it is critical for Daewoong employees to understand the significance of data and statistics; targeted statistics training is therefore deployed companywide. In Kim's group, researchers also receive regular training on quality by design (QbD) and design of experiments (DOE) methods to adapt their research to new challenges.

Because statistical results play a key role in decision making, data quality is of utmost importance, and the research team has to have a thorough understanding of the implications of their data and subsequent statistical analyses. Says Kim: "The team helps both management and decision makers understand the results with sufficient statistical explanation and understanding."

> With JMP, we can get more data and we can more easily incorporate QbD into all aspects of our projects.
>
> Kyoung-Yun Kim, NABOTA Research Team Leader

Adapting to regulatory requirements

Essential to the development of good manufacturing processes is product purification and the achievement of consistent yield. In the course of their ongoing research, Daewoong developed a patented purification process, "High Pure Technology," which reduces product impurities. This quality initiative is driven, in part, by robust regulatory requirements. "Agencies want tight control of the impurities, so we have to develop state-of-the-art technology to analyze these impurities," Kim explains.

Once a company's research is submitted to a regulatory agency for approval, the agency can ask questions and require more detail about the quality control processes. Further complicating matters, each country has their own requirements, and companies must keep abreast of the constantly evolving guidelines provided by each of these regulatory bodies. Regardless, new approaches like QbD are spreading and becoming the global standard, and as a result, companies must have stringent process management systems, auditable data trails and thorough analytics to support their applications no matter where they go.

'In my case, JMP is more efficient and easier to use than other programs.'

Regulatory agencies don't stipulate which statistical software package must be used to gain approvals, but how that software affects the process or quality is important. As a biochemist, Kim didn't start his research career with formal statistical training. He has, however, learned statistics on the job, taking courses and attending workshops over the years to address whatever challenges arise. Though there are some statisticians at the company for support, the research team primarily deals with their own data issues; thus, facility with statistics has become a key part of their research.

It was during a workshop organized by the Ministry of Food and Drug Safety where Kim was first exposed to JMP.® The trainer "was immediately able to demonstrate the wide applicability of JMP to our work, helping me to understand how JMP is very relevant in our efforts to venture into overseas markets," he recalls. Kim has since used and compared a variety of statistical tools, but, he says, the powerful analytical engine that underlies JMP is what makes the tool a true standout. "And I've been using JMP ever since," he says.

It wasn't easy to get everyone on board at first – Kim's colleagues were used to other software, and they didn't necessarily want to invest time in learning something new. Eventually, it was his business argument, not his scientific one, that convinced the company to make the switch. "I explained to my boss that if I use JMP, we can get more data and we can more easily [incorporate] QbD into all aspects of our projects."

To implement the QbD concept in their research, Kim's team must determine critical quality attributes and set the limit of the process parameters related to their experiments. Using the DOE function in JMP allows them to create a systematic approach to identifying and defining these critical parameters, and from this data, the researchers set control statistics for their processes. With these results implemented, they can submit their data to the regulatory agency.

Using the right software allows Kim's team to interpret and manage data effectively, streamlining both scientific research and the regulatory application process. "JMP is able to showcase big data that is not viewable in commonly used tools – and do so in a user-friendly interface. [We can therefore] present more insights for decision making and analysis than compared to other tools."

Building internal capacity for future growth

Currently, the NABOTA team primarily uses the DOE function in JMP for custom design and some discipline analysis, but in the future, Kim says he hopes to deepen his JMP expertise and position his team to more fully exploit the full suite of JMP functionality. Still, JMP has already expanded the research team's capacity for complex statistical analyses and allowed them to effectively communicate their results on a global scale, facilitating NABOTA's entry into the US and European markets. Says Kim: "We are expecting this tool to be a big part of Daewoong's growth in the global pharmaceutical industry."

Solution

Increasing in-house statistical knowledge with robust methods like quality by design (QbD) and design of experiments (DOE) gives researchers tools to adapt to changing market and regulatory demands.

Results

By harnessing large quantities of data and implementing JMP® to analyze them more effectively, Daewoong can increase the quality of its products and satisfy diverse regulatory requirements, expanding access to patients globally.

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