Customer Story

Siemens Healthineers

Challenge

Optimize the manufacturing, testing and performance of an innovative and complex blood-analysis system.

Structure and Sustainability in Manufacturing Help Shape the Future of Healthcare

From quality engineering to machine learning, Siemens Healthineers turns to a statistical tool to keep manufacturing at the cutting edge

In the clinical point-of-care diagnostics market, Siemens Healthineers subsidiary Epocal is a leading example of innovation in manufacturing. Epocal's cutting-edge blood analysis system, known as the epoc® Blood Analysis System, enables medical professionals to measure a patient's blood gas, electrolyte and metabolite levels in real time, without leaving the bedside. With lab-quality results delivered in minutes to a handheld, wireless device, epoc technology has helped transform care delivery around the world.

To remain at the vanguard of healthcare innovation, a company such as Epocal – and its parent Siemens Healthineers – must continually improve its products: not just their performance at the point of care, but also their manufacture, from process reliability to the quality of component materials. "We have fairly complex products and innovative but exacting manufacturing processes," says Greg Mattiussi, senior director of manufacturing for Siemens Healthineers in Ottawa.

New cost and time constraints require a new approach to quality

As a leader whose purview encompasses everything from improvements in manufacturing, testing and shipping processes to product quality and validation, Mattiussi has long had a view to how trends and changes in the marketplace are affecting the company's bottom line: "The cost of using a traditional approach where you investigate one thing at a time is getting to be too high," he says, "and the time associated with gaining [process and product] understanding is becoming too long, so we have to look to Quality by Design to get the cost and the time that we want."

A concept first outlined in the late 1990s, Quality by Design (QbD) is an approach to achieving breakthrough innovation by building quality controls and their oversight mechanisms directly into a manufacturing system. QbD methods aim to establish comprehensive process and product knowledge in manufacturing environments, thereby helping engineers to predict and mitigate risks.

When it comes to QbD evangelism, Mattiussi is far from alone at Siemens Healthineers, where statistical approaches to manufacturing have become a part of the culture. "I've found that most engineers value rationality and sustainability in their work, and by sustainability, I mean manufacturing yields that are improving because we understand our processes better," he says. "So, in a way, they're very open to structured approaches to productivity and quality enhancements. An approach such as QbD still allows individual manufacturing sites to have their autonomy, because ideas of how to do things better that are data-based are embraced by the engineers and scientists responsible for the manufacturing outcomes."

To build up the capacity for such data insights, Mattiussi says, Siemens Healthineers "has to employ more and more powerful tools." And one of those tools is JMP software.

Moving beyond spreadsheets allows the team to evaluate multiple quality characteristics at once

Mattiussi oversees a team of engineers who focus on identifying opportunities for optimization. "And we have a significant validation role in the company," he explains. "There's a product component to what we do, and also a process component. We're involved from raw materials all the way to product performance in the field." That validation is far from simple. "We have multiple manufacturing lines now. We test not only finished goods, but across a product's lifetime, and we confirm the shelf life." In other words, he says, "We manage a lot of data here."

jmp® Statistical Discovery.™ From SAS.

One of the biggest challenges Mattiussi faces is the complexity of the diagnostic system itself; the epoc system handles 13 types of blood tests on a single test card. When Mattiussi's team conducts its analyses, multiple input parameters affect output, and output covers a wide range of values, namely, the typical concentrations of each analyte or substance in the blood being tested. "It's 12 sensors (and more calculated outputs) times 2 or 3 key process parameters times 2 or 3 key analytical levels," he explains. "Very quickly, you get into a matrix of input-output dependencies that is highly daunting."

In the past, the group relied on Microsoft Excel spreadsheets to manage its data. But achieving useable results became too time-consuming, and testing one variable at a time was slow and costly. "We're at a stage where the issues we can deal with on an individual basis have already been addressed," Mattiussi says. "Now we have to consider several quality characteristics at once. And there are more constraints on changes we can make, because the changes are more complex.

"We were spending a lot of time with Excel just trying to get the right view of the data. Instead, we found that JMP can much more easily connect data and shift from one view to another, changing one parameter, slicing the data a certain way. There were productivity gains to be made just from the interface and the data-centric view that JMP has." Mattiussi and his team began using the software to work their way from the most- to the least-problematic issues. For example, they used JMP software to perform an operational qualification that explored the space of several key inputs for their most complex sensor. They then mapped out the available process space to produce the appropriate analytical accuracy.

Regulatory considerations are also increasingly important. "Our whole product specification is based on levels of confidence," Mattiussi says. "It's a certain performance in the product analytically and a certain confidence level that we're hitting that analytical accuracy. That was the basis of our regulatory submission."

JMP software opens the door to machine learning

The capacity for more complicated analysis – and the ability to test out new methods – that JMP software brings to the table has also enabled Mattiussi and his colleagues to experiment with transformative new concepts such as machine learning. With its multiple deep-learning platforms, Mattiussi estimates that "JMP has the potential to simplify the software that's in the product and improve the finished-goods yield, which is one of the most important parameters that affect the cost of goods sold."

Machine learning can be used to predict single or multiple response variables based on a flexible function of inputs or hidden nodes. The primary advantage of these approaches is that, given enough hidden nodes and layers, a surface can be approximated to almost any level of accuracy. In the case of Siemens Healthineers epoc technology, machine learning is helping Mattiussi and his team to convert sensor outputs to a more accurate and precise analytical concentration.

Mattiussi is able to then see these interactions using graphic visualizations in the JMP software. "To achieve visualization in Excel, we'd have to buy prewritten macros or do a lot of macro- or script-writing ourselves," he notes. "With JMP, we can find the most effective way to slice up the data or show the results of a machine model without spending a lot of time making the program do something it wasn't explicitly designed to do. I've definitely noticed less pushback from management when we use JMP visualizations."

Optimizing products, the lifeblood of the company's success

Finally, Siemens Healthineers relies on JMP software to support testing; design of experiments (DOE) helps engineers reduce the overall number of tests by strategically selecting which factors to examine. "DOE enables us to build better and better models by adding data," Mattiussi says. Case in point: Because of product incubation, there's a delay between the manufacturing date and finished-goods testing. "In a lot of cases, we run an experiment and have to wait a number of days for the results. If we design the experiment properly, when we get results we didn't expect, we can do a supplemental test and incorporate it directly into the previous results," he explains. That allows the company to gain new process understanding while reducing the number of runs. It decreases materials and production line usage, saves time, and accelerates understanding. And the benefits are significantly enhanced by JMP software.

"Multivariate analysis is going to be big for us," Mattiussi says. "We're looking at analysis with Hotelling's T-squared distribution [for multivariate hypothesis testing]. It incorporates inputs and outputs and generates a control chart that monitors both. Eigenvectors made up of particular combinations of inputs and outputs can be identified that provide early warnings for lower yield. One control chart gives you clues about events and dependencies you otherwise have to really dig for. There are productivity gains just from the multivariate capabilities and the data-centric view in JMP."

Most important is the eventual outcome for patients. "We expect JMP to help us continuously improve the precision and accuracy of our analytical values," Mattiussi concludes. "That benefits us, but in the end, it also benefits our customers."

Solution

Use JMP® statistical software for Quality by Design and design of experiments to improve materials testing and analysis, optimize product- and process-related experiments and develop machine-learning applications for better overall product performance.

Results

JMP software enables Siemens Healthineers to conduct complex analyses and visualizations, giving the company the insights it needs to optimize all aspects of product development and operation, from raw materials to performance in the field.

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