Customer Story

Perrigo

Challenge

Meet new regulatory demands in pharmaceutical and health care product development in a cost-effective and time-efficient way, without jeopardizing quality.

'Business scientists' refine the science – and strategy – of research and development

Perrigo reduces product variability and other inefficiencies by growing the use of statistical analysis in experimentation and testing

Testing is a key aspect of product development in health care and pharmaceuticals, and has traditionally come with a hefty regulatory burden. With extensive post-development testing, pharmaceutical companies could iron out any kinks late in the process, and fulfill the strict trialing requirements set out in law. But recently, the onus has been shifting from testing quality into the products to designing quality, and that is making leading pharmaceutical companies like Perrigo reassess their approach to research and development.

Founded in 1887 as a packager of home remedies, Perrigo has built a unique business model that is best described as the convergence of a fast-moving consumer goods company, a high-quality pharmaceutical manufacturing organization and a world-class supply chain network. Over the past decade, the company has grown from its roots producing over-the-counter generics by acquiring a variety of brands including an infant formula division and an animal health division. Today the company has over 10,000 employees, working on 3,000 different formulations with more than 18,000 units, and producing 50 billion doses of oral, solid or liquid products each year. And these products are developed and manufactured at facilities around the world from the North America to Europe to India to Australia.

Research and development is the bread and butter of any health care manufacturer, but at Perrigo it's more than that. With its rapid expansion, Perrigo has had to invest in creating systems for R&D in order to ensure quality standards are maintained throughout the company's many products and manufacturing plants, regardless of geographic location. Additionally, Perrigo's diverse catalogue of products and the extensive testing that goes into each new release has produced a trove of invaluable data over the years. That's where Rob Lievense, Research Fellow in Global Statistics for Perrigo, comes in.

A growing company embraces a new way of thinking about quality

With a background in biostatistics and previous experience in R&D in the automotive industry, Lievense seemed like a natural fit. "I started in Perrigo's technical operations group because they didn't really know where to put me at first," he says. "The pharmaceutical industry hasn't traditionally known as much about their processes as other industries do, because they've always had such high margins. Their [foremost] worry was regulatory, not whether they were losing money. Now, that's changing."

Expectations from regulators like the American Food and Drug Administration (FDA), however, have changed in recent years with a growing emphasis on quality by design (QbD). Recognizing the early signs that this shift was underway, Perrigo appointed Lievense to take charge of a companywide statistical effort, coordinating the implementation of analytical methods for product development.

Using statistics to fix physical formulation problems

Gaining widespread buy-in was a gradual process, but Lievense has since proven a statistician's worth several times over, by becoming Perrigo's go-to problem solver. "We had a very troublesome formula that got bounced back from operations to development because they just couldn't make it work. It had way too much variability, but the product was a big moneymaker," he explains. Extensive testing revealed mixed results, but the company sought to meet the strict product specifications imposed by the

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>
> Rob Lievense, Research Fellow in Global Statistics

FDA. "When you have a highly variable product, there may be unrealistically tight specifications that you initially agree to because you ran three batches and they fit that box." When larger batches don't then conform to preliminary expectations, Lievense is called in to help teams identify and resolve variability issues.

In the case of the troublesome formula, Lievense says he "told the operations team and the development team, 'Give me everything you have. I want machine settings. I want lots of material. I want anything we can measure for this product.'" Lievense and his team then turned to JMP® to produce the sophisticated predictive modeling they needed to solve the puzzle. "We had to do all these weighted averages of anything measurable, so we ended up doing a lot of partitioning," he explains. "Then we also did some generalized modeling, and came down to three factors that kept popping up: a physical attribute of a key material, a performance attribute of a polymer resulting in changes that would slow the release down, and a key processing attribute ."

Lievense then used design of experiments (DOE) to identify the optimal design space for those factors: "We found a design space with JMP which allowed us to show management: 'Here's your sweet zone. If you stray outside of that sweet zone, you're in trouble.' Without using JMP I don't think we really would have gotten there."

Data modeling can help cut costs without sacrificing product quality

Using statistical techniques like DOE to increase efficiency is still new in Perrigo, but Lievense is confident that it is a viable way to reduce R&D costs and increase quality. "There's always a natural conflict between a statistician and a scientist," he observes. "I think having somebody there with a statistical background helps the team avoid doing things that are really going to invalidate the results."

By introducing JMP to teams of scientists developing products, Lievense aims to actually change the way scientists think and design experiments. He tells of a team leader who was shown the benefits of statistical analysis and JMP by one of his summer interns. "He said, 'I used to always work off the principle of science and expertise, so I always designed my experiments on what I thought was going to happen. Since then I've totally learned to use that as only my starting point. From there, I design an experiment and let the data tell me where to go.' So he's completely changed how he develops products."

Lievense now runs three-day JMP courses for employees across Perrigo's sites in the US. The goal is to coach scientists in using JMP to carry out more effective design of experiments. "We have to show the value," says Lievense. His goal is to expand the use of JMP for predictive modeling through database query, and eventually to up the ante to figure out how to fit good experimental designs into some of the most complex analytical methods they employ at Perrigo.

More than just software, JMP® is the solution

"We have to lead by doing studies and then extracting the value," he adds. That is the norm in many industries, but not necessarily in pharmaceutical development, when often a physical problem may need solving in order for a product to get marketed, and cost often comes second. "What we also need to do: start putting cost functions in all of our models," says Lievense. "What's the cost of this material or that material? What's the cost per minute of this process, that process? It adds a whole other dimension to your modeling." Lievense believes that by looking at data rather than results, scientists can find out ways to meet their requirements and cut costs, rather than just look for the optimum solution.

Lievense works closely with management, pushing for statistical analysis to be rolled out further, and employed more widely across Perrigo's global R&D operations. "When people are using JMP, and using it well, management will see the value."

Solution

Train scientists to take a strategic, data-driven approach when designing experiments, and to incorporate data analysis in product development. JMP makes it easy for scientists to augment processes with quality by design methods.

Results

Perrigo has adopted streamlined development processes that factor in cost from the outset, and reduce the need for extensive testing.

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