CHALLENGE

Providing integrated research, development, packaging and manufacturing services to pharmaceutical and biotechnology companies.

SOLUTION

Using experimental design capabilities in JMP®, Almac tests multiple formulation and manufacturing parameters to find an exact drug release profile.

RESULTS

Almac produces powerful multi-factor investigations with the minimal number of experimental runs to arrive at the ideal drug formulation, maximizing time, effort and resources.

A medicine is created

Almac uses JMP® to improve efficiencies and assist in bringing new drugs to market

We are all familiar with the work of pharmaceutical companies: years of research and vast sums of investment yield promising new drug therapies. But what happens once the new compounds have been discovered? A chain reaction of activity is triggered: manufacturing process development, formulation, packaging and stability assessments, all in order to produce an efficacious quality product that meets regulatory requirements. Enter Almac, a contract pharmaceutical company that does all those things, saving time and money for drug discovery companies and speeding the entrance of new medications to market.

"Almac's competitive advantage is the rapid and integrated end-to-end service we provide to pharmaceutical companies. We need a powerful software solution to handle the vast amount of data we analyse, and JMP is the natural choice," says James Hurst, Analytical Manager at Almac.

From laboratory to pharmacy

With a global staff of more than 2,500 people, Almac provides integrated research, development, packaging and manufacturing services to market leaders in the pharmaceutical and biotechnology sectors. When a life sciences company discovers a new compound, Almac takes that compound and completes the research and experimentation needed for drug substance manufacture, formulation development, product manufacture, clinical and commercial packaging, storage and distribution.

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"Once a company has discovered a molecule that may provide a therapeutic benefit, we provide the next step. Almac develops the drug from start to finish: we develop and scale drug substance manufacture, develop the administered formulation and manufacturing process – for example in either tablet, capsule or suspension form, we manufacture products for both clinical and commercial supply, establish the shelf life of the product via stability studies, and perform both commercial and clinical packaging operations, storage and global distri-

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bution; all within the framework of current Good Manufacturing Practices (cGMP)," explains Hurst.

Although discovery of the key compound is crucial in creating a new drug, the work that follows is no less important. For example, depending on what effect a drug is meant to have in a person's system, the way is it formulated can make a huge difference.

"Where and how quickly a drug dissolves in someone's digestive system can affect the way the drug acts in their body," Hurst explains. "Something that quickly dissolves in the stomach and is rapidly absorbed into the bloodstream can produce a fast but short-lived effect. To sustain this effect, the rate at which the drug dissolves may need to be controlled." Some drugs are best delivered via a time-release schedule, dissolving slowly as they move through the body, and a special type of formulation is required to enable this.

JMP software from SAS supports that process. A core team of 14 people use JMP, and their work influences the work of virtually every other part of Almac's product development service offering. "We need to be able to make informed decisions throughout the development process and design the best possible experiments to provide this level of service," says Hurst. "JMP allows us to create experiments that return scientifically valid results and ensure we have sufficient data to apply statistical analysis."

Getting the right formula

Almac does a great deal of work on drugs which are delivered via modified release formulation rather than a traditional tablet that breaks up immediately and dissolves in the stomach. To design this type of formulation, there are many different substances which may be put into the tablet to ensure the delivery of the drug at different points or throughout the digestive system.

"What JMP has allowed us to do is design streamlined experiments where we can try out multiple different formulation ingredients (excipients), and manufacturing parameters in order to get the exact drug release profile the client is looking for. We have used it to great success in achieving that," says Hurst. Once Almac gets the results of these experiments, the data is then fed back into JMP, which then helps predict the ideal formulation.

The experiments carried out in the modified release formulation trials are done by multiple in-vitro tests, which give some indication of how that the drug will be dissolved in the human body. The formulated product is then given to the client, which does tests on the actual human subjects and verifies the results by measuring levels of the drug in the blood.

"JMP is a great help in this area because there are a vast number of different ways to approach formulation development experiments. The software has an excellent design of experiments (DoE) capability that allows us to produce powerful multi-factor investigations with the minimal number of experimental runs. This helps us control costs for our clients as it consumes less of the very expensive raw materials that are used in each experimental run, and reduces the time and effort required to complete the formulation activities, but importantly we still arrive at the same quality endpoint," explains Hurst.

Why SAS

"I think the visuals of JMP are very good. The visual output is intuitive, and the graphs and charts are very simple and easy to understand. You don't need an in-depth understanding of statistics to run an analysis with our JMP system," says Hurst. "I think the application is getting easier and easier to use – and equally, it is very powerful. Every single analytical process you would need is there."

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Almac considered a range of other solutions before choosing JMP, but after a six-month trial, JMP proved to be ideally suited. Says Hurst, “It has everything we need, and the training to go with it, so JMP seemed the logical choice. Before we had JMP, we were limited to viewing data in tables and using less comprehensive software packages, but now we are able to do reliable and sophisticated analysis, trending and forecasting with ease.”

According to Hurst, SAS also performs well as a technical partner to Almac. “I have found that SAS is very open to discussing our needs and making sure that we get the right solutions and training, rather than just getting as much software as possible through the door. On an ongoing basis, we have regular contact with SAS for technical support and learning to use the application. SAS takes on some responsibility for seeing that we progress properly, and we appreciate that kind of partnership.”

In summary, Hurst says that Almac’s JMP solution is going from strength to strength, and enables the business goals of the company. “We aim to provide not just services, but value added partnership and support. JMP lets us be a much more integrated partner to our clients, and do our part in advancing human health therapies.”

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To contact your local JMP office, please visit: **www.jmp.com**