ALMAC

Partnering to Advance Human Health

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CASE STUDY

SMARTER, FASTER, CHEAPER: THREE WAYS FOR API MANUFACTURERS TO STAY AHEAD OF THE GAME

Pharmaceutical companies are increasingly enlisting the help of API contract manufacturers to improve efficiencies. But as the field becomes more and more competitive, how can specialist contractors ensure they don't get left behind? Elly Earls caught up with Almac Group's Denis Geffroy to find out.

Earlier this month UK pharmaceutical giant AstraZeneca confirmed rumors of yet another round of cuts, announcing that it will eliminate 7,300 positions throughout the company in an effort to save $1.6bn annually by 2014.

This is just one in a long line of similar announcements across the industry, which serves to highlight the fact that Big Pharma's business model is changing - to the benefit of outside contract manufacturers.

According to a recent Visiongain report, pharmaceutical contract manufacturing revenues will reach $64bn in 2016, a significant proportion of which will be generated by active pharmaceutical ingredient (API) manufacturers.

According to the report API manufacturing remained the largest market sector in 2010, accounting for 71.1% of the total market, while demand for generic and highly potent APIs will drive growth in the sector from 2011 to 2021.

KEEPING ACTIVE: WHY BIG PHARMA NEEDS OUTSIDE HELP

For Denis Geffroy, vice president of business development at Almac Group, an established contract manufacturer which, among other services, offers API manufacturing and chemical development, Big Pharma's increasing reliance on outside help is driven by two factors: cost and technology.

"The best way to stay cost-competitive is to be as efficient as possible," he said. "Contract manufacturers like Almac work with hundreds of clients and aim to reach 100% capacity utilization in manufacturing. We can therefore be much more cost competitive."

The technological sophistication that contract manufacturers can offer is also key. "More and more APIs are classified as highly potent and manufacturing these products requires special containment facilities," Geffroy explained. "Pharmaceutical companies don't want to invest in these in-house."

Moreover, many processes which were traditionally carried out using classical chemistry are now being created using biocatalysis, a technology which takes many years to develop in-house. Pharmaceutical companies are, therefore, turning to organizations like Almac Group, which has a dedicated biocatalysis group, to make use of their expertise.

"Finally, more and more pharmaceutical companies are looking at the whole process - the API and the drug product – to realize efficiencies and avoid the pitfalls of working in different silos," Geffroy added.

"They are looking for contract manufacturers that can do both, in an integrated fashion."

TECHNOLOGICAL INNOVATION: HOW API MANUFACTURERS CAN STAY AHEAD OF THE GAME

API manufacturing has always been an extremely competitive market, but as pharmaceutical companies farm out more and more of their manufacturing, this is only set to intensify.

"There are several hundred companies worldwide that manufacture APIs," Geffroy confirmed. "The top five in the world only have a few percent of the market share." So how can API manufacturers ensure they stand out in such a fragmented market?

The answer is simple for Geffroy: "Be very innovative and have something your competitor doesn't have."

For SAFC, Sigma-Aldrich's custom manufacturing and services business unit, the differentiator is having the only antibody-drug conjugates (ADC) GMP manufacturing facility in North America, while for Almac, the main point of difference is the company's biocatalysis expertise.

"It's a clear technology differentiator, which has allowed us to stay ahead of the game. It's not a new technology, but it's a continuously evolving technology and the more we invest in it, the more we set ourselves apart."

Two months ago, Almac decided to invest another $3m in biocatalysis research to discover and develop new enzymes, building on its already impressive technological capabilities. "We recently had a late phase project in Phase III clinical trials, and we were able to reduce the number of clinical steps from seven to three," Geffroy said.

"That is a breakthrough technology, if you can do an API in three steps rather than seven, you are definitely ahead of the game."

With highly potent APIs increasing hugely in popularity, another way API manufacturers can distinguish themselves from the crowd is by promoting their credentials in this area. "We've been involved in highly potent API manufacturing for more than ten years, but we have definitely grown that share of the business. It's about 40% of what we do now.

"We can't compete when it comes to easy-to-do APIs as these jobs go to the cheapest manufacturers, which tend to be in Asia, but if you're talking about highly potent compounds, not only do you need a dedicated containment facility, you need a track record too. If you have ten years' experience in this field, it's definitely a strong point of difference."

It is for this reason that Almac's manufacturing facilities are based entirely in the UK. "Six months ago we announced our plan to expand our manufacturing capacity significantly, and at the time we considered opening a plant in China or India.

But it was felt that we would lose some control by going to a low cost economy," Geffroy explained.

That's not to say the manufacturer doesn't make any use of the low costs in Asia. "We have a network of preferred manufacturers that manufacture non-GMP intermediates, but when the drug starts to become highly potent, we keep that close to home," he said.

SMARTER, FASTER, CHEAPER: THE IMPORTANCE OF LISTENING TO YOUR CUSTOMERS

Even with Almac's significant technological expertise, relationships with large pharmaceutical companies are by no means easy to maintain.

"It's a never-ending process. The market keeps changing so it's not about listening to what the client wants once and sticking to it, you need to be continuously listening and trying to make sure that what you offer is in line with their expectations."

Having said that, Geffroy has identified three of Big Pharma's recurring objectives: speed, affordability and the ability to anticipate problems before they occur.

"For example, if you are developing an API for Phase I clinical trials and you find out later on that the API is completely insoluble so you can't make it bioavailable, that is not acceptable," he explained.

"Pharmaceutical companies expect an organization like Almac to anticipate this and offer a solution at the beginning of the process, such as developing a different salt, which improves solubility and bioavailability."

While having a strong technological differentiator is absolutely key for API manufacturers looking to get ahead in an increasingly competitive field, this is rendered almost useless if you are not meeting the expectations of your clients in other areas.

"Pharmaceutical companies want things smarter, faster and cheaper," Geffroy underlined. "Everything needs to be focused on these three objectives."

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