

A vital cog in the machine



Given the complex manufacturing process of biopharmaceuticals, achieving operational excellence is an organisational challenge. To do this and drive efficiency at the same time is a benchmark worth emulating. **Dr André Overmeyer** of Merck Serono talks to Nic Paton about the benefits of reducing the cost of goods sold.

Manufacturing pharmaceuticals has never been a game for the faint hearted. From research and development right through the production cycle, distribution and marketing, it is an expensive business, with heavy and lengthy start-up and development costs and, even then, no guarantee of a lucrative revenue stream at the end of it.

Against that backdrop, doing anything to drive efficiency or curb costs is going to give a pharmaceutical company an element of competitive advantage, which is why what Merck Serono has achieved over the past five years is so compelling and, feasibly, an object lesson for other pharma firms.

The company has, since 2006, put in place a series of efficiency pilots, programmes and models that are now reducing costs which, according to the BMI's Pharmaceutical Manufacturing Efficiency Index (PMEI), has led to the company spending a smaller proportion of total sales on manufacturing than any other pharmaceutical player. And this is despite the company's drug portfolio being weighted towards traditionally more expensive biologics products.

This emphasis on reining in the 'cost of goods sold' (COGS), encompasses an array of different programmes, modelling software and, crucially, cultural and mindset shifts, all under the common goal of providing the highest quality products to Merck Serono's customers and patients, argues Dr André Overmeyer, the company's head of strategy and operational excellence.

"Bio-pharmaceuticals have more complicated manufacturing processes," he explains. "The raw materials tend to be more expensive, so process modelling and a generic production platform strategy based on standardised cell lines and chemically defined

media becomes very important. There is a clear need to have programmes in place to facilitate operational excellence and direct learning from each other."

Cost savings

The company runs intensive programmes focusing on these areas, and continual improvement means that, since 2006, it has cut costs by approximately 5% a year. For Merck Serono, COGS encompasses everything that relates to production processes and costs.

"We were at a point where we could see our costs were rising year by year, so it was about focusing on best practice, sharing good practice and expertise, and harmonising our learning so we were better able to embed global business practices," says Overmeyer. >>

Efficient manufacturing

For every \$1 Merck Serono spent on COGS in the first quarter of 2010, it generated \$6.39 in revenue, giving it a score of 6.39 on the BMI index.

This was despite the fact that some of the Geneva-based firm's leading products, such as Rebif (interferon beta-1a), are biologics, which because they are typically produced within specially engineered cells, can be expensive to culture.

An expansion project is currently being developed to increase the manufacturing capacity of the plant to allow for production of additional medicines, including the targeted cancer therapy Erbitux (cetuximab).

Of the ten firms in the BMI's PMEI for the first quarter of 2010, seven saw their score decrease, indicating other drug makers were becoming less efficient in manufacturing.

André Overmeyer

André Overmeyer is head of the strategy and operational excellence group within Merck Serono technical operations. Previously, he led the expansion of the Merck Serono Biotech Center in Corsier-sur-Vevey, Switzerland.



The company's global programme, 'House of Operations', fosters cooperation in different areas with the aim of raising the standards according to predetermined measures. The global roll-out of its Six Sigma and Overall Equipment Effectiveness programmes were a priority for the company, and successful examples of elements within the House of Operations.

"With biopharmaceuticals, one of your priorities has to be increasing and improving yield, gaining more products while reducing unit cost for the drug," says Overmeyer. "In 2010, we put in place Six Sigma, which has led to yield improvements in a number of process steps and some substantial cost savings.

"It is about focusing on process improvement; just doing things in a better way. The trigger has been to look at things in a much broader perspective, to look at our processes and see how we can move people away from a silo mentality to one where there is more co-operation across departments, businesses and across our site network, where there are more holistic solutions."

“ When a new product comes on to the pipeline we have a number of tools to simulate the cost of manufacture. This allows us to test and better direct our processes as they develop. ”

A coordinated approach

Merck Serono focused on a greater exchange of knowledge and information, and more contact between people. It also encouraged looking at the global perspective. Global projects within the Six Sigma programme concentrated on production and manufacturing processes from A-Z, covering end-to-end lead-time processes, and cross-departmental and organisational procedures.

"It was also about coordinating the exchange of information and knowledge between different sites and facilities," says Overmeyer. "For example, people from Italy working within our packaging businesses might be encouraged to speak to staff within API or people from the selling end in a bid to improve best practice."

One of the key tasks was bringing people together to share their problems and solutions, with the aim being to foster cultural change and to facilitate a rethink of methodologies.

"There was an emphasis on encouraging cooperation and an exchange of information that was not happening before," Overmeyer adds. "This could have been down to human nature, and the result of having global sites where there may be distance, time-zone or language barriers, as well as different ways of working. One practical change in this context was to introduce a common organisational language and terminology to express facts, results and achievements; for example, the cost structure or the measurement of cost benefits, so that staff could understand each other clearly and easily. It helps give the business much more of a global framework."

The company also implemented a programme that streamlines its packaging lines in different locations and connects them more to its distribution and sales teams. This provides better forecasts, which allow it to produce economically optimised batch quantities. Merck has also made a considerable investment in IT tools and in processes to align and harmonise orders, products and production.

"We have 50-60 selling subsidiaries, so it's important to be able to adapt to local needs and regulations," says Overmeyer. "You need to be flexible within your supply chain. We've also invested in tools for process simulation at different stages of production. When a new product enters the pipeline we have tools to simulate the cost of manufacture. This allows us to test and better direct our processes as they develop."

Design quality

Another significant issue has been instilling the concept of Quality by Design (QbD) throughout the business.

"We have been using QbD since 2006, which has been invaluable in developing cost-effective manufacturing processes. It is also an important way to understand the manufacturing processes, especially in biopharmaceuticals. It helps to reduce variation within processes, and introduces a much greater stability," says Overmeyer.

Ultimately, while cost savings have been a clear, tangible benefit of COGS, there are equally intangible benefits: a changed mindset, attitude, global outlook and harmonised culture. They have all proved important as well, emphasises Overmeyer.

"There are also advantages that come from creating a culture of and emphasis on operational excellence. It is about wanting to do things right, and to do them better all the time," he says. "The improvements we have been able to deliver in the manufacturing chain; for example, have saved costs but also made our supply more flexible and responsive, which is very important. Before, as a company with different sites, each with a different history, we used to be more fragmented; there were a lot of island to island solutions. So it has been important to foster and facilitate a mentality that does not involve working in silos, but rather one where people are collaborating instead of competing with one another. It is vital people learn from each other, and share and exchange information to improve processes." ■

COGS: a definitive view

Different companies use different definitions of 'cost of goods sold' (COGS). Some firms will include expenditure, such as 'cost of sales', while others simply limit it to 'materials and production costs'.

Generally, however, COGS is defined as the direct costs attributable to the production of goods sold by a company.

To this end, it will include the cost of materials used in creating the goods, along with the direct labour costs, but exclude indirect expenses such as distribution costs and salesforce costs.

COGS appears on income statements and, according to the BMI, is divided by total sales to give its PME1 score.

