

Mixed messages

Kim Steffensen

Kim Steffensen is an expert on the CMO market and has been head of contract and licence manufacture at Novo Nordisk since 2004, responsible for evaluation, establishment and support to local manufacturing partners.



Information often gets 'lost in translation' when outsourcing business to emerging markets. Nic Paton talks to Novo Nordisk's **Kim Steffensen** about how to successfully work with CMOs in emerging markets on the effective planning and management of geo-separation issues and risk mitigation strategies.

From a business and communications perspective, the world may be shrinking, but for the global pharmaceutical firm wrestling with an intensely competitive commercial environment and the potential of key emerging markets such as China and India, that doesn't make managing a contract manufacturing organisation (CMO) located halfway around the globe any easier.

Equally, getting it right with CMOs is an issue that pharmaceutical companies cannot afford to ignore. In 2009, a report by market researcher Business Monitor International predicted that the pharma market for CMOs would be worth \$33.7 billion by 2014, with the pipeline for biologics products one of the key factors driving this growth. >>

Challenges of working with a CMO

The attractions of CMOs are not hard to fathom: the lure of being able to reduce your fixed costs by using someone else's expensive manufacturing facilities, while driving down your own costs and (hopefully) tapping into the growing expertise of many CMO destinations. But, according to Kim Steffensen, head of contract and licence manufacture at Novo Nordisk, one of the key challenges that pharma firms face when dipping their toes into the CMO market is that of information getting 'lost in translation' when manufacturers over-confidently or complacently outsource, particularly within emerging markets.

"There can definitely be cultural differences and a lack of understanding sometimes," says Steffensen. "It can go right back to the basic contract negotiations with both sides having different views on a lot of things.

"The key is, simply, to ensure the CMO and the company are aligned, and that is something that has to happen from the initial negotiations all the way through to when you come into more operational issues. Each side has to understand the plan that has been agreed; they have to know what the milestones are."

“ Good CMO management is little different to good multinational or global office management. ”

Key areas of misunderstanding can include different requirements regarding the level of documentation and regulation required between one market and the next, and issues over validation or product sophistication.

"A lot of companies, especially in emerging markets, are trying to harvest the benefits of CMOs without the right guidance or rules," explains Steffensen. "CMOs are now big business, but the whole market has become blurry, because there are so many different forms of outsourcing.

"It is also about purchasing and in-sourcing as well as conventional CMOs, with many big pharmaceutical companies now deciding that it can be more cost-efficient simply to buy up other companies rather than outsourcing or contracting to them. From a production point of view, this has the advantage that it mitigates their risk, with the buyer company remaining more in control."

But, says Steffensen, whatever option you choose, what is important is to take a country-specific approach rather than assume you can work to a single, one-size-fits-all CMO template.

"For example, ten years ago we [Novo Nordisk] did not have a very strong presence in South America, so in order to develop a stronger footprint in an area where we saw considerable opportunities, we ended up buying one of the larger insulin manufacturers in Brazil," he says. "It meant we were buying into something that already had its own footprint as well as an up-to-date product facility. So, while it was about going into somewhere new to gain a larger piece of a market, it was also about being aware of it being a local South American player.

"In comparison, in India we were content to go with a more conventional CMO and that has worked for many years. We can still import products from Denmark or Europe without compromising business there."

Key pharma CMO pressures and opportunities

Downward pressure on drug prices and the emergence of new markets in Asia, Eastern Europe and Latin America are opening up market opportunities and creating new potential CMO/partner opportunities.

- Fewer new drug approvals mean that pharma companies are having to work harder to leverage costs and ensure their production and manufacturing processes are much leaner: working with CMOs is an obvious solution.
- The cost of maintaining and establishing expensive in-house manufacturing sites versus moving wholesale to a CMO model, or even simply acquiring a manufacturer in a local, emerging site, can make a CMO an attractive option.
- An imperative is to ensure the CMO is using all its facilities to the full, perhaps embracing just-in-time production methods and enterprise resource planning systems, as well as effectively managing its supply chain to create more value.
- A country-specific approach to compliance can smooth out many of the regulatory headaches that can arise from CMOs.
- Being keenly aware of cultural distinctions or differences in working methods and approach is a key element of successful CMO activity.

Full engagement required

There are many new CMO markets emerging, primarily within the economic powerhouses of India and China, with huge potential for pharmaceutical companies. Moreover, the technical skills and knowledge being taught to the upcoming generations in these markets is giving them an increasingly competitive edge compared with traditional Western manufacturing sites. But issues such as geo-separation and supply chain and risk mitigation must be considered not only before taking the plunge, but also throughout the CMO relationship, advises Steffensen.

"It has to be more than just coming out from Europe or the US once in while," he explains. "You need to be engaged and make a proper investment in terms of time and money, and give the CMO the knowledge and know-how in order to get there."

Outsourcing within emerging markets is often at a distance, so it can be more difficult to control. Then there are the logistical issues, the different demands and restrictions of country authorities, as well as the need to be, in some way, local. It does not necessarily mean a company always has to be everywhere, but it can often be important to have a presence of some form on the ground.

"Novo Nordisk has worked in many emerging markets for a number of years," says Steffensen. "At the beginning it may have been a small presence, but having that presence has meant we have been able to build better relationships and understanding. So we know each other better and why we do things and how to diminish risk. There is, simply, much less chance of things being lost in translation or lost between the two companies."

When it comes to buying outright, there may be equally challenging complications, not least difficulties around process and people integration and, again, the need for cultural awareness and understanding. "There is the danger when you make a very large purchase you are imposing your own organisation on the CMO, that the way you work and operate may simply not be appropriate for the local conditions," says Steffensen. "So there can be big contradictions. There needs to be attention paid to the requirements



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of the culture that you are going into and an understanding of that. There also needs to be a local presence and the establishment of someone from your organisation on the ground.

"If you go in force to take over, you need to be a little bit humble and try to understand how things work; for example, Novo Nordisk has very clear internal guidelines of how we need to behave and the steps we need to follow."

Living the value

In many respects, good CMO management is the same as good multinational or global office management; for example, pharmaceutical firms have to learn how to demonstrate good cultural and process understanding, focusing on communication and recognising that the learning may not all be in one direction; however, the relationship is technically weighted, argues Steffensen.

"It's all about demonstrating throughout your organisation that you are living your values in everything you do, not just talking about them," he says. "The way we go out and approach CMOs and suppliers has to be with the strong set of values that we have grown into and lived with over a long period. If you really want to change perceptions on the ground, there has to be much more than just presentation. It is often less about new products and more about new markets."

Steffensen stresses the importance of the global pharma firm assessing its pharmaceutical portfolio, its areas of operation, how it will be divided up in the countries in which it will operate, where

CMOs: questions to ask to avoid cultural misunderstanding

- Is a CMO still a viable option that will show financial benefits, or might outright purchase be a more efficient use of resources?
- How can I effectively plan and manage geo-separation issues and cultural differences to ensure the CMO is established and maintained?
- What are the risk mitigation strategies I need to employ to provide a shield against failure?

current and future customers are likely to be located, how they will access the CMO footprint and what their demands and priorities will be in the future.

"The world is getting smaller, especially from the pharmaceutical perspective, so there are fewer barriers," he explains. "There is much better and faster communications and IT systems, but, if anything, a globalised outlook that works with and reflects the local as well as the international market is something pharma has been a little late in adopting. There has been some regard of it, but there is still an element of having to catch up within many organisations.

"You need to decide whether you are going to go down the CMO route or simply take over a local company; what is the best and most efficient way to go into this country or market; and what are the barriers." ■

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