

Is Manufacturing just 'bad news'?

In recent times many pharmaceutical companies have suffered from some serious shortcomings in their manufacturing operations. Why?

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About the author

Mark Phillips has over 30 years' experience in the pharmaceutical and life science industries, covering product development, manufacturing and supply chain operations, business strategy and change.

For the past ten years Mark has been working at GlaxoSmithKline in strategy development and implementation and, more recently, in new product development (as SVP Medicine and Process Delivery, R&D) and new business ventures (as Head of Development Supply and Service, Diagnostics). He has also acted as a coach and mentor to developing leaders. He is currently working with a number of start-ups and SMEs on business planning, R&D strategy and supply chain issues.

Over the past few months one could have been forgiven for thinking that outsourcing supply to Indian manufacturers was a major problem. The recent spate of FDA Warning Letters, and actions, against the likes of Hikma, Wockhardt, Fresenius, and Ranbaxy, has made headline industry news. But these weren't the only places with manufacturing challenges. In 2013, the FDA has also taken action against Boehringer Ingelheim (Germany), AMRI (USA), Wyeth (Italy), Apotex (Canada) and then there were the major issues at J&J over the past few years and, GSK and Lilly in mid/late 2000s. In recent times many pharmaceutical companies have suffered from shortcomings in their manufacturing operations. Why?

In some organisations, the corporate 'focus' is on R&D or on Commercial operations, these being

seen as the core 'value adding' activities. For some, even, manufacturing may be seen as just a 'cost'. However as the examples above show, it is much more important than that. This is the means by which your products are made and delivered to patients. Performance here (or lack of it) can have a serious impact on patients, your customers, and ultimately your reputation.

In today's global economy, most pharmaceutical supply chains are complex, with a network of suppliers, contractors and plants scattered across the globe. There is no simple solution to managing these complex systems, but there are some foundations every manufacturing operation should have in place.

An absolute fundamental is a safe and environmentally sound plant. The plant is full of your people and your equipment; your critical

assets and your business depend on these. It is therefore important that the plants are well maintained; that the workers have a clean, safe and secure environment. A poor safety record, poor housekeeping and poor maintenance are often indicators of much more deep-rooted problems.

Another fundamental is to understand the processes you're a running, and continuing to improve that understanding. Knowing which steps critically affect quality and output are key to good control. Despite years of 'Design for Manufacture', Six Sigma and other 'initiatives', pharmaceutical process often still have major gaps in understanding and knowledge, and small deviations in operating conditions, input materials, or ways of working across shifts can impact quality and output.

Remembering that value is only created when you actually sell the product; ensuring that the manufacturing processes work and product 'flows' is crucial. Many plants have adopted lean manufacturing principles,

although the pharmaceutical industry still lags behind others in this regard and adoption is variable. But in any manufacturing business, understanding what adds value (i.e. someone will pay for) and ensuring your process and support activities are aligned to making the product 'flow' (i.e. not sit around in warehouses, awaiting tests), is common sense.

More often than not, the reason why plants do not operate as well as they could is down to one simple thing - Management Attention. In many organisations the culture often results in managers directing their attention upwards - to what their boss wants. But, if you are always managing (and looking) up you cannot see 'your shadow'. Your shadow is the impression you leave on your team, your workers, what is actually allowed to go on, on the shop floor, good or bad.

In any successful manufacturing organisation, the focus of the 'first line' leaders and line managers should be on making the process, plant and people work at their

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best. That is about understanding how it's going now – in real time. It's about helping their teams deliver, helping them solve problems and removing distractions and waste. For the more senior leaders it's about ensuring the environment supports the production processes, removes bureaucracy, distractions and above all creates a culture where people want to do their best and enjoy it.

Managing your own plants well provides a strong link in your supply chain, but you are only as good as the weakest link in your chain. Your contractors and suppliers have a key role too. In the past suppliers were often selected on the basis of cost/price. Today Quality is critical. Poor quality has hidden cost implications. But ensuring your suppliers perform to the highest standards comes at a cost too. The balance comes from reducing the number of suppliers and contractors, focusing attention on a few that have proven track record, and are willing to work to improve standards and performance.

Many of the 'challenges' facing manufacturing are not new and are not complicated. It's often about making sure the fundamentals are in place and that performance is managed across the entire supply chain. It doesn't have to be 'bad news'.

About Alacrita

Alacrita is a transatlantic consulting firm that provides expertise-based consulting services to the pharmaceutical, biotechnology and life science sectors.

We combine extensive industry experience and broad functional capabilities to help our clients create sustainable value.

Alacrita's team has industry experience and a consulting track record, ensuring that projects are delivered with both professionalism and real-world relevance.

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