



## Certainty in an Uncertain World

**Steve Hemsley at Lanner examines how pharmaceutical companies can ride out unstable times by making decisions based on accurate, up-to-date information**

Last year was bleak for much of the manufacturing industry, with many companies facing up to the harsh reality that they would be forced to cut budgets severely in order to survive, through significant redundancies or temporary closure. In some instances it was even worse, with a number of companies sinking without trace in what seemed like a matter of days.

Yet such events were not exclusive to smaller, independent manufacturers or those who were irresponsible with their expenditure. Instead, the effects were wide reaching, affecting many household names as well. It is true that manufacturers who trade in fast-moving consumer goods were worst hit, but the trend for 2009 looks set to expand into other areas of manufacturing, which is, of course, a concern for pharmaceutical companies.

Just how prepared today's pharmaceutical manufacturers are in facing the economic downturn is difficult to assess. They already face a number of considerations to which their predecessors were not so exposed. They have to make decisions on where product manufacture should take place, how it should take place,

how much investment is required, whether it should take place in an existing facility or requires a new one, and whether capital equipment can be justified. Pharmaceutical companies are intrinsically complex, and the risks associated with making the wrong decisions are high. In order to mitigate against this risk, decisions can only be made with up to date information on all variables involved at a given time.

### DECISIONS, DECISIONS

A poor decision at the beginning of the product lifecycle can easily propagate throughout the entire manufacturing and supply chain, resulting in costly mistakes. And now on top of this, pharmaceutical companies have to factor in what is quite simply an economic landscape which refuses to sit still long enough for observers to take note of its characteristics, let alone explore it.

Variables relating to decisions come from a number of different sources. Capital expenditure in the sector is high; when a new product emerges from the R&D process, it has to move into a pilot plant quickly and with the right production

processes. Often there is not time to spend months assessing the optimum way to manufacture a product, and new bespoke facilities may need to be established. A high proportion of pharmaceutical companies' profits are channelled into R&D, and therefore operations have to be as lean as possible in order to squeeze inefficiencies and unnecessary cost bases out of the business to maximise R&D spend.

Compliance, too, continues to absorb significant resources. While some improvements are evident through greater collaboration between the industry, the FDA and the MHRA respectively, changes in legislation mean that often, major amendments to production processes are required, which can stall the lifecycle of a given product. Lack of predictability in early lifecycle phases means that pharmaceutical production plants must always be prepared for the unexpected. But establishing a plant which can provide both production integrity and economies of scale is often hindered by cumbersome planning methods.

Ultimately, pharmaceutical companies need to reduce the overall product lifecycle and associated costs. This can only be achieved by re-modelling and confirming decisions at every stage of a product's lifecycle, in order to optimise profitability.

But, while manufacturing sectors such as automotive and fast-moving consumer goods (FMCGs) have made great strides in improving their operational processes to ensure that costs are minimised and output maximised, the pharmaceutical sector has been slow to follow. This is largely due to the fact that, for many years, the industry was shielded through high margins and high profits, stemming the sense of urgency for deriving greater operational efficiencies.

#### PAST ITS USE-BY DATE

Traditionally, pharmaceutical companies have adopted a number of techniques and models when making major decisions about the production and lifecycle for a new product. Lean and Six Sigma workshops are fairly commonplace, while many companies use consultants for significant periods of time to ascertain the best approach to the lifecycle of a new product. Many plants use spreadsheet-based planning methods on a day to day basis. These are effective up to a point, but simply cannot cope with the complexity and the inherent dynamic variability involved in manufacturing a new product. They lack the capacity to access information which influences forecasting schedules, and in most cases, all relevant information exists, but is stored in silos. This hinders effective analysis and incurs a significant proportion of the time and resources in the manufacturing cycle.

Instead, manufacturers need quick, easy access to information which will allow them to make decisions with which they are 100 per cent confident, and offer the maximum

return on investment. On achieving this degree of access, pharmaceutical companies can formulate accurate product introduction plans which will achieve maximum speed to market in the most efficient way possible.

#### CERTAINTY AT A COST

To help achieve this, many pharmaceutical companies have turned to bespoke simulation solutions, which have proved beneficial. Indeed, typical improvements in productivity over the initial 12 to 18 month period are around 20 per cent, and these tend to rise dramatically to around 150 to 200 per cent over two to three years following implementation.

Simulation software has also recently been used by a leading global pharmaceutical company to provide a working model of a plant before production had started. A modular approach to the plant was adopted, and the team working on the project developed a process board to give an instant indication of plant status. In addition, the implementation of a scheduling system, controlling the movement of material batches between the production plant and the warehouse area, efficiently controls the inventory. This led to an indicated increase in production capacity of 57 per cent and a more efficient use of resources.

The benefits of using simulation are compelling. However, they can come at a price. This is largely because simulation is often used as part of a project comprising consultancy and process modelling which can take up to six months to complete.

In addition, such initiatives rely on the expertise and experience of specialist users and involve the creation of a unique model for every project and decision. This can be massively time-intensive and risky, as the expertise and experience resides within the user, not the software. If the user leaves, so does much of the functionality, deeming the solution redundant until that expertise is recouped. This reliance on just one or two simulation 'super-users' also means that requests for decisions or projects to be modelled might have to sit in a queue until others have been completed, limiting the potential for them to be useful to the plant as a whole.

As pressures increase, resources are squeezed, and the grip of red-tape continues to tighten, there has never been a greater need for a tool which can quickly build watertight business cases which take the risk out of decision-making, and set out the best approach for production to be optimised.



Until recently, such a tool simply did not exist, and the only option available to pharmaceutical companies was to throw additional resources at the problem in the form of consultants or to take on additional simulation 'super-users' – options which are simply not feasible in the long term, as financial pressures continue to close in.

#### THE THIRD WAY

And as the demands placed upon pharmaceutical manufacturing have increased and become more complex, simulation technologies and techniques have moved on. Following successful pilots with a number of pharmaceutical companies, a simulation-centric toolset is now available to build scientific, evidence-based business cases, with the added benefits of being cost effective, user-friendly and quick to implement (typically just two or three weeks).

Available on a license and subscription basis, this toolset can be modified and used beyond the lifespan of a single project to benefit future projects, and therefore has longevity and the propensity for greater return on investment (ROI).

Having a ready-made solution at their disposal is now critical for pharmaceutical manufacturers. Simulation technology can stay ahead of the ever-changing climate by offering proven results in days and weeks, not months, which is crucial now, more than ever. Indeed, decision-makers are now under intense pressure to achieve targets in a short space of time in order to survive. If embraced and used to maximum potential, new simulation techniques will soon become relied upon, and seen as a pharmaceutical company's best friend.

#### About the author



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