

## **A Dose of Excellence for Pharmaceutical Manufacturing**

*New solution enables operational excellence in the pharmaceutical industry at the touch of a button*

### **Abstract**

Having escaped the operational scrutiny experienced in recent years by many of its manufacturing counterparts, the pharmaceutical industry is now turning its attention to potential efficiencies and productivity gains lying latent in its production processes and lifecycle management.

This paper looks at how the pharmaceutical sector can drive sustained productivity and efficiency savings in its operational processes, reduce the new product development lifecycle, and increase profitability through adoption of a new breed of simulation software.

### **Background**

The UK pharmaceutical industry employs around 73,000 people and generates a further 250,000 jobs in related industries. The industry invested £3.2 billion in UK research in 2004 and exported products to the value of £12.2 billion in 2005.

On average, it takes around 10 to 12 years and £550 million to develop every new medicine<sup>1</sup>, with no guarantee that medicine will go on to be a commercial success. Both the rewards and the risks in the pharmaceutical industry are high.

Pharmaceutical manufacturers face continuous 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.

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<sup>1</sup> ABPI

A poor decision at the beginning of the product lifecycle can easily propagate the entire manufacturing and supply chain, resulting in costly mistakes.

Variables relating to decisions come from a number of different sources. Capital expenditure in the sector is high, as 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 isn't 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 channeled into R&D, 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.

And compliance continues to absorb significant resources. While some improvements are evident through greater collaboration between the industry and FDA and MHRA, 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 mean that pharmaceutical production plants must be prepared for the unexpected at all times. 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-modeling and confirming decisions at every stage of a product's lifecycle in order to optimise profitability.

But while manufacturing sectors such as automotive and FMCG 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 owing 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.

## **The Challenge**

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 still use spreadsheet-based planning methods on a day to day basis.

Consultancy projects can yield the best quality information in order to make the best decisions; however these can be immensely costly and take large amounts of time – a resource which is precious and simply not viable in today's pharmaceutical manufacturing environments.

Spreadsheet-based solutions are effective to a point, but simply cannot cope with the complexity and the inherent dynamic variability involved in manufacturing a pharmaceutical product portfolio.

Many pharmaceutical companies use bespoke simulation solutions but these rely on the expertise and experience of specialist users and involve the creation of a unique model for every project and/or 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 modeled 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 taking on additional simulation 'superusers' – options which are simply not feasible in the long term, as pressures continue to close in.

### **A New Approach**

Pharmaceutical companies have seen dramatic efficiency gains through adopting Dynamic Simulation Modelling. Typical improvements in productivity over the initial 12 to 18 month period are around 20% and these tend to rise dramatically to around 150 to 200% 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, effectively and efficiently controls the inventory. This led to an indicated increase in production capacity of 57% and a more efficient use of resources.

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

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

Px-SIM is a simulation solution which encompasses all of the complex demands and variables of pharmaceutical manufacturing, available in a toolset which can deliver decisions in a matter of weeks, and be deployed across multiple projects at any one time. The functionality inherent within Px-SIM delivers huge economies of scale, as high volumes of new projects can be optimised at the touch of a few buttons and without the need to start from scratch.

### **In Practice**

*Pharmaceutical case studies are available but bound by confidentiality. Contact Lanner directly for more information.*

### **Conclusion**

Ever demanding targets and incessant improvement pressures mean that pharmaceutical companies simply do not have the luxury of unlimited time to make major decisions which drive performance. While such decisions must be based on thorough research, they also need to be made very quickly.

Px-SIM is a decision-support tool which offers a solution to this challenge, through equipping pharmaceutical companies with a tool which can map out numerous scenarios based on multiple, dynamic variables, and quickly create a business case. Px-SIM can help pharmaceutical manufacturers to reduce operating costs and inventory, deliver performance assurance and improve speed to market.

Based on Lanner's 15 years of experience in the simulation and pharmaceutical markets, Px-SIM can be implemented in just a few weeks and is both user-friendly and cost effective. The Evaluation edition of Px-SIM, complete with training materials and case examples is available to download. It's then a simple task to activate Px-SIM on a subscription basis when you need it.

Pressure to make operational improvements is only going to increase and in order to maximise profitability in the future; pharmaceutical companies require innovative tools which deliver fast, accurate decision-making power.

A tool which incorporates multi-dimensional intelligence in order to enable scientific, evidence-based business decisions is integral to every pharmaceutical company operating in the world today.

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