The Pharmaceutical Business Case for MES

Manufacturing Execution Systems provide the missing link between the top floor and factory floor, making it possible to integrate existing systems and improve overall manufacturing efficiency

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The pharmaceutical industry has been subject to mounting competitive pressure between manufacturers over the last ten years. The need to increase manufacturing efficiencies, reduce costs and accelerate new product time-to-market has never been more prevalent due to increasing research and development (R&D) costs, regulatory overheads and price reduction demands. This article discusses these issues and offers potential solutions entailing the use of Manufacturing Execution Systems (MES).

Despite the increasing necessity to ensure factories have efficient manufacturing systems, the pharmaceutical industry still appears to be plagued by manufacturing inefficiencies when compared to its peers. Historically, pharmaceutical companies have cited regulatory demands as a reason for being slow to adopt manufacturing change; however, in the current market, pharmaceutical manufacturers must change their ways in order to survive. Even regulatory bodies such as the US FDA are pushing manufacturers to embrace technologies such as Process Analytical Technologies (PAT) that promote process understanding and continuous improvement in the name of ultimate customer safety. However, readily-available solutions to some of these issues seem to be passing by unnoticed. Manufacturing Execution Systems (MES) enable the seamless flow of information from the business level to the factory and shop floor and vice versa. Bridging this information gap between the ERP (Enterprise Resource Planning) system and the plant floor is widely accepted as a prerequisite for a successful production strategy. It appears, however, that much of the manufacturing sector remains somewhat in the dark as to the business benefits of an MES system. Consequently, improvements in three of the major problem areas within the pharmaceutical industry – which can be defined as asset efficiency, operating margin and revenue growth – are now beginning to separate the industry leaders from those struggling to compete in a fierce market.

DEALING WITH ‘DEAD-TIME’

Asset efficiency is an over-arching issue for the pharmaceutical industry as it has a direct impact on operating margin and ultimately revenue growth. This is a key area for financial loss within any manufacturing plant and – consequently – an area where even the smallest changes can have significant impact on bottom-line results. Asset efficiency is represented by one core problem within manufacturing – ‘dead-time’. Utilisation figures of 10-30% for equipment are not uncommon in secondary plants. Historically, pharmaceutical manufacturers regularly simply purchased and qualified new plant as new products came to market, rather than investigating whether the additional production capacity could be provided by existing machines. This trend has tended to lead to inflexible and under-utilised manufacturing assets, resulting in companies finding it increasingly difficult to maximise the production value of both their machinery and man-power. Alternatively, pieces of highly-utilised equipment are known to break down on a regular basis, but instead of upgrading (for fear of invalidating qualification status) or scheduling regular pre-emptive maintenance reviews, companies blindly lose money on reactive maintenance call-outs and product down-time as repairs are made.

On generic equipment, such as packaging lines, scheduling issues cause further problems as plants are asked to produce a number of different batch products on a daily basis. This leads to increased ‘dead-time’ on the asset due to the number of changeovers required from product to product; the machinery and man-power needed to change a product run can create significant idle periods until the changeover is complete and the line becomes fully operational again. The lack of ability to monitor staff also creates plant-efficiency issues; those un-registered ‘tea breaks’ all add up and can lead to companies losing upwards of 30 minutes a week in production time.

In order to maximise asset efficiency, pharmaceutical manufacturers must first gain accurate measurement of
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spent on non-value added tasks for the company, commercial availability of automated Electronic Batch Record (EBR) systems. This can mean hours of time processing on the factory floor are still mainly carried out by employees using pen and paper, despite the use ofMES. The data capturing capabilities of the system can be used to set up regular maintenance checks prior to expected malfunction time-frames. If the machine needs to be taken off-line for servicing or repairs, the MES will also indicate available employees and time-slots to carry out the necessary checks in order to minimise the impact on production.

Such scheduling facilities also extend to production runs; multiple packaging lines can be scheduled to run a number of different batches simultaneously to satisfy demand. Alternatively, instead of creating small batch runs on a ‘fit-to-order’ basis, companies can schedule batch campaigns of longer production runs in order to minimise changeover times and react to expected surges in demand; these may be linked to the release of new products or marketing drives in particular areas. Depending on the business drivers of the moment, different scheduling strategies can be enforced to make production more cost-effective and efficient.

MANAGING COSTS
The ability to control and reduce manufacturing costs is essential for a pharmaceutical company in order to sustain its business in a competitive market, specifically in the case of consumer health, generic and toll manufacturers. Some key areas for concern can be categorised as follows:

Man-Power
Administrative tasks for batch-record data collection and processing on the factory floor are still mainly carried out by employees using pen and paper, despite the commercial availability of automated Electronic Batch Record (EBR) systems. This can mean hours of time spent on non-value added tasks for the company, ultimately wasting money. Similarly, huge time and effort is expended on paper-based batch release processes, which could be more efficiently reported on exception (deviation) using an EBR solution. It is important for manufacturers to regularly re-assess their working practices in order for employees to ensure that their time is spent on meaningful jobs rather than paper-shuffling.

Inventory Control
The difficulties faced by pharmaceutical companies here are two-fold: first, specific to pharmaceuticals, the paper-based batch release process mentioned above necessitates the holding of quarantined finished goods (of huge value) for significant time periods (usually weeks) until the paperwork is approved; and second, the generic costs surrounding inventory logistics and distribution within manufacturing plants are substantial. Issues can include the optimisation and removal of excess/returned/unused stock in a warehouse, and engineering sufficient agility into manufacturing processes to satisfy demand with a lower finished goods inventory. An issue for many secondary plants is that having to produce a wide variety of products all under one roof means that a constant financial strain is placed upon the staff and equipment to change over product lines often and quickly; this is a costly process and, without an integrated automation system, can mean hours of time wasted if changeovers are not optimised.

Utilities Consumption
Although not traditionally a major concern for pharmaceutical manufacturers, rising energy costs and increasingly tight controls on environmental issues are creating a sharper focus on utility costs.

Waste
The issue of wasted product is inevitable on the factory floor. Whether wastage occurs through product changeover from batch lines or breakdowns causing an entire product batch to be scrapped, the cost of product waste is significant – particularly in the typically small-volume, high-value world of pharmaceuticals. Waste reduction will often be high on the priority list for manufacturers when it comes to assessing areas for improvement.

Robust Production Capacity
There are clear solutions to the above issues, all of which can be provided by an integrated MES product. For example, wasted man-power time can be reduced as manual data entry can be replaced by automating batch records or communications between ERP and the production plant. By providing more accurate data relating to material usage and reporting this information in real time, an MES system can also provide a more...
accurate raw materials inventory—allowing a reduction in stock across the board. Scheduling tools can be used to reduce unnecessary product-line changes, automatically reducing the amount of natural wastage from a plant. Moreover, waste costs can be minimised by providing electronic instructions and collection of information in electronic form, thereby reducing the incidence of operator errors. Batch genealogy recording can also be improved: automatic electronic recording of all information on all batches permits complex reports on each batch without manual overhead. By monitoring the energy usage of machinery on the plant floor, operators and engineers can determine where energy is being unnecessarily wasted and adjust operating procedures, machine automation and scheduling to minimise consumption. Revenue growth for an individual manufacturer is closely linked with the asset efficiency and operating margin of their plant. Production capacity must be at its most robust if the issues surrounding revenue growth are to be tackled. These issues can be broken down into four distinct categories.

Cost of Bringing a Product to Market
It is frequently quoted that the R&D costs incurred in bringing a new product to market are approximately $1 million a day. The impact of reducing R&D time, even by a matter of days, could have a significant financial impact on revenue growth—both in terms of R&D costs and lost market opportunity.

The Ability to Create a Guaranteed Supply
From product launch to maturity, it is essential for companies to ensure the security of their supply chain and maintain a guaranteed robust supply to distributors. This is a major issue as doctors and consumers will quickly swap to an alternative treatment if the ‘regular’ product is not available. However, once this change has taken place, the consumer will rarely return to the original product. The supply chain must remain robust in order to keep a current loyal customer base, whilst still attempting to increase overall market share.

The Ability to Sell More of a Product
This issue has a direct link with the asset efficiency of a manufacturing plant. Manufacturers can find themselves ‘capacity-constrained’ due to inefficient processing, particularly for blockbuster drugs. Further difficulties arise once a production process has been approved by the regulators; it then becomes difficult to implement changes for fear of invalidating the qualification status. Hence, technical services groups must attempt to build systems with the flexibility and understanding to allow change without invalidation of the process. Production lines must run at maximum efficiency and speed in order to increase overall capacity. A company will then have the scope to accept larger orders and expand their supply chain distribution.

The Ability to Remain Flexible in Response to Consumer Demand Changes
Often led by top-floor promotional campaigns or national media focus, consumer demand for a product can change within hours. For many companies, it is essential to maintain flexible manufacturing processes in order to accommodate a surge in demand. Failure to respond to this effectively could lead to a loss of faith from consumers and distributors, and subsequently lost revenue as both parties switch to a more reliable supplier.

The key to solving each of the above issues is to maintain efficient and versatile production capabilities within the plant. An integrated MES system will provide the data analysis and tools to aid reduction of R&D time when introducing a new product to the manufacturing plant and, in turn, bringing the new product to market. At the same time, supply chain reliability can be increased by maximising production capacity and flexibility. The lack of fully integrated top-floor to shop-floor systems within the manufacturing sector has historically left a missing link in terms of improving revenue growth from an automation perspective; an MES system can fill this void and enable streamlined manufacturing processes.

At Siemens, we have developed the Simatic IT system which allows full integration of all existing IT systems from PLCs to ERP, improved data integrity across the enterprise, automatic batch data recording and a reliable and user-friendly interface for plant operators. The most important factor for manufacturers to consider when implementing an MES product is: how easily will the system integrate into existing programmes? How difficult will the system be to operate from a factory floor perspective, and how will the change be managed?

An MES solution provides a framework capable of connecting the plant floor with the rest of the enterprise, making it possible to integrate existing systems and manage the business and workflow process to control and improve the plant’s production and performance. However, the full benefits of this advancement in factory automation seem to remain relatively hidden from manufacturers. The business case for MES is a clearly positive one; the benefits can be seen across financial, environmental and productivity angles which all lead to the same conclusion. In order to compete in the ever-changing manufacturing and supply chain sectors, companies need to embrace the MES solution.

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