

A QUICKER WAY TO GET TO MARKET

by Mark Perry

Probably the biggest single driver for any manufacturer in the pharmaceutical industry has to be the time it takes to get a potential product through the research and development phases and out to market. With R&D costs to bring a new drug to release approximated at \$1 million a day, only when a product is in daily use does the huge investment undertaken by drug companies seeking the next blockbuster product begin to pay back.

There are plenty of examples across many industries of companies being late to market with a product, only to find further down the line that competitor products have subsequently appeared with a resulting substantial hit in potential operating profits. Once a company is in the process of research, product development, testing and manufacture, it needs to shorten associated time scales for each area, while still adhering to all legal and regulatory controls, so that its new product has the best chance to succeed on the open market. This is especially true in the pharmaceutical arena where competition is fierce.

There are a number of key areas in which some enlightened thinking can have a powerful impact on the time taken to launch a potential new product. A move towards the benefits offered by a manufacturing execution systems (MES) electronic approach in some areas of research, testing and production can proactively impact on R&D time input, improve information flow, increase knowledge and, ultimately, boost speed to market.

Making paper-based systems obsolete

A good example of how an MES electronic solution can bring real and tangible benefit comes in the required area of paper-based sign-off procedures through the product research and development process. For some new drug development scenarios to reach fruition, many thousands of signatures can be required to satisfy all legal and regulatory approval processes before any launch to market. In a global industry, this will,

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inevitably, involve large numbers of participants often spread among research, testing and production sites across the world. It is clear that it only needs an integral part of the human sign-off process to be ill, or away or on holiday for the paper-based signature system to grind to a halt and incur unnecessary stoppages – delays which will prove costly at the end of the development and production process when you want your product in the marketplace making sales.

Simply instigating an MES system will remove the need to rely on associated paper-based systems and, instead, provide a single electronic driven signature recording process. Effectively, this means any number of people can concurrently review, test and sign-off constituent parts of the development process without having to wait for someone else to complete their part. Crucially, the project leader has a clear overview of the 'live' sign-off and testing status at any one point and can make important strategic decisions based on the information easily to hand.

An electronic system also acts intuitively. For example, if integral sign-offs are missing from the overall process, these are flagged up as part of the holistic project plan. On some occasions, paper-based signature systems have seen a product developed and ready for clinical trial stage only for a missing signature or signatures to be discovered and the whole process is then subject to potentially costly delays while the process is retraced.

Electronic systems in the area of electronic batch records (EBR) removes the potential for human error and, instead, allows instant, continuous and concurrent product research and development sign-off processes to take place. It is a simple and easy remedy to what can be a long winded and time costly, but necessary, part of bringing a new product to market.

Cost savings

Industry estimates predict that almost six months can potentially be taken out of R&D time scales through an electronic approach to the signature sign-off process. While the costs associated with product research and development are more or less fixed, pharmaceutical companies can simply and easily attack the most important factor they face – time to market – by implementing an MES system which increases the speed by which they get their products in front of users. These six months at a R&D cost of \$1 million per day equates to something like \$180 million and can have a real impact on the bottom line and the financial viability of a new product.

Forward planning

MES can assist in other important time-to-market areas as well. Take forward planning for example. Usually, a pharmaceutical company will have no real idea when it will be ready to instigate clinical trials of a potential new drug. Gathering together the number of people required for such statutory required trials can take many months and with no forewarning about product availability, delays are inevitable in getting the clinical trials established and underway. The benefit of an MES approach is that the system will electronically map such timings and thus a more accurate forecast can be made when the developed product will be ready for the clinical trial phase. This, in turn, allows the departments responsible for delivering the trials to be working alongside the R&D stage and not after it. This is a crucial element when it comes to assessing readiness for market and speeding up the whole delivery process.

Automating the laboratory

MES products complement the benefits delivered by embracing an electronic approach. Traditionally, the integrity of laboratory new product testing data may be open to question. With many results recorded on paper and with potential for human time delays in the testing process (people have lunch breaks, or are interrupted) the testing information can be compromised, especially in a time sensitive scenario.

The data gathered in the testing environment and recorded via MES are time stamped and fully underpin the robustness of the information gathered. MES takes out any manual intervention and automates the essential processes taking place in the lab. This not only speeds matters up, but also provides a wholly accurate and strong audit trail whenever such information is required.

With MES solutions automating the laboratory testing process, other components can automate the product development and manufacturing process. It can bring together the many differing aspects of a product's existence, ranging from the raw materials that make up the product compounds, to the packaging and labelling. It allows concurrent specification management from across the globe that can ultimately reduce R&D and manufacturing time and drastically increase the financial benefits brought by earlier release to market.

Waste control

Other areas after release to market such as waste control can also be more easily managed through embracing an MES approach. Exact control can be provided over production in terms of manufacturing processes and distribution control. Any faults on the production line can be quickly identified and remedial action taken, minimising potential waste.

Fresh thinking needed

Embracing the advantages offered by MES is really a state of mind and requires fresh thinking to traditional ways of operating, particularly in the pharmaceutical industry. MES provides real time information, allied to significant R&D timescale reductions and alleviates the possibility of human error. Users can work alongside each other, not just in a pre-ordained formation but with greater flexibility and in the certain knowledge that data integrity is sound at all times and can be easily and systematically traced. For 21st century focussed pharmaceutical companies looking to capitalise on the market opportunities offered by getting their products to market as quickly and as safely as possible, then examining the particular and wide ranging solutions offered by MES has got to be high on their business agendas.