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THE TECH ADVANCEMENTS DRIVING PHARMA

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How automated technologies can help manufacturers prepare for the new world order.

For pharmaceutical manufacturers, one of many issues that Covid-19 has highlighted is the need to be ready to quickly meet demand spikes. The requirement for vaccines to be brought to market and production scaled up at a much higher velocity is shaking up traditional research & development (R&D), clinical trials, and the supply chain, with their well established and often protracted processes. In recent months the profile of drugs in demand has changed significantly. Some drugs have seen spikes as a result of induced or panic buying, others have seen troughs, along with shortages due to supply chain disruption. While legislative compliance and process control remain critically important, the rapid development of Covid-19 vaccines has set a positive precedent and the ongoing expectation that drugs will continue to come to market faster than in the past. The pandemic has disturbed the equilibrium and Pharma 4.0 is well underway.

FINDING A SOLUTION

When a pharmaceutical manufacturer discovers a new drug, in most markets they typically own its patent for 20 years. Many factors can affect the duration of a patent, however, and in addition, exclusivity laws depending on drug and market, mean actual market exclusivity from generic competitors

is often far less. This, coupled with the high probability that it will take the manufacturer some time to bring a new product to market means the race is on. The speed with which manufacturers can bring a drug to market can directly impact the time they then have to drive up return on investment. So, a faster time to market translates to far-reaching commercial benefits to manufacturers.

But how can improved velocity best be achieved? The timeline required for clinical trials is often the key element. Product development can be a factor but typically only if the company concerned is not confident they will get approval, and therefore does not parallelize the requisite scale-up component. That said, we would expect the industry's experience with Covid-19 to permanently reset expectations, including the belief that innovation may compress the clinical trial timeline and put increasing pressure on product development to accelerate processes and ensure parallelization.

Coupled with all this, rapid batch release requires electronic batch records to be verified instantly. Analytical techniques need to be fast enough to allow corrective actions before quality is affected. Clean data allows for faster, better insights. That equates to faster, better decisions to be made. However, in a world where workflows remain heavily manual and paper-oriented and much time is taken processing, checking and cleaning data rather than making timely decisions based on it, that's a massive challenge.

The latest digital technologies can help by eliminating non-value add processes, giving decision-makers visibility on product quality and consistency faster than before, but also providing them with deeper insights that would previously have been out of reach. This can allow them to reduce time taken and number of iterations to get the manufacturing process correct and validated, enabling them to reduce costs and improve public health. The effect on the time to market will depend on whether this important data access is on the critical path to product launch, but at least this increases the robustness of the manufacturing process and reduces the risk of the product launch being subject to delay.

In addition, process simulation tools can be used to help select and deploy the right processes and assets to scale up from pilot to full scale manufacture. Simulation tools will allow users to look across their supply chain for the right asset, or to understand that with some tweaking or re-engineering of their existing processes, they will be able to manufacture a new drug product in their existing plant.

Another trend helping manufacturers is the increased use of multipurpose plants. Historically, plants were built for specific drugs, even if global demand was tiny, in some cases to the extent that such plants ended up mothballed when annual drug production was complete. As a result, there is a growing trend toward multipurpose and continuous plants, which can streamline drug throughput, reduce capital expenditure and save money and time through better use of resources.

However, there are challenges to overcome too. There may be demand from multiple different drug lines for the same equipment. Manufacturers therefore need to consider when they can fit processes in, and where and when they have the necessary bandwidth or time in the day to do so.

HOW AUTOMATION DRIVES EFFICIENCIES

The use of electronic batch records (EBRs) can be another key factor driving reduced inefficiencies and delays in the manufacturing supply chain. Traditionally, plants would create paper-based batch records, and the majority of pharmaceutical plants still run on paper.

Manufacturers end up producing reams of paper per batch record. Each record then has to be manually checked three times for errors. As a result, for example, a manufacturing process taking three weeks to complete might then be bookended by a paper-checking process taking months. During that time, the drug would remain stored, gathering dust and racking up warehousing and demurrage charges. By automating the batch release process, highlighting only exceptions, EBR can take months out of the process. In addition, the EBR creates a wealth of easily accessible data, from which further analysis can be applied and an EBR solution that is integrated with enterprise information systems improves compliance by providing industry required, high levels of control, transparency and traceability.

Process analytical technology (PAT) is now starting to come of age. Although regulatory bodies such as the FDA have long advocated the use of PAT, wide-scale practical applications have been relatively slow to take up, primarily due to the availability and complexity of technologies and infrastructure. Many manufacturers now have the sensors in place and the right data systems to carry out multivariable processing; manage feedback online in real time and close the loop. These technologies are allowing the sector to produce high-quality product in greater consistency. They help reduce bad batches, ensuring the market gets the quality product it needs.

COLLABORATING FOR SUCCESS

Solutions that enable technology transfer and collaboration are increasingly prized in the development and manufacturing process. Simulation tools provide organisations with a common vocabulary. Project stakeholders can work on theoretical processes from the outset and pass work forward to those who have to fit it into the manufacturing workflow. It is a process that promotes collaboration and is far more efficient than traditional approaches.

This collaborative approach is one further example of how the Covid-19 pandemic and the subsequent vaccine roll-out has reset the parameters. Technology can help drive faster time to market, improve quality consistency, reliability and capacity in the manufacturing process, ultimately helping guarantee an effective and efficient drug supply chain. That will clearly be the direction of travel for the pharmaceuticals industry in the years to come. Manufacturers wedded to traditional and paper-based processes need to take action now to avoid being left behind.