Why the Pharmaceutical Industry Should be more Worried about Workarounds

As pharmaceutical companies aim to cut their production costs, James Wood, director of business development, EMEA & APAC at Aptean, looks at how they can still make product quality their number one priority.

The pharmaceutical industry needs to ask itself a big question: could the placebo effect be covering up a medical crisis that the developed world is yet to see the full extent of? Most people are aware of how the placebo effect works – people receive what they think is treatment for an ailment and experience a positive reaction to the medicine, even though they've actually taken a sugar pill.

This is the basis of hospital trials around the world, and also, incidentally, the premise of homeopathic treatments. The placebo effect is powerful and can provide a noticeable boost to patients, but isn't capable of actually treating or curing an illness or disease.

Why is this a problem for the pharmaceutical industry? On top of the placebo effect, there's a great deal of complacency over medicine in the developed world. Adverts appear everywhere offering the cure for all kinds of ache and pain – not to mention cold, flu and digestive issues. People are taught to take a pill, or a dose of medicine, and they'll be fine in no time. The problem with this is that the message has been successful. The cure for everything is to simply pop a pill.

However, this hides a great source of worry in the industrialised world – that disease and health problems are actually being caused by people taking medicines that are in poor condition, or are subject to a health alert. Combine this with a population used to taking aspirin for the slightest issue and there's a public health crisis just waiting to explode into public view.

Society expects – quite reasonably – that pharmaceutical companies (manufacturers or distributors) and their employees are in control of the entire production process. From sourcing raw materials to delivering the product to the end consumer, it's the responsibility of the pharmaceutical industry to ensure quality (if not, at the very least, safety). People expect (and assume) that these companies are taking all the precautions needed to ensure the product is fit for consumption. This is the basic standard that any pharmaceutical company has to meet to continue operating – and the first major challenge for businesses.

The second major challenge is product cost. Despite estimates that say the global pharmaceutical market will be worth around $1.43bn by 2020[1], companies themselves face more difficult times than overall industry growth might suggest. For starters, pharmaceutical companies are often in the firing line for their pricing strategies – especially when it comes to NHS provision of medicine. For better or for worse, cost against profit is an ever-present part of the conversation when it comes to the pharmaceutical industry.

A few years ago, profit margins in the pharmaceutical industry were much higher than they are now, which has led to enforced cost reductions through government pressure. This means that businesses have had to cut the amount it costs them to develop and manufacture their products – mostly by improving their production processes. Those that can't face losses, and even those that can may struggle to maintain the same standard of security and quality as before.

For pharmaceutical companies, the challenge of maintaining product quality is the same as it is for any big business managing a complex supply chain. With the threat of potential scandals forever looming large, they organise themselves to make sure that production and distribution processes are kept under close control. This is becoming ever more difficult to achieve, however, as the companies look to find areas in which they can reduce their overall costs.

Historically, the pharmaceutical industry has achieved improved quality in products by taking what's known as a transactional approach to the manufacturing process. This means that companies prioritise the monitoring and security of their production process above all else. It's easy to see why the approach makes sense. Companies have to monitor the state of each batch of products, decide when they're ready for approval, assign approved batches to orders, and keep track of use-by date. There's a lot going on, even at the most basic level of operation. Companies and their employees need to have oversight of it all if they want to avoid issues of quality and public safety.

Maintaining product quality involves subjecting the raw, semi-finished and end products to alerts that launch monitoring processes and activate inspections of the products' physical characteristics and the production process. Among a product's physical characteristics are variables – including microbiology, density, and pH, to name a few – that have to be checked at different times depending on the values attributed to them. If these values fall within control margins, then the frequency of the checks may be different than if they fall outside specific confidence intervals.

Sometimes manufacturers know that, if a product variable falls outside its range, it may be due to the influence of other independent variables. If they adjust the second variable, the first may then correct itself. This constant monitoring and

quality maintenance – together with detailed analysis of results – helps to keep manufacturing processes on track, and even optimise them. This highlights just how complex the production processes in the pharmaceutical industry can be – and why the improvement of quality is a major challenge even before companies attempt to cut costs.

To optimise their process and reduce costs, businesses are beginning to change their manufacturing philosophy by rebuilding their entire organisations around lean manufacturing theories. Under this model, companies emphasise the fact that each individual worker is responsible for manufacturing and quality – as well as improving productivity.

It's essential for companies to record and be aware of production line losses due to issues like lack of usage (length of time the team is available against total availability), lack of output (quantity of acceptable product produced against total quantity produced), and lack of speed (real production speed against nominal speed). These three values are summed up by a metric known as Overall Equipment Effectiveness (OEE) – a tool that gives a quick overview of a site's productivity. The key to improving a factory's performance against this metric is making sure the right people have the right information at any time, wherever they are.

To improve productivity, pharmaceutical companies have to record and monitor the variables above – along with the causes of each loss and the subsequent reduction in efficiency. They can only take appropriate action when they know what needs fixing – and that can only happen in an environment driven by the accurate reporting of results and the visualisation of production losses linked to each cause. From here, companies can build a picture of what the future impact of their actions will be.

The ultimate goal for pharmaceutical companies is to improve productivity with the resources they already have at their disposal. In other words, they have to minimise the resources they need within an already-established production process – while keeping the result of that process the same. Again, it's the same challenge as any other business on the planet is facing; however, the price of failure can be considerably higher when dealing with a critical issue of public safety.

Lean manufacturing is an effective place for companies to start their move towards more efficient, more cost-effective production processes. What they have to realise, though, is that simply trying to adhere to the goals of lean manufacturing is not enough. The philosophy behind productive manufacturing is only a framework for success – a goal for companies to reach for. Pharmaceutical businesses also need the right tools in place to help them deliver an improved process that raises the standard of product quality while cutting out production losses and their causes as much as possible.

Placing the responsibility for productivity on the shoulders of specific teams can be an effective way to begin the process of overall improvement. As the teams identify their own small improvements and actions, these marginal gains come together to create major changes at the business level. The challenge in this decentralised model is ensuring consistency across different teams. How do they all have visibility of the problems identified by their colleagues – or the actions taken to remedy them?

The other question is, how does management gain a useful overview of all the actions being taken on their factory floor? Pushing for greater autonomy among factory teams can easily lead to a completely new barrier to efficiency – workarounds. These are small processes (a spreadsheet here, a manual data entry task there) that might not seem like a big deal. However, because they sit outside proven company-wide systems, workarounds can actually create an existential threat to the entire production chain within a pharmaceutical company.

Given the freedom to optimise their own sections, teams will often develop their own ways of managing processes and tracking product quality. This is how workarounds appear in a workplace. Teams will identify the information that matters to them and the challenges preventing them from being more productive. Unfortunately, every team will execute in a way that might be similar to others, but will likely be incompatible with processes across the factory floor.

From here, more workarounds are created to manage the transfer of data from one team to another. The issue isn't just the extra work and effort that managing these workarounds requires; it's also the fact that companies are less able to trust product quality data as it travels through the various factory teams. When it passes through so many hands, is entered into so many spreadsheets and in so many different formats, there's too much room for human error.

What seemed like the cheapest, easiest option in the short term quickly becomes not only more expensive but also more inefficient. As mentioned previously, you cannot drive OEE without the right information in the hands of the right people – and workarounds are a major barrier to this happening at many critical points on the factory floor. Also, making complex processes even more complex is an almost guaranteed way to reduce product safety, meaning that workarounds completely fail to support companies in addressing their two major challenges.

It's simple for pharmaceutical companies to identify the need for change, but how do they manage that without creating new (and potentially worse) problems? How do they prevent the introduction of workarounds by individual teams to manage processes and issues? Without the right systems to support their philosophy, pharmaceutical companies could quickly find themselves sacrificing oversight for autonomy – making it even harder to audit quality and safety.

However, if companies can combine philosophy with technology, they'll

find it much easier to overcome their biggest challenges. They'll have the ability to improve the monitoring and security of their processes – all while driving cost reductions, protecting their brands and minimising the risks to their very survival.

It might seem a bitter pill for the pharmaceutical industry to swallow, but it can't simply introduce a new framework for manufacturing without the support systems needed to make it a success. In the short term, companies might well see the cost reduction they're aiming for, but may not fully consider the longer-term risks they're taking with product quality, public safety and their own survival as a business.

The way manufacturers do business is transforming around the world – and the pharmaceutical industry is no exception. In the past, pharmaceutical companies put most of their efforts into improving production quality, but now they're realising that (with the changing environment) they have to focus on efficiency as well. There's no point having the best product if the numbers don't add up. Companies have to protect their ability to be competitive as well as their product quality if they wish to ensure a successful future.

The only way to address both major challenges at once is to give manufacturing teams the tools they need to truly drive productivity and limit production losses. Failure to do this could well see pharmaceutical businesses caught out by the placebo effect – thinking they've found a cure for their problems when they're only making them worse.

REFERENCES

1. https://www.europeanpharmaceuticalreview.com/article/72418/continuous-manufacturing-regulatory-and-quality-assurance-challenges/

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