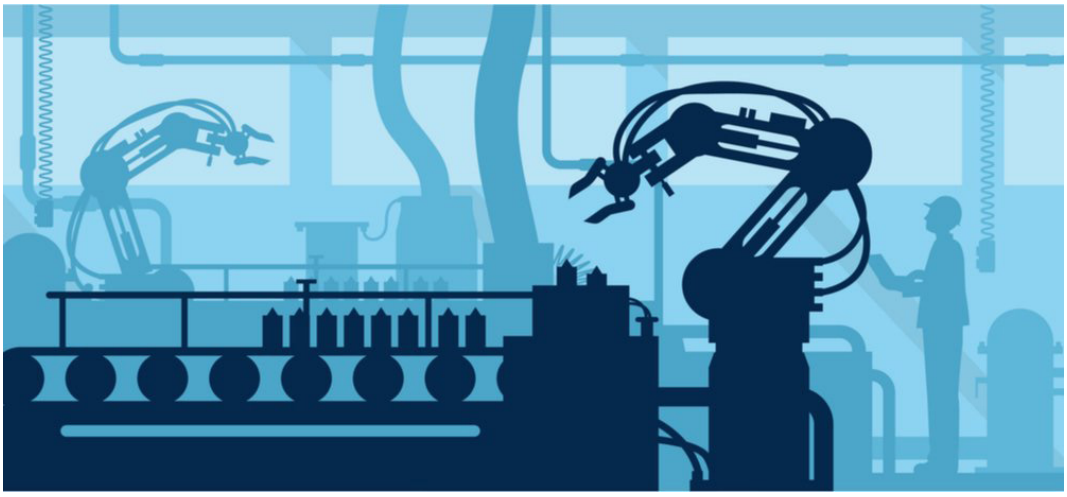
european PHARMACEUTICAL manufacturer

# Safe from harm: making pharmaceutical manufacturing fit for the future

BY KELLY DOERING 22 JULY 2022 14:56

*Kelly Doering, senior director Industry Marketing, Pharma, AspenTech, explores how pharmaceutical manufacturing should embrace change in its methods and solutions to stand out in an ever-advancing field.*



Ever-increasing customer expectations in the digital age, especially around speed of delivery are putting further pressure on pharmaceutical companies to achieve fast time-to-market for new products.

Covid has thrown further random variables into the mix, affecting the ability of plants to function at full capacity when they are subject to social distancing measures and suffer from staff shortages. In addition, the virus has triggered demand for new medicines, while at the same time causing widespread disruption to the supply chain.

The pandemic could be a pivotal point for the pharmaceutical industry, however. Organisations can see that the manual processes they commonly use in manufacturing will remain difficult to execute optimally if social distancing is again required during further virus surges. Nobody wants to be caught out again in the way they have been during the pandemic.

In any case, many of the pressures remain. The supply chain continues to experience disruption that threatens the production of ingredients and materials. The sudden emergence of choke-points in global transport networks such as the Suez canal blockage in March, and the shortage of shipping containers remind pharmaceutical manufacturers that security of supply should be one of their major aims.

In this context, change and innovation are essential so organisations can improve resilience and efficiency. Yet in many cases, they must first overcome internal barriers. Many companies, for instance, still work in silos, with maintenance and technical teams operating in isolation. Data scientists experiment with new approaches but a lack of collaboration and communication with C-level decision makers can mean that innovative ideas are never taken to market. In many organisations a strict hierarchy of command makes direct interaction difficult, inhibiting collaboration and innovation.

Pharmaceuticals manufacturing is, after all, a complex process. Manufacturers focus on reducing supply chain disruption, increasing batch production capacity, and reducing batch losses. Yet so many factors impact a pharmaceutical company's ability to ensure supply of end products, including equipment failures and changes to operating conditions, all of which have consequences for process health. All can cause batch quality failures, resulting in costly production downtime and disruptions to supply.

The current challenges are so substantial and potential gains so great, however, that the industry is becoming less conservative and focusing more attention on applied innovation. This follows on the heels of advances in supply chain management and maintenance technology specifically aimed at the pharmaceuticals sector. Across the industry there has been a rapid increase in demand for solutions and approaches capable of predicting when equipment anomalies will occur, to understand what causes them and prescribe how to avoid potential failures; approaches in other words that deliver predictive and prescriptive maintenance capabilities.

These are capabilities found in asset performance management (APM) solutions. APM is the use of data and analytics to produce specific equipment and asset performance outcomes. Artificial intelligence (AI) and machine learning are the power behind these highly deployable solutions that focus on increasing equipment reliability and throughput. Predictive maintenance, multi-variate analytics, and enterprise insights tools in APM solutions now deliver tangible results for pharmaceutical companies at all stages of the digitalisation journey. Predictive maintenance technology, for example, delivers the earliest, most accurate warning of equipment failures. But it also uses machine learning to recognise precise patterns in operating data that indicate degradation and impending failure, even before it happens.

Manufacturers using these solutions gain significant competitive advantage by reducing maintenance costs and eliminating production losses to ensure security of supply. They identify factors that affect product quality and process efficiency much earlier than is otherwise possible and can anticipate changes or disruptions in their supply chains to optimise outcomes through proactive intervention. The overall effect is to increase equipment effectiveness and yield. When companies deploy them to scale over multiple products, assets and sites, very significant benefits accrue over time.

All these developments inject higher levels of efficiency into manufacturing and its processes by, for example, increasing collaboration, from lab to pilot plant to API and finished pharmaceutical product manufacturing. They are able to simulate end-to-end batch processes with first-principle models, accelerating regulatory approval and scale-up to full production.

A recent study by professional services giant PwC confirmed how advanced data-driven solutions at this level are capable of delivering definite gains in pharmaceutical companies. The study reported: "Advanced analytics in the pharmaceutical and life sciences industry – including tools such as artificial intelligence (AI), machine learning and data mining – has the potential to transform the commercial function. Process automation and data-driven, predictive insights, have the ability to dramatically change how executives make strategic decisions and manage financial performance across all commercial areas."

Historically, however, pharmaceuticals manufacturers found it difficult to embrace change. All pharmaceutical businesses by necessity have well-established, often complex, validation processes in place. If a technology has been through this cycle and is working, in the manufacturing environment, businesses are often reluctant to take on further 'evaluation pain' in a bid to achieve a more rapid time to value.

This conservatism is changing but should accelerate or many companies will find the next crisis – however or wherever it emerges – plunges them into shortages and supply chain constrictions. Without APM solutions, companies will continue to run equipment and processes that operate sub-optimally, or which suddenly fail, causing immense process disruption and damage to profitability and commercial relationships. The major gains in reliability, efficiency and operational agility that are achievable and which today's pharmaceutical markets demand, will continue to elude them.