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Is Industry 4.0 Promising The Moon?

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As pharma grapples with rising complexity, costs and regulation, the sector is looking to industry 4.0 manufacturing as a solution. Smart factories managed with next generation technologies will lower pharma manufacturing costs, improve quality and reduce capacity constraints. Let's look at how pharma is adopting industry 4.0.

As pharma shifts from generic drugs to personalised medicines, it has become apparent that conventional systems lack the capabilities to keep up with complex manufacturing processes. Traditional manufacturing technology was built for large-scale, standardised drug batches. That's why the industry is turning to much faster and more agile solutions. They're leveraging the predictive capabilities of artificial intelligence (AI) and machine learning (ML) to build smarter, more secure, and future-ready manufacturing centres. Redesigning the traditional Good Manufacturing Practice (GMP) cleanroom to accommodate closed and automated processes is a necessary step toward improving the cost and quality of tomorrow's medicines.

In a smart factory, machines autonomously run entire production processes. Technologies like robotics, data analytics, distributed ledgers, vision systems, augmented reality, virtual reality, artificial intelligence (AI), and the Internet of Things (IoT), digital twin, come together to connect different operations, respond to new situations, and adapt as a result of those responses. As lean manufacturing, alternative sourcing, and other traditional improvement levers mature, the smart factory is set to bring the next dramatic shift in manufacturing efficiencies.

The increasing number and variety of therapies, as well as the increased number of fast-track review paths, means CMC (chemistry, manufacturing and control) activities have become more important in ensuring speed to market. Digitalisation and automation can also be seen to allow scalability for a range of manufacturing processes, including cell and gene therapies.

"Manufacturers are seeing the potential of data analytics to understand the current performance of their production lines and mitigate the risk of downtime with investments in data analytics to provide predictive maintenance and condition-based monitoring," said **Michael Larner, Research Director, ABI Research, UK.**

Adoption of pharma 4.0

The pharma industry has been relatively slow to embrace concepts such as Industry 4.0, but COVID-19 is serving as a catalyst for sweeping changes within the industry.

Industry's regulated nature, high cost, manufacturing complexity are some of the reasons the industry is lagging in establishing smart factories.

"I guess this is still a very novel concept for the industry. The capabilities of vendors and service providers are evolving. The existing manufacturing set up needs to be revamped completely to accommodate such future ready systems. The talent is also limited in the market who can deploy 4.0 manufacturing processes and manage such facilities. It needs significant investments and until the payouts are clearly defined, industry will hesitate to get into this direction. It also needs a change in the mindset to allow the machines and software to run processes with lesser human control or intervention. It will take some time," said **Aditya Sharma, Head – Bioprocessing, Merck Life Science India**

Pharmaceutical firms persist with paper processes – there is inertia to change current practices. In some cases, it's a reflection of an adversarial relationship with regulators and wanting to hinder regulators' ability to locate procedural information.

"In addition, there aren't enough individuals with the required skills in analytics and artificial intelligence entering the pharmaceutical labour force. I expect this will change in due course as the role of vaccine production to tackle outbreaks of diseases has raised the perception of the industry. But historically the pharma industry has struggled to compete with retail, banking, and consumer goods manufacturers for digital talent," said Michael.

Regulatory agencies including the U.S. FDA (Food and Drug Administration), EMA (European Medicines Agency), and China's NMPA (National Medical Products Administration) have encouraged pharmaceutical companies to modernise their manufacturing processes.

The USFDA has dedicated significant effort over the past several years in establishing both research and regulatory programmes for advanced manufacturing, computational modelling, and other emerging technologies. These efforts have led to updated regulatory processes, guidance documents and dozens of peer-reviewed research publications to identify characteristics of advanced manufacturing processes that can provide regulatory evidence of quality, safety and efficacy. The FDA also encourages use of advanced manufacturing through involvement in new standards development and industry outreach.

"As industry moves towards AI, deep learning, machine learning and self-improving manufacturing systems, regulations will play a crucial role. The key challenges would be – how to regulate and monitor such self-controlling and self-managed systems. Human intervention will keep reducing and the whole digitalisation/automation of the manufacturing processes will increase. The need to find a balance between the two will be extremely critical," said Aditya.

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