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Pharma 4.0: Redefining Product Development and Regulatory Operations

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Sathyanarayanan Krishnamurthy Aligning with the industry requirements has always been a priority for organizations. En route, they are heavily relying on revolutions that can help them stay ahead of the competition. One such revolution is Industry 4.0 – an amalgamation of pathbreaking technologies like industrial internet of things (IIoT), big data, artificial intelligence (AI), etc. The industry 4.0 has automated and optimized companies' business processes and business models.

As industries across the world reaping the benefits of Industry 4.0 and its technologies, the pharma industry has taken a nimble step towards embracing and adopting the change commonly referred as Pharma 4.0. The move is aimed at digital transformation of two most important areas of pharma, namely, product development and regulatory operations.

Product development: Using traditional approaches for manufacturing medicinal products is an arduous task. Every step must be reviewed from time-to-time and the process must always be closely monitored to ensure the safety and efficacy of medicinal products. In such cases, it is a viable idea to monitor such processes with the help of advanced tools. The entire facility can be functioned from a single interface with minimal human intervention, i.e. by virtually connecting all the equipment with Pharma 4.0 technologies such as, IoT and Cloud.

Regulatory Operations: The data collected during research, clinical trials, product development, and post-market surveillance often remains disparate. When put together, without a right means to analyze the entire data from various perspectives, the results can either be inconclusive or be ambiguous. There, Pharma 4.0 comes into picture with big data analytics that implement algorithms to sum up clusters of data and to analyze it in less time.

Pharma manufacturers are willing to simplify their manufacturing processes and streamline regulatory operations. But do all the technologies of Industry 4.0 suit the needs of the pharma industry? Apparently not. Only a few of them, as listed below, fit the required criteria.

a. Big data
b. Smart factory
c. Internet of Things (IoT) and cloud computing

d. Artificial intelligence (AI)
e. 3D Printing

Pharma 4.0: functionalities in focus

Pharma 4.0 is here to help the medicinal product manufacturers to evolve and become more efficient and at the same time to reduce the costs. But in what way? Which parts of regulatory operations can they be applied to?

a. **Drug research and development**

Pharma companies rely heavily on innovation, and research for drug development. Companies are turning towards new revolutionary digital capabilities to reduce the time spent on R&D and boost their productivity. In such scenarios, AI-powered dashboards can help companies to keep track of the latest updates from the health authorities and comply accordingly.

As is well known, in the early stages of drug development, clinical data from public repositories is collected to analyze the history of proposed drugs' ingredients. With machine language and deep neural networks, the advanced extensions of AI, such data can be utilized to derive insights on possible effectiveness/risk/benefits of a new compound. They allow manufacturers to enhance the nature of the human study and their decision-making while optimizing their workflow. In a way, stakeholders can identify the patterns and nature of patients to develop more customer-centric products and can bank upon less chances of failure and increase the cost efficiency.

b. **Clinical research**

With a large number of resources involved in clinical research and trials, manufacturers should work upon developing statistical analyses plans and protocols. Apart from this, there are several documents which demand ample amount of time for analysis. With the help of AI-based tool integration, all these processes can be streamlined and expedited with minimal errors. AI-powered tools help researchers to go through research documents and extract necessary data with utmost accuracy within the time required. They can help in analyzing clinical information in real-time to ensure compliance while compiling, validating and submitting clinical trial data.

c. **Manufacturing**

Health authorities across the world are emphasizing on implementing continuous manufacturing process by applying concepts of smart factory which make the process more connected, flexible, smart and precise. With the continuous process, manufacturers would not have a need to stop the manufacturing process in between for evaluation. This reduces the overall downtime of the process and also the human errors. This shift is helpful for manufacturers who are catering to the need of personalized medicines.

Pharma 4.0 assists manufacturers to minimize consumer risk and increase process optimization by statistically analyzing data with the help of big data. The insights drawn from the data can help manufacturers make necessary changes to the manufacturing process to achieve the desired level of product quality. It helps them to follow the manufacturing best practices.

d. **Quality management**

The Pharma 4.0 technologies have the capability of transforming each and every function of the value chain. They allow manufacturers to rely solely on results obtained from the real-time data. Digitization will help manufacturers to ensure better quality and compliance while reducing human errors. For example, for publishing and submissions, companies have become paperless and are relying heavily on electronic records and electronic dossier submissions. With Pharma 4.0 technologies, they are assured of data integrity is maintained across the life cycle.

Challenges in adoption

Though the revolution of Pharma 4.0 is set to create limitless opportunities, there are challenges for companies to overcome.

a. **Unclear regulations for new-age technologies**

Pharma 4.0 seems relevant and advantageous for both manufacturers and data reviewers, but there is still a vacuum in terms of regulating these technologies. While some health authorities are taking quick measures to establish the standards, others are waiting for regulated markets' reflections.

b. **Lack of skill set**

Pharma 4.0 requires an extensive technical skill set to carry out operations efficiently. The workforce to be deployed should possess knowledge with respect to Regulatory aspects and the technological improvements as well. As a radical improvement in the knowledge is necessary to sustain the revolution, organizations are required to build teams that are dynamic to adopt the technological transformations.

c. **Data integration**

One of the main concerns for pharmaceutical companies is maintaining data integrity. While many companies have started using technologies for electronic conversions and paperless submissions, some are lagging behind with the legacy technologies integrated. Without the electronic version of data sets, collating and migrating data on to virtual platforms will become a challenge for companies, which in turn will lead to difficulty in comprehensive data access and assessment.

Conclusion

The pharma industry is on the verge of a radical change. Across clinical trials, manufacturing processes, technology integrations, and ever-evolving regulations, the industry is in need of complete transformation.

By adopting new-age technologies, companies can streamline their processes, increase productivity, accelerate their regulatory processes and reach the global markets in an expedited, cost-effective, and compliant way. But the regulation question prevails. How regulated are these technologies? While some of the global health authorities are taking considerable measures to regulate Pharma 4.0 technologies, a few are still considering their viability. Sooner or later, however, they will be the future of the pharmaceutical industry.

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