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5.0 Ways Quality 4.0 Will Improve Manufacturing

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Pharmaceutical quality and manufacturing teams will face two significant challenges in the coming year.: drug shortages and rising new types of complex therapies, such as precision medicines.

Recently, the U.S. FDA Task Force on Drug Shortages shed light on the impact quality has on drug supply. It found that nearly two-thirds of 163 drugs that went into shortage between 2013 and 2017 were a result of supply disruptions associated with manufacturing or quality problems ***(1).***

To the second point, complex therapies are typically produced in smaller volumes and their delicate requirements for care create difficulties along the supply chain. Traditional drug manufacturing processes are not suited for these highly individualized medicines.

Quality 4.0—the digitalization of quality management through technologies that increase operational efficiencies, product quality and patient safety—provides the foundation for addressing both drug shortages and precision medicine production. With Quality 4.0, companies adopt advanced, digital systems to streamline and automate processes, connect global partners and suppliers, and enable agility that's so crucial to succeed in a changing regulatory environment.

Despite the tremendous potential and the importance of quality on drug supply, only 13.8% of companies have started their Quality 4.0 journey ***(2).*** Some organizations are paralyzed not knowing how to get started on the path to Quality 4.0 or the right technologies to adopt. Making this first decision is critical to maintaining the pace of innovation and getting medicines to patients quickly.

Here are five top advantages that Quality 4.0 can bring to the life sciences industry.

1. Increased Scalability to Meet Changing Regulations

The only constant in the regulatory environment is change, yet life sciences companies are limited by rigid legacy systems that cannot adapt easily. With Quality 4.0, however, companies benefit from flexible applications that are easily reconfigurable without having to revalidate the entire system. These technologies are also designed for continuous uptime to respond faster to change, reduce risk, and stay compliant.

Cloud-based technologies also bring new regulatory rules and guidance updates from across all 180 countries globally directly into a quality system so manufacturing teams can respond to updates in real time. This seamless connectivity even affords companies the extra time to carefully determine whether a new regulatory rule impacts their specific production line or if they want to set a higher standard than the regulation requires because it impacts quality and patient safety.

2. Greater Visibility of Risk Across Product Lifecycle

Most companies still operate in silos and implement disparate systems across different areas of the business. This limits both visibility and collaboration across the enterprise. Quality 4.0 connects systems and processes to provide greater transparency across the product lifecycle and enable smart decision-making and resource allocation. One area where this has a significant impact is audit management.

With a quality management system connected with other related systems (i.e., quality risk management tools and training applications), manufacturers can define the most pertinent CAPAs to holistically address all related audit findings and connect this information to the training curriculum. Further, by connecting audit findings with quality risk management, companies can proactively manage their overall risk profile to meet the evolving expectations of regulatory agencies. This gives companies a clearer understanding of risk upstream during clinical manufacturing and how to make sure those risks don't become problems downstream during commercial manufacturing.

3. Increased Agility on the Shop Floor

The shop floor is ripe for digital transformation. Manufacturing operations are still mostly paper-based, with aging systems in use long past their shelf life. Adopting new processes for manufacturing or testing methods to meet higher quality requirements is often challenging because of manual processes and rigid systems in silos. Without the implementation of modern

technologies that enable digital distribution of procedures and work instructions, it is hard to keep information current when sites or manufacturing lines need to make updates and changes to produce new products.

Quality 4.0 empowers companies to modernize manufacturing operations with advanced mobile applications that can bring workstations online and significantly improve agility and efficiency, while maintaining compliance. With a connected shop floor, facilities can support 24/7 manufacturing and gain real-time visibility for smarter decision-making. Important information is always accessible to operators, even for offline viewing. Synchronizing content onto mobile tablets at each work station also allows operators to quickly access correct information at the point of need to perform their jobs efficiently.

4. Connecting the Manufacturing Ecosystem

Paper-based processes and legacy systems create many business gaps between manufacturing, quality management and content management systems, making it challenging to effectively deliver quality products. Quality 4.0 brings together these complementary systems for a more holistic view and seamless execution.

Connecting end-to-end processes across the manufacturing ecosystem helps resolve issues faster. For instance, when a manufacturing execution system detects a potential nonconformance, it can immediately send the information to a quality management system (QMS). This enables rapid detection, triaging and remediation of non-conformances. Additionally, connecting the QMS to the content management and training systems enables timely push of appropriate content into operators' training curriculum to reduce the incidence of similar non-conformances in the future.

5. Improved Collaboration with Global Partners and Suppliers

Many life sciences companies struggle to work with suppliers and leverage the expertise of external partners worldwide. This is particularly problematic when developing precision therapies and rare disease medications that often involve an expansive network of partners and suppliers that need to work together and bring these innovative therapies to patients.

Unified systems increase transparency across all parties for greater collaboration between employees, suppliers, and contract partners such as CDMOs. As an example, modern systems allow pharmaceutical manufacturers to automate supplier qualification processes and effectively manage supplier corrective actions (SCARs). Linking SCARs to related deviations from incoming raw materials from the supplier can reduce risk of releasing batches and also save time when evaluating suppliers for future products

The Future of Manufacturing

Quality 4.0 is starting to become a reality in pharma manufacturing as companies adopt solutions to enable agility while improving operational efficiency and product quality. The technologies fundamental to Quality 4.0 initiatives provide real-time visibility across content, data and quality management processes for better tracking and more meaningful and actionable insights.

Next generation solutions that emphasize flexibility, connection and visibility position manufacturers for success in the years ahead. Eliminating siloed systems in favor of streamlined Quality 4.0 applications allows for stronger collaboration while enhancing compliance and end-to-end control. This is the key to meeting the new demands of quality manufacturing and support innovation in a new area of medicine.

References

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