OPINION

Pharmaceutical production re-envisioned: Increasing agility for global patient access

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ABSTRACT

The centralized facilities that allow for mass production and distribution are the primary emphasis of the traditional pharmaceutical manufacturing paradigm. Although this system consistently upholds high standards for both product quality and reproducibility, its rigidity places restrictions on emerging manufacturing technologies that could boost productivity and promote supply chain resilience. Agile manufacturing approaches, which make use of flexibility through portability and decentralization, enable manufacturers to immediately respond to patient needs and offer a potential solution to ensure timely access to life-saving medications. Agile methods are very useful when creating small-batch, individualized medicines that need to be tailored for each patient individually close to the point of service.

INTRODUCTION

The pharmaceutical industry is renowned for using cutting-edge approaches in research and development to regularly give patients access to life-saving medications and biologics, but the sector has encountered significant difficulties in utilizing cutting-edge technologies to modernize manufacturing processes and quickly adjust to an evolving technological landscape. From the standpoint of manufacturing, the majority of international pharmaceutical companies' use of the current standards of manufacturing and production processes hinders the use of innovation to promote continuous development. The rigid and frequently inconsistent worldwide regulatory standards that influence manufacturing and product quality demands also present considerable obstacles. The traditional, centralized manufacturing paradigm, in particular, is a fixed model system that generates high-quality, reproducible pharmaceutical products in large quantities, but it also contains significant systematic rigidity that may impede innovation, speed, efficiency, and resiliency in a volatile market. As a result, present procedures may contribute to delays in patient access to medications and drug shortages brought on by broken supply chains. Patient accessibility, as used here, relates to a patient's physical closeness to therapies for localized or point-of-care manufacturing considerations within a logistical framework. The emergence of personalized or precision medicine necessitates a shift from low-volume, high-mix product manufacture at numerous dispersed locations to mass production of a small number of goods at one location. Agile manufacturing approaches are suggested as a potential solution to enable greater flexibility. They include organizational and manufacturing methodologies that improve business flexibility by enabling organizations to react to different process inputs in real-time, improving industry's ability to better serve individual -patient needs. Agility is further enhanced by portability, which offers the freedom to provide medications tailored to a particular patient at the most suitable location. However, a supportive and adaptable regulatory framework must emerge alongside cutting-edge manufacturing technology to facilitate flexible production in order to fulfill the changing demands of industry stakeholders. In order to further improve patient access to medications and enable patients to acquire medications near to the location of manufacture, where they are made, production at the point-of-care can only occur with a mix of manufacturing and regulatory innovation. Traditional, centralized biopharmaceutical production chains are extremely complicated, involving a global network of suppliers for various raw ingredients, machinery and technology, and manufacturing facilities. Traditional methods are rigid, comparatively immobile, and unable to change to

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meet the evolving demands for medical care brought on by the development of personalized medicine. Since the Industrial Revolution of the late 18th century, when sophisticated factory systems, assembly line production, and mechanized tools were introduced, the centralized manufacturing approach has dominated large-scale production tactics. The low cost of mass manufacturing, the sparing use of resources, and the improvement in product consistency and uniformity are notable benefits of centralization. The modernization of manufacturing and distribution processes can aid in accelerating patient accessibility, addressing current gaps causing drug shortages, reducing time to market for emerging therapies, and minimizing barriers for the production of complex, precision therapies that depend on personalization and flexibility in production. Despite the fact that these characteristics remain highly relevant and valuable qualities of current manufacturing and production systems. Manufacturers and regulators must now take a larger variety of production strategies into account to address both high-volume, standardized medicines as well as comparably more sophisticated smaller scale therapies due to growing business, customer, product, and environmental complications. While smaller, identical, modular facilities may better support regional production as well as patient customization, centralized manufacturing approaches used to support mass production of pharmaceutical products on a global scale require a gradual scale-up of production throughout a product's lifecycle. Agility is eventually necessary for all modality, even while novel modalities, including autologous cell-based treatments, demand the most financial flexibility. Manufacturers across all product categories and therapeutic areas are under significant financial and time-related pressure to deliver new medications to patients, meet regional production standards, and control manufacturing tools and procedures throughout the whole supply chain. The conventional manufacturing model continues to be highly valued and significant to industry despite the changing requirements for agility, as centralized, mass production of medicines is still a viable option for many products. Although many new or complicated modalities call for alternative techniques, not all goods or businesses will necessitate decentralization or the implementation of agile approaches. From a regulatory standpoint, producers should have the choice to explore agile ways when appropriate (such as tailored, point-of-care medicines). With recent acceleration in bispecific, multispecific, cell, and gene therapies, the biopharmaceutical sector has made significant development over the past five years, moving from creating mostly small molecule medicinal products to including complex protein medicines. There is limited historical precedent for developing these highly tailored medicines, and these new modalities are incredibly difficult. Since every batch of cell-based therapies, including Chimeric Antigen Receptor (CAR) T cells, is custom-made for each patient, a highly tailored and adaptable production system is necessary. Comparably, the production of regenerative drugs using human cellular and tissue components needs to be done in tiny batches by a variety of regional manufacturers, some of which may be run by a single researcher or physician. Throughout the lifecycle of the product, agility and adaptability are required due to the diversity in new modalities with unique manufacturing requirements. These new modalities also present a special set of regulatory challenges in addition to manufacturing and clinical challenges.