Rethinking the Supply Chain in the Personalized Medicine Age

Personalized medicine is leading to extensive change across the life-sciences industry, not least in the manufacturing and distribution of products.

Typically, pharmaceutical manufacturing has involved large batch production. However, personalized medicines are highly complex and can't be made to the same scale or delivered using the same siloed supply chain processes.

This poses several organizational challenges for companies, which will need to adjust for complex personalized medications that depend on eliminating error rates. Indeed, there has been speculation that the impact personalized medicine will have on the supply chain has been underestimated.

But while there are difficulties in adjusting to this new supply chain paradigm, it's also an opportunity for the industry to improve its bottom line. That's because supply chain expenses account for between 25% and 40% of overall pharmaceutical costs, so improved logistics could result in significant cost savings.

To adjust for these changes and realize process improvements, the supply chain will need to evolve and embrace digital technology in which the entire process is tracked from end to end. According to Strategy&, digitizing will make it easier for companies to integrate their supply chain and enhance their operational processes, which will lead to planning precision, manufacturing efficiency, better control over inventory levels, and improved service levels.

Adapting Processes

Experts recommend the use of innovative technologies that allow for flexible, multi-product, small batch production. Production variables need to be carefully monitored so any change can be quickly addressed while ensuring the system continues to function. In this environment, quality control and assurance become paramount.

The third-party supply chain network is also impacted by personalized medicine, which moves production away from high-volume, low-profit margin and toward sophisticated production. For example, leading logistics services providers now employ pharmacists and patient coordinators to coordinate between sites, hospitals, clinics, and patients. Often personalized medicine involves using the patient's own cells, so the patient needs to be involved in the collection of samples and the delivery of the medicine.

One such example is Novartis' Kymriah, a gene-modified cell therapy that requires T cells be extracted from a patient's blood, re-engineered in a lab to target cancer cells, and then put back into the patient. This makes the supply chain process complex and requires careful capacity oversight, from ensuring the relevant healthcare providers know in advance when a patient's cells need to be collected to ensuring all parties further downstream are prepared to receive the material.

To mitigate potential issues, Novartis has built a system and facility designed to adapt to individualized treatment requirements. The company is also working with a cold chain logistics provider to help get the products to treatment centers around the United States.

Cold chain or temperature-controlled logistics with personalized medicine is crucial, and affects all parts of the supply chain – from storage to transport. This has led to advanced cold-chain packaging to prevent temperature variations throughout the supply chain and temperature and logistics monitors to ensure the product or sample in the container remains temperature controlled and to safeguard the quality of the biologic material contained in the package.

Keeping Track of the Supply Chain

Serialization and other counterfeit reduction initiatives across the supply chain will be increasingly important in the age of personalized medicine, given the cost of manufacturing and supplying these medicines.

An important consideration for companies will be shipping integrity. Some experts warn that existing technologies for managing the supply chain, such as enterprise and manufacturing systems and quality management systems, don't provide the precision needed when managing highly complex personalized medicines, such as Kymriah. This has led to the advent of cell orchestration platforms that make it possible to collate, track, and document critical information in the cell and

The Benefits of Digitizing the Supply Chain

Life-sciences companies must address many challenges across the supply chain, such as the complexity of operating globally, juggling many partners, the demand for greater efficiencies, greater customer segmentation, addressing counterfeits, and better quality control and visibility.

Digitization will enable the following:

- Real-time visibility and faster decision-making thanks to sensors across the supply chain
- Improved operational processes and maintenance through digitization and analytics
- End-to-end supply chain integration and greater network scalability through capabilities such as cloud computing that make it possible to develop global integrated supply chain networks
- Manufacturing efficiencies and productivity gains thanks to automation and digitization in areas such as filling, loading, replenishing, and troubleshooting

Source: Strategy&, strategyand.pwc.com

gene therapy process — from development to delivery.

There is growing emphasis across the supply chain — driven in part by personalized medicine — on having technologies that provide real-time or near real-time visibility and transparency into the location of a shipment, temperature, barometric pressure, and any potential risks while in transit.

In this way, companies know where their product is at any time and can react quickly to product shortages or holdups, and better control distribution.

In addition, experts say the need for capabilities that assure the chain of custody and identity will affect the current supply chain model, since it means companies will need to be able to track products from manufacturing to delivery to the patient and even back from the patient to the manufacturer.

Again, the use of digital technologies such as Internet of Things (IoT) tracking sensors will make it easier to monitor products in transit and in storage.

Compliance is another key consideration when it comes to keeping track of the supply chain. In the U.S., the Drug Supply Chain Security Act (DSCSA) requires companies to identify and trace certain prescription drugs. The reason for this is to protect consumers against products that are counterfeits, contaminated, or in any other way harmful.

The New Supply Chain Network

One of the biggest challenges with the supply chain and personalized medicine is the growing number of parties involved, including suppliers, contract manufacturers, distributors, third-party logistics vendors, and more. Experts warn that personalized medicine ultimately leads to more touch points, making it difficult for companies to get clear insight into the various suppliers involved. This again places the emphasis on technologies that enable companies to gain insight into each step in the supply chain process. But it's not only technology that will be needed. Companies will also need to assess the types of partnerships required to enable a secure and traceable supply chain so they know where, when, and how materials are sourced, manufactured, and delivered.

And for partners within the supply chain, such as contract manufacturing organizations (CMOs), personalized medicine presents some serious challenges that will require many to adapt their processes and develop models and solutions that ensure better integration across the supply chain and the ability to respond to the real-time needs of personalized therapies.

Ultimately, innovative technologies and digitization will be critical elements in transforming the supply chain in the age of personalized medicine. But it will also require companies to adapt both their solutions and processes. For example, pharma companies will need to ensure their solutions are aligned with partners in other parts of the supply chain. It will also require understanding the changing environment, collaboration, and managing risk such as cybersecurity. PV

EXECUTIVE VIEWPOINTS

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Re-Imagining the Supply Chain Model

Pharma companies will need to expand their perception of the supply chain from the traditional "pick, pack, and ship" models to more direct "just-in-time" models with enhanced tracking and monitoring during every touch point. They will also need to build logistics processes to support special handling requirements for precision medicines such as deep frozen capabilities, low unit size shipments, etc. Pharma companies should look for opportunities to simplify the distribution network by partnering with suppliers with deep expertise and capabilities. In working with distribution partners, consider whether they are located in close proximity to where the bulk of your volume is going. This can help decrease lead time for order fulfillment and support a just-in-time model, while reducing the amount of inventory you and your customers are required to carry. Also, as global manufacturing grows, consider whether your distribution partner has the ability to import and export with ease.

Protecting the Chain

It is important to be engaged in current track and trace initiatives, such as DSCSA, which involves serializing product and having the ability to track that data throughout the supply chain. As the industry continues to evolve in this space, stay current on new technology such as blockchain and its possible applications in the healthcare supply chain, and look for opportunities to be an early adoptor.