Solving Today's Patient-Centric Supply Chains

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Precision oncology, CAR-T cell therapy, gene therapy, CRISPR-Cas9 — scientific advances in the space of cell and gene therapy have made a significant impact on patient care. Biopharma company pipelines are developing advanced treatments at an inspiring pace. Even amid the ongoing COVID-19 pandemic — and sometimes in response to it — precision and personalized therapeutics continue to evolve. Now, the biopharma supply chain must innovate, to accelerate this wave of patient-centric innovation.

Orchestrated Supply Chain

Next-gen therapies require more than just supply chain "management." They demand precise, industrialized orchestration, powered by sophisticated technology. And this need is urgent. Specialty drugs are expected to represent about 65% of global drug launches through 2023.[1] Advanced therapies, such as cell and gene therapies, comprise a small segment today, but are anticipated to reach $37.9 billion by 2024.[2] More than 1,060 advanced therapy clinical trials are underway worldwide.[3]

Traditional, linear supply chain paradigms cannot support this growth. Next-gen therapies require not only mass production for scale, but mass personalization. Advanced therapy workflows are circular and multi-dimensional, starting from, ending with, and continuously looping around the patient and their provider team. The patient journey and the product journey for cell and gene therapy are often complex, multidimensional, and interconnected in ways unlike others. Manufacturing batches are often as small as one per patient. Therapy manufacturing varies based on the type (open systems vs. closed system), with some having differing degrees of variability and risk. Patient-specific drug products must be delivered to the right patient, safely, every time — with stringent regulatory requirements. And the supply chain extends far beyond the norm, from patient qualification to reimbursement and long-term monitoring.

Five Proven Strategies for Next-Gen Products

Here are five proven innovation strategies.

1. Plan your supply chain around patients and healthcare providers. Advanced therapies are patient-specific treatments. Successful supply chains will proactively prepare for patient — and treatment — specific factors and remove barriers to care. This starts with effective, two-way communication and transparency among all stakeholders. Simplicity is another key. Providing protocols and processes in easy to use, standardized ways ensures patient safety and a positive, successful experience for healthcare providers. At Vineti, our digital Personalized Therapy Management (PTM) platform is used at hundreds of sites of care, helping providers manage thousands of advanced therapy doses simply and safely.

2. Prepare for a diverse, distributed supply ecosystem. Many of your stakeholders and activities will be outside of the manufacturing facility and include players with little cGMP experience. Care site personnel need training in cGMP and tools to ensure safety and cGMP compliance for every therapy. Standardizing, streamlining, and compliance are best achieved through automated workflows and user-friendly digital systems. Reliable orchestration platforms deliver compliance and quality for every product, driving costs down and value and efficiency up.

3. Anticipate all your stakeholders. Your next-gen supply chain will have a larger set of participants than traditional drug products. For example, payers may verify each patient process and outcome for reimbursement. The key here is capturing high-quality chain of identity and chain of custody data at every step, and ensuring this data is available on demand. These chains must be fully linked through coordination across stakeholders. Digital platforms such as Vineti's PTM power the end-to-end process by providing standardized, secure data capture and reporting across the entire supply chain, while supporting all stakeholder roles and responsibilities.

4. Rethink Quality Risk Management (QRM). QRM becomes exponentially more important in advanced therapies. Supply chain complexities create new opportunities for deviations and issues, requiring a collaborative, technology-enabled approach to QRM. Patient safety is the key driver. A robust program satisfies regulatory requirements and speeds health authorities' approvals. It also ensures quality, compliance, operational efficiency, improved decision-making, better customer service, and lower costs.

5. Embed the right technology up front. This is a brave new world — traditional e-systems won't work. Trying to contort legacy technology, or scale with manual systems, will waste resources and increase risk. The additional complexity of advanced therapy supply chains requires modern technology solutions. Companies must strategically implement modern digital platforms, potentially much earlier than expected. Regulators are often setting high expectations for traceability at the time of IND filing. In fulfilling both compliance requirements and business needs, companies should look to proven, purpose-built solutions that connect the value chain and scale efficiently.

Reaching Patients In Need

There's rarely been a better time to be innovating in biopharma. Alongside progress on COVID-19, inspiring growth continues in speciality and advanced therapy products, including the recent Nobel Prize in Chemistry for the discovery of CRISPR-Cas9. Now, we need supply chain strategies and technologies as advanced as our treatments, so that we can truly reach all patients in need.

References:
1. *IQVIA, The Global Use of Medicine in 2019 and Outlook to 2023*
2. *Evaluate Pharma, 2020*
3. *Alliance for Regenerative Medicine, 2020*

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