Bringing Your Cell and Gene Therapy Offerings to Market

Stan Bonn

There is nothing more exciting in the biopharmaceutical industry than the rapid advancements in cell and gene therapies (CGTs). As scientists develop new technologies and solutions, developers work to translate research and learnings from academia into tangible, life-saving cures. Successfully developing new therapies hinges on extensive collaboration, not only among academia and industry, but also among manufacturers and their quality-control (QC) partners. Collaboration aids discoveries that pioneer the future of medicine and shortens the learning curve for all stakeholders through sharing knowledge from research, trials, and experiences. Immediately after companies secure funding, they consult their QC partners to help navigate the regulatory landscape with the vision and agility necessary to bring revolutionary offerings to the market safely and effectively.

My company works with CGT manufacturers to create robust safety-testing plans to support development. No two therapies, testing strategies, or companies are the same when it comes to the development of individualized medicines. To be reliable collaborators, QC partners must prioritize collaboration to identify areas where performance meets compliance and address the needs of each therapeutic in a cost-effective way.

To the Summit: Good relationships between pharmaceutical companies and QC partners mirror those of mountain climbers and their guides. Although no two journeys are the same, guides understand fundamentals and best practices in their area of expertise. They can pivot as needed to ensure a successful journey. In climbing, an effective guide earns a climber's trust by sharing knowledge and experiences about routes and terrain that are drawn from past experiences. To develop CGTs successfully, developers must trust their testing partner to navigate a dynamic landscape with expertise that has been built across disciplines and experiences in multiple settings.

Partners in CGT Success

Because time is a critical commodity, developers increase their chance of success by joining with QC partners in the preclinical phase to design robust, trustworthy testing plans that are tailored to their specific laboratory needs. A valuable partner understands constraints and can apply knowledge and learnings to optimize the QC process within a company's existing framework.

Our company works in the CGT space to enable our partners to bring their offerings to market. Often, certain microbiology practices must be learned as they arise. In such cases, we help customers fill in knowledge gaps and offer counsel toward developing successful testing plans. We alert clients to new developments and advancements in research and technology that affect CGT development. We also understand the challenges and regulatory standards that affect manufacturers and laboratories. Rapid CGT-development methods require extensive labor and funding investments to bring offerings to market.

Developing a Challenge Framework: Testing solutions should be designed to meet both short-term and long-term organizational goals. This can include helping companies set up a laboratory for the first time, identifying a reputable outsourced partner, assisting with testing identification, or aiding in other projects. Understanding such priorities enables us to meet underlying needs such as those for streamlining, standardizing processes, securing data integrity through automation, and providing guidance for balancing suitability and validity for therapies that are hoping to reach the market.

Optimizing Resources To Achieve Goals: There is not an off-the-shelf testing portfolio that can meet the needs of every customer. The right QC partner will help address qualification, suitability, and method validation testing needs at the right time during each phase of development. That partner should also design tests with an optimized workflow to minimize contamination risks and reduce reliance on highly skilled labor to achieve testing confidence.

Ongoing Education: Despite a recent increase in US Food and Drug Administration (FDA) approved therapies, the CGT segment is still considered an alternative to traditional biopharmaceutical development. Researchers are publishing clinical-trial learnings and other data at an accelerated rate, and companies should incorporate that new information throughout development. The right partners have a pulse on the changes that shape the sector's landscape and can proactively assist clients in real-time learning.

The importance of teaming up with a knowledgeable QC-testing partner cannot be overstated. Successful diagnostic testing plans require creativity, a commitment to analyzing real-time data, and an efficient workflow crafted to reduce contamination risk. As CGTs continue toward rapid adoption, our industry has an opportunity to pioneer the future of medicine and develop game-changing testing solutions to save lives.

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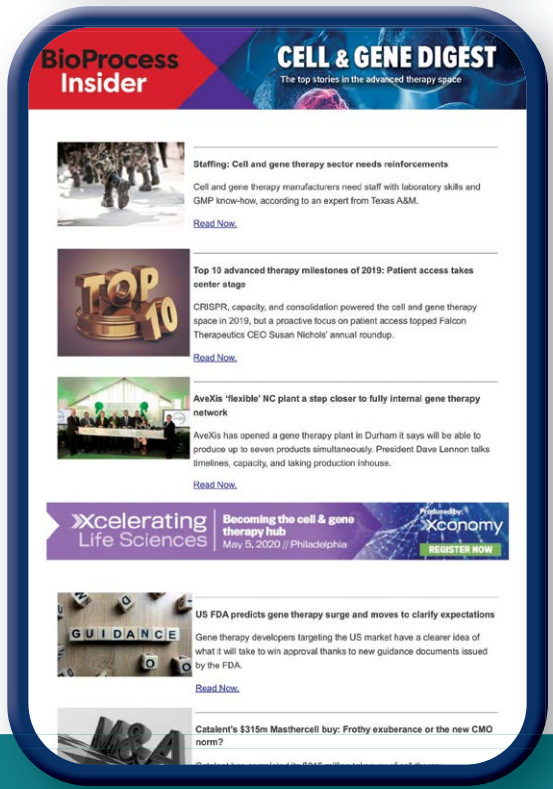

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