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Fact Sheet

Transforming CGT quality testing to accelerate time to patient

The rapid evolution of cell and gene therapies (CGTs) marks a new era of transformative care, offering hope for conditions once considered untreatable. However, the journey from discovery to delivery is fraught with challenges, particularly in quality control (QC). Unlike traditional biologics or small molecules, CGTs often involve personalized batches manufactured for individual patients, adding layers of complexity. Even minor delays or errors in QC can have profound, potentially life-or-death consequences for patients awaiting treatment.

These challenges are further compounded by the need to manage vast datasets, maintain data traceability, and scale operations efficiently—all while adhering to stringent regulatory standards. Here, we explore the key data-related hurdles in CGT QC and highlight how TetraScience helps biopharmaceutical companies deliver life-saving therapies faster, safer, and at scale.

Challenges in quality control for CGT

1. Inherent biological complexity

CGTs rely on living cells and biological materials (e.g., viral vectors and recombinant DNA), which introduce significant variability in both raw materials and final products. Therapies using patient-sourced materials, such as chimeric antigen receptor (CAR) T cells, are especially tricky due to their individualized nature. Ensuring product quality and safety across these diverse inputs requires advanced data systems capable of tracking and analyzing variability.

2. Time sensitivity

The perishability of CGT products requires fast and efficient QC processes, as any delays in testing can threaten product viability and endanger patient outcomes. To address these time-sensitive demands, streamlined and automated testing workflows are crucial.

3. Regulatory complexity

The regulatory landscape for CGTs is complex and continually evolving. Regulatory bodies like the U.S. Food and Drug Administration (FDA) enforce detailed guidelines for chemistry, manufacturing, and control (CMC) processes to ensure compliance. Meeting these stringent requirements requires efficient workflows and robust data management systems that enable real-time updates, comprehensive documentation, and complete traceability.

4. Large, heterogeneous datasets

QC processes for CGTs generate massive volumes of data, including but not limited to sequencing results, potency assays, and batch records. Traditional methods often leave QC teams struggling to manage this complex and diverse data for analysis and reporting. Centralized platforms are essential for integrating and contextualizing these datasets, streamlining workflows, and ensuring data is ready for actionable insights.

5. Deviation management

Errors or inconsistencies during QC can cause deviations, delaying batch release and impacting patient treatments. For instance, such issues may result in failing to meet potency assay specifications during final product testing. Rapidly identifying and addressing deviations—or preventing them altogether—is crucial for maintaining manufacturing timelines and ensuring product quality.

6. Scalability and standardization

As CGTs scale from niche treatments to broader adoption, many labs still rely on manual processes that are time-consuming and prone to error. Scaling these processes while maintaining consistent quality is essential to meet growing demand. Automated and standardized QC workflows provide a pathway to efficiency and consistency without compromising quality or compliance.

How TetraScience accelerates and improves CGT quality testing

TetraScience empowers QC teams to harness their data for faster, more reliable testing of CGTs. This involves efficiently collecting and preparing scientific data—from all its sources—for analysis and reporting. At the heart of these operations is the Tetra Scientific Data and AI Cloud™. It enables automated end-to-end workflows that support timely, data-driven decisions for CGT quality testing, while reducing the compliance burden on QC teams.

Enhanced data accessibility

Data silos in biopharma organizations make it difficult to compile and analyze large, heterogeneous datasets used for CGT quality control. TetraScience eliminates these barriers by automatically consolidating and contextualizing scientific data into a centralized platform. The Tetra Scientific Data and AI Cloud replatforms and engineers raw data from instruments and systems, such as chromatography data systems (CDSs) and laboratory information management systems (LIMSs). This creates a single, contextualized source of truth, enabling QC teams to efficiently access, analyze, and share data across the organization.

Real-time analytics and AI-driven insights

The Tetra Scientific Data and AI Cloud transforms raw scientific data into AI-ready datasets, unlocking powerful insights through advanced analytics and AI-driven applications. With these capabilities, QC teams can proactively monitor trends, predict and mitigate potential deviations, and accelerate root cause analysis by up to 90%. The result is fewer errors and delays in CGT production.

Analytics dashboards provide insights into batch trends, instrument performance, and assay variability. They equip QC teams with the tools needed to manage complex manufacturing processes effectively, ensuring consistent quality.

Case study spotlight: Andelyn Biosciences

Andelyn Biosciences, a leading gene therapy CDMO, partnered with TetraScience to digitalize their QC workflows. By centralizing nine years of assay data and automating 90% of their instruments, Andelyn eliminated manual delays, enhanced compliance, and improved scalability.

Bryan Holmes, VP of Digital and Technology Solutions at Andelyn, remarked, "TetraScience is the core platform for our scientific data and a real differentiator and accelerator to our business."

Learn more

Fast, scalable workflows

Speed is critical for CGTs. TetraScience supports near-real-time release testing, allowing rapid analysis of quality attributes and quicker decision-making. Automated data transfers eliminate manual inefficiencies, creating faster and more reliable workflows. This acceleration is vital for biopharma organizations aiming to scale up the production of personalized medicines while minimizing patient wait times.

Streamlined compliance and risk mitigation

The Scientific Data and AI Cloud ensures data accuracy, traceability, and regulatory readiness, adhering to global standards such as 21 CFR Part 11 and ALCOA++. Audit trails enhance transparency, mitigate compliance risks, and simplify regulatory submissions.

TetraScience's GxP package streamlines validation processes, reducing efforts by up to 80%. By leveraging the latest Computer Software Assurance (CSA) framework and a comprehensive set of validation documents, the platform enables customers to efficiently standardize and automate industry best practices.

Reimagine your CGT QC

As CGTs evolve, QC processes must adapt to increasing complexity and demand. TetraScience empowers labs to:

- **Minimize time to patient** and maintain consistent product quality
- **Improve patient outcomes** with data-driven insights and faster decision-making
- **Stay ahead of regulatory changes** through scalable, compliant solutions that adapt to evolving standards

Discover how TetraScience can transform your CGT QC processes. Contact us today.