Cell and gene therapies demand a robust system

Standardizing your CGT platform to ensure consistency during experiements is essential for improving future clinical outcomes

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Q: What are the primary challenges clinical labs face during cell and gene therapy (CGT) assay development?

A: The lack of rapid analytical methods means that quality control testing can be extremely time-consuming. For example, some cell-based potency assays can take one to three weeks to execute. Another challenge is that there is no one-size-fits-all approach to CGT assay development. Because there are not enough standardized assays currently available, each assay must be specifically designed fit-forpurpose. Along with the many regulatory requirements in clinical research, a fast turnaround time with minimal intervention is crucial to advancing CGT assay development.

Q: How should labs approach CGT development to mitigate some of these challenges?

A: First, assays can be assessed as fit-for-purpose commercially and clinically; this assessment should be performed as early in the analytical method cycle as possible. Second, transitioning assays from the development stage through the analytical science and technology and quality control environments can pose a challenge both on paper and at the bench. Leveraging tools like Smart Gain Technology from Miltenyi Biotec can mitigate these challenges, increasing the likelihood of comparable and reproducible data. Developing multi-attribute methods that can generate several important outputs from a single analysis can also maximize research and reduce the need for redundancy.

Q: Why is standardizing CGT assays important for clinical research and applications?

A: Standardization can expedite the preclinical and developmental stages of CGT assay development. Using a standardized method such as Express Modes, a unique add-on feature for MACSQuantify Software™, reduces the burden on developers to create bespoke methods during R&D processes. Such software can yield high-quality data in less time and analyze processes of interest, such as CAR persistence in T cells, immune cell composition, and activation markers. Standardizing CGT assays promotes consistency and accuracy in data collection, which leads to better results.

Kitman Yeung is a biopharmaceutical specialist at Miltenyi Bioindustry, a division of Miltenyi Biotec, with 14 years of experience in cell and gene therapies. Her expertise in technology transfer, analytical development, and quality control testing supports the production of Phase 1/2 GMP cell and gene therapies. Yeung is currently an MSAT analytical manager at Miltenyi Bioindustry, where she leads technical and operational teams in developing, characterizing, and qualifying analytical tools for cell and gene therapies across multiple modalities.

Q: What are some best practices to ensure that assays continue to perform well after development?

A: To maintain consistency and accuracy, there are a number of best practices you can adopt, including:

- A robust change control system to monitor and track modifications to the assay
- Regular monitoring of equipment, performance, and calibration
- Reference standards and controls to assess assay performance
- Ongoing statistical control procedures that employ reference standards and assay performance built into the system

Regular validation can also help detect any variations and ensure that assays are performing as expected. Instruments that automate some of these tasks, like the MACSQuant® Analyzers offered by Miltenyi Biotec, can help labs monitor their performance with confidence and ease.

CGT experiments are complex and require high standards for approval and progression to routine clinical use. You can use the software, tools, and tips outlined here to save time, reduce potential pitfalls, and improve the outcomes of your CGT experiments.

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