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Solution Brief

Automation Advancements in Immune Cell Therapy Workflow

Ella meets the demand for fast, efficient QC release testing of interferon-gamma (IFNg)

Introduction

Cell and gene therapies (CGT) have ushered in a new era of personalized medicine and offer exciting promise to treat life threatening diseases. To fulfill this promise, developers in today's CGT market continue to intensify their efforts to improve therapeutic treatments, along with robust, state-of-the art study methods.

As with all therapeutic drugs, critical quality attributes (CQAs) are vitally important to ensure product stability, safety, and efficacy. Analytical developers and quality control (QC) scientists rely on a number of analytical techniques to characterize and verify CQAs, helping to demonstrate safety, consistency and reproducibility.

Immunoassays play a leading role in this effort, helping to evaluate the functionality and characterization of modified immune cells such as in CAR (chimeric antigen receptor) T cell therapy, and in the quantifying of interferon-gamma (IFNg). Given the central role of IFNg in cell therapy and immunology—including as a QC release testing criteria—consistent and reliable methods of quantifying IFNg levels are imperative.

Accelerating discovery through expert collaboration

While CQAs are critical for the successful development of cell and gene therapies, the overarching goal is to know your product inside out and as early as possible. That's where advanced analytical tools combined with expert collaboration can help drive important advancements. Case in point is the Cell and Gene Therapy Catapult, which recently completed a multi-year consortium with 24 other partners to apply novel process analytical technologies (PAT) to a standardized immunotherapy cell manufacturing process.

Established by Innovate UK, the Cell and Gene Therapy Catapult (CGT Catapult) is committed to the advancement of cell and gene therapies, with a vision for a thriving industry delivering life-changing advanced therapies to the world. Its work includes fostering collaborations between academia, industry, and healthcare providers to gain a better understanding of cell bioprocesses and the sufficient control needed to develop advanced therapy medicinal products (ATMPs). CGT Catapult experts cover all aspects of advanced therapies, from research and development to clinical adoption and every step in between.

Catapult's CGT initiative began in January 2021 with a series of experiments designed to monitor process parameters of an exemplar 8-day T-cell expansion bioprocess using primary T-cells. A three-stage process underpinned the work of the consortium: establishing the test environment; using technologies in an impartial environment; then monitoring the process via established and novel process analytical technologies.

Data were gathered on multiple platforms from five independent bioprocess experiments to generate an extensive, world-first dataset. An analysis of multiple cytokine targets including IFNg was conducted using Simple Plex™ assays running on the automated ELISA platform, Ella™, from Bio-Techne , leading to rich insights into cell activation and potency. The project helped provide CGT developers with deeper insight into ATMP bioprocessing methods and a better understanding of the next steps required for better process automation to advance cell therapies.

CGT Catapult Skills and Training Laboratories

Achieving reproducible data in an automated workflow

Reproducible data and high-precision QC results underpin informed decision making during therapeutic development and help pave the way to regulatory approval. This is where improvements in analytical assay performance and instrument automation are delivering substantial value.

In the CGT Catapult project, the automated Ella workflow proved to be particularly amenable to the efficiency, accuracy, and throughput demands inherent in a bioprocess manufacturing environment. Ella is considered the platform of choice on the market for QC release testing for IFNg and is now incorporated into the CGT Catapult Skills and Training Labs, among other labs around the world.

Traditional plate-based assays can be time consuming with lengthy assay workflows that can introduce human error at every step. More automated analytical platforms, like Ella, have been shown to deliver more consistent results with greater throughput. These platforms also enable simple and reliable transfer of assay results from upstream departments like analytical development and quality control.

Learn More about Ella at
www.bio-techne.com/ella