

Cell and gene therapy

A streamlined, optimized viral vector workflow to drive cell and gene therapy innovation

With support from Thermo Fisher Scientific, the UK's Cell and Gene Therapy Catapult developed an efficient and scalable process for adeno-associated virus production

The challenge

As part of the UK's Cell and Gene Therapy Catapult's (CGT Catapult's) work to support innovation in cell and gene therapies, their team needed to establish a robust viral vector workflow. To maximize viral vector output for clinical and commercial manufacturing applications, CGT Catapult sought to build a process using reliable products and scalable solutions backed by access to industry expertise to help navigate production challenges.

Background

The CGT Catapult is an independent innovation and technology organization from the UK committed to the advancement of cell and gene therapies. It is part of a network of organizations established by the UK government with the aim of turning great ideas into products and services by bridging the gap between industry and academia.

CGT Catapult's Braintree Manufacturing Innovation Centre is a facility designed to support the development of late-stage clinical and commercial manufacturing processes for advanced therapy medicinal products (ATMPs) in collaboration with industry. This includes technology transfer, cGMP-compliant manufacturing, quality control, quality assurance, and validation for mRNA vaccines and therapeutics, cell therapies, gene therapies, and viral vectors. To deliver on this mission, the CGT Catapult team needed to establish viral vector production capabilities that could advance research, development, and manufacturing in this growing clinical space.

The solution

CGT Catapult leveraged Thermo Fisher's extensive product portfolio and expertise to create a process for adeno-associated virus (AAV) production. Thermo Fisher's deep scientific and product knowledge proved essential in helping CGT Catapult rapidly troubleshoot and optimize processes, setting the stage for future growth and innovation.

Challenge: maximizing viral vector output to deliver more therapies to patients in need

The cell and gene therapy sector has undergone a rapid expansion of its clinical pipeline over recent years with an expanding portfolio of products nearing approval and commercialization. In order to accommodate the anticipated demand for key technologies and materials to support the commercialization of ATMPs, cell and gene therapy researchers and manufacturers have understood the importance of building efficient workflows backed by robust supply chains to ensure these products reach their potential to transform the lives of patients.

In building a viral vector production workflow, the CGT Catapult team wanted to create a process that would allow them to maximize yield and output to provide the most efficient and effective methods of production while reducing costs and maintaining product quality and safety. Increasing throughput in viral vector production presented unique technical challenges that needed to be addressed prior to moving forward with larger-scale production. The team at CGT Catapult sought solutions that would help overcome these core challenges for efficient viral vector production that could then be scaled to meet the forecasted demands of the industry.

Response: building an optimized, scalable viral vector workflow

To help achieve a scalable viral vector process, CGT Catapult turned to Thermo Fisher's established portfolio of equipment and products. The resulting workflow leveraged a HEK293 suspension cell line, Gibco™ cell culture media designed to support high-density cell growth without the need for media change or supplementation, and the Thermo Scientific™ DynaDrive™ Single-Use Bioreactor (S.U.B.) with the Thermo Scientific™ HyPerforma™ G3Lite™ Bioprocess Controller. The specific ability of the DynaDrive S.U.B. to support both low- and high-volume production allowed CGT Catapult to bypass the need for extra equipment, a larger facility, or an expanded footprint to meet scale-up goals and increased capacity demands.

With a workflow in place, CGT Catapult focused on optimizing their viral vector process. To establish key parameters and ensure the process was robust, the team conducted a series of three experiments using the 50 L DynaDrive S.U.B. The primary goal of these initial studies was to evaluate AAV production from suspension HEK293 cells by demonstrating successful cell culture and transfection prior to scaling to larger volumes. Ultimately, CGT Catapult achieved a robust, scalable cell culture and transfection process for AAV production.

Value delivered: advancing cell and gene therapies through collaboration

Thermo Fisher's partnership with CGT Catapult extended beyond providing the reliable products needed to build a viral vector process. Thermo Fisher supported CGT Catapult throughout the building of their AAV vector production workflow, providing insights and guidance in optimizing production. When CGT Catapult observed cell viability issues, Thermo Fisher's technical support team helped troubleshoot and fine-tune aeration and agitation parameters in the DynaDrive S.U.B. to achieve optimal cell growth and cell viability of >95% throughout the duration of subsequent experiments.

By providing product knowledge and scientific expertise, Thermo Fisher's technical support team helped CGT Catapult navigate challenges and quickly adapt their AAV production parameters, saving both time and money while establishing a robust, reliable, and scalable workflow. The result of these collaborative efforts is that CGT Catapult has furthered its objectives to support cell and gene therapy innovation, ultimately helping to develop and deliver critical treatments to patients in need.



The DynaDrive S.U.B. (left) and HyPerforma G3Lite Bioprocess Controller (right).

Find out more at thermofisher.com/cgt

Intended use of the products vary. For specific intended use statements, please refer to the product label.

© 2022 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. COL26741 0922