

DEVELOPMENT OF A SUBCLONAL HOST CELL LINE FOR AAV PRODUCTION

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The Genomic Medicine Unit (GMU) CMC group at Sanofi is dedicated to the establishment of best-in-class manufacturing platforms to support development of life-changing advanced cell and gene therapy products. Recombinant adeno-associated virus (rAAV) has emerged as one of the leading viral vectors for gene therapy. Sanofi's AAV producer cell line (PCL) platform represents a leading technology for rAAV vector production due to its scalability and the capacity of the platform to produce viral vector of high and consistent quality. PCLs supporting projects within the Sanofi GMU portfolio are typically generated from a HeLaS3 host cell line. There are a few reasons for creating a new host cell line: first, reducing the heterogeneity that is characteristic of the HeLa cells; second, selecting a new host that has improved critical attributes compared to our current host, such as improved Population Doubling Time (PDT), growth kinetics, transfection efficiencies, vector yield, etc.; and finally, selecting a subclone capable of single-cell growth in a serum-free media, enabling process efficiency and reducing potential viral risk.

The current abstract focusses upon the technologies available to produce recombinant adeno-associated virus (AAV)-based viral vectors towards treatment of various diseases. Efforts to develop a new HeLaS3 host cell line have been initiated and the current content will highlight upon Sanofi's PCL based platform for production of gene therapy vectors and will zoom in on the development of a subclonal host cell line.