

# A fully characterized, GMP-banked HEK293 suspension cell line enabling scalable, flexible, and high-quality rAAV production

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## Introduction

Advanced therapeutic medicinal products (ATMPs) development is increasing the demand for robust, scalable, and well-characterized manufacturing platforms for recombinant adeno-associated virus (rAAV) vectors. Although HEK293 cells remain the industry standard for rAAV production, most commercially available derived cell lines lack deep genetic characterization and show variable performance across scales, media and production processes. We present NBX-Eng-HEK293, a novel clonal, suspension-adapted, GMP-banked HEK293 cell line specifically engineered for rAAV manufacturing.

## Methods

The cell line has been comprehensively characterized at the genomic, transcriptomic and functional levels. Previous studies demonstrated rAAV yields comparable to, or exceeding, widely used commercial HEK293 cell lines. Here, we extend these findings by demonstrating process scalability, operational flexibility, and improved vector quality across various production formats

## Results

rAAV vectors encompassing multiple capsid serotypes and reporter or therapeutic transgenes were produced using NBX-Eng-HEK293 and benchmarked against a leading commercial HEK293 cell line. Production was evaluated from shake flasks to multiple stirred-tank bioreactor platforms, and across diverse commercially available culture media. NBX-Eng-HEK293 consistently delivered comparable titers across scales and production systems, demonstrating strong platform scalability and process robustness. Notably, rAAV produced in NBX-Eng-HEK293 showed significantly improved full-to-empty capsid ratios, indicating enhanced genome encapsidation efficiency and packaging fidelity.

Vector quality was assessed using long-read sequencing and mass photometry, confirming higher proportions of full particles relative to comparator cell lines. In addition, both research and master cell banks displayed stable phenotypic and genotypic profiles, along with consistent rAAV productivity, supporting long-term manufacturing reliability from early research through GMP-compliant production.

## Conclusion

In summary, the NBX-Eng-HEK293 cell line enables a highly scalable, flexible, and quality-driven rAAV production platform. Its consistent performance across serotypes, transgenes, media, and bioreactor systems positions it as a robust solution for both early-stage development and industrial-scale gene-therapy manufacturing.

