

## **FAST-TRACK LENTIVIRAL VECTOR UPSTREAM PROCESS DEVELOPMENT: LEVERAGING HIGH-THROUGHPUT PROCESS MONITORING, SINGLE-USE BIOREACTOR SCALABILITY**

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The design and applications of recombinant viral vector have significantly increased over the past years for various therapeutic areas such as gene therapy, cell therapy and vaccines. To respond to this growing demand, viral vector production processes should demonstrate robustness and scalability. Thus a high-throughput development method has been implemented to allow fast-track process optimization and scale-up of non-replicative lentiviral vector production by transient transfection.

A state-of-the-art process development strategy was put in place to develop robust and highly-productive lentiviral vector production platforms by transient transfection of cell suspension in serum-free conditions. Lab-scale representative models are developed allowing parallel large number of experiments. Designs of experiments are applied to identify interaction between identified or selected optimized parameters. Disposable solutions are implemented all along the process to decrease development timelines and provide flexibility for panel vectors manufacturing. High-throughput process monitoring tests were also developed to support associated analytical needs.

Comparative analysis of results observed within different scales models are presented and discussed, demonstrating good scalability from 15-mL micro-bioreactor up to 200L production scale.