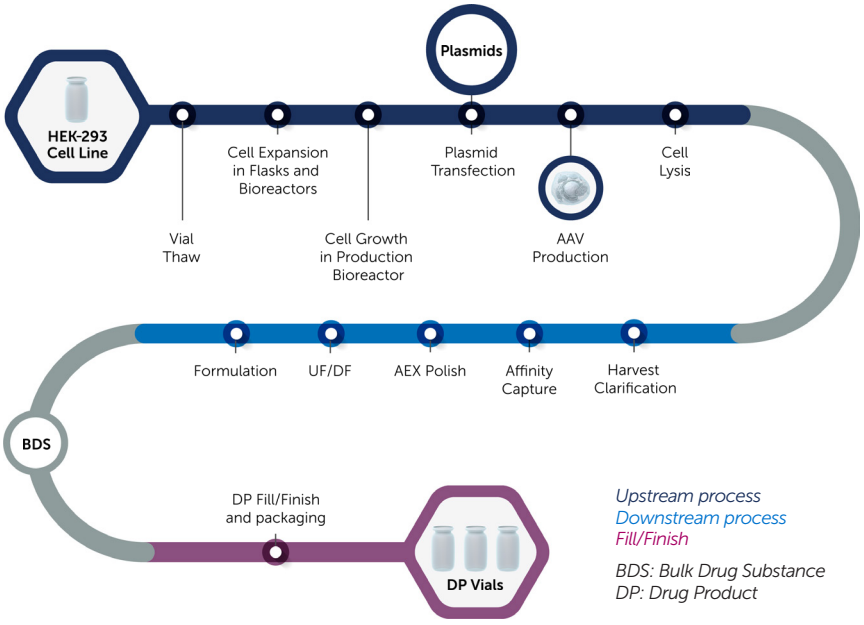
Addressing AAV Manufacturing Challenges

Your AAV development partner, from construct design through GMP manufacturing

- ✓12 months from project initiation to GMP Drug Product
- ✓Optimized formulation for improved Drug Product stability
- ✓ Dual-Plasmid system, proven in GMP, increases productivity
- ✓ In-house analytical development
- ✓ Manufacturability assessment to enable long term success
- ✓ Improved product quality with higher ratio of full capsids
- ✓ Increased titre
- ✓ Optimized process and scalability from 2L up to 2,000L

Schematic process flow of OXB's transient transfection AAV manufacturing process



Upstream process
Downstream process
Fill/Finish

BDS: Bulk Drug Substance
DP: Drug Product

Construct & Plasmid Design

Analytical Method Development

Process Development

GMP Cell Banking

GMP MFG

QA Release

Stability Studies

Regulatory Support

AAV: Adeno-Associated Virus

Benefits of our Dual-Plasmid transfection system

- ✓ Our approach has demonstrated cell culture titre to over 1E15 vg/L for multiple serotypes across multiple genomes (construct dependent)
- ✓ Significant increase in AAV vector productivity with >50% full capsids in the bioreactor and >90% full capsids in the final Drug Substance (construct dependent)
- ✓ Reduced number of GMP plasmids needed compared to triple transfection, decreasing costs

Upstream process development

- ✓ Novel transfection process delivers higher productivity
- ✓ Deep knowledge of bioreactor operations design space ensures robustness
- ✓ Scalable from 2L to 2,000L

Downstream process development

- ✓ Anion exchange chromatography (AEX) has achieved <10% empty capsids with yields as high as 75-90% (construct dependent)
- ✓ Delivers the same level of purity across other major serotypes
- ✓ Reproducible operational success at 50L, 500L, 2,000L

Analytical development capabilities

- ✓ In-house quality control and stability testing capabilities
- ✓ Comprehensive suite of in-house analytical methods
- ✓ >45 product characterization assays (run at small and large scales)
- ✓ Phased approach potency assay development
- ✓ Deep product characterization expertise using Next Generation Sequencing and Mass Spectrometry

Quality and regulatory services

- ✓ Support regulatory activities such as IND and CTA submissions
- ✓ Stability testing plans, shelf-life determination, and release specifications
- ✓ Clinical supply storage and stability study management
- ✓ Support regulatory filing strategy and author clients' CMC

inAAVate™

Let's deliver life-changing therapies together

We are a global quality and innovation-led CDMO in cell and gene therapy with 30 years of experience, committed to helping our clients deliver therapies that transform patients lives.

We offer end-to-end capabilities, from plasmid design and optimisation, to clinical and commercial GMP manufacturing, accompanied by robust control systems, analytical methods and deep regulatory knowledge.

To discuss your project, please contact our team at **partnering@oxb.com**

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