



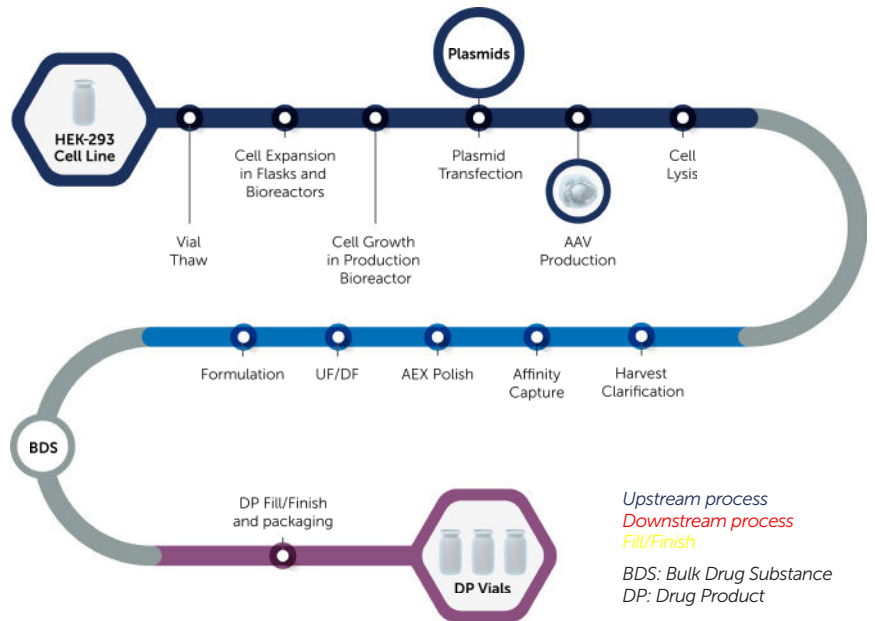
Addressing AAV Manufacturing Challenges



Your AAV development partner, from construct design through GMP manufacturing

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

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



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



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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