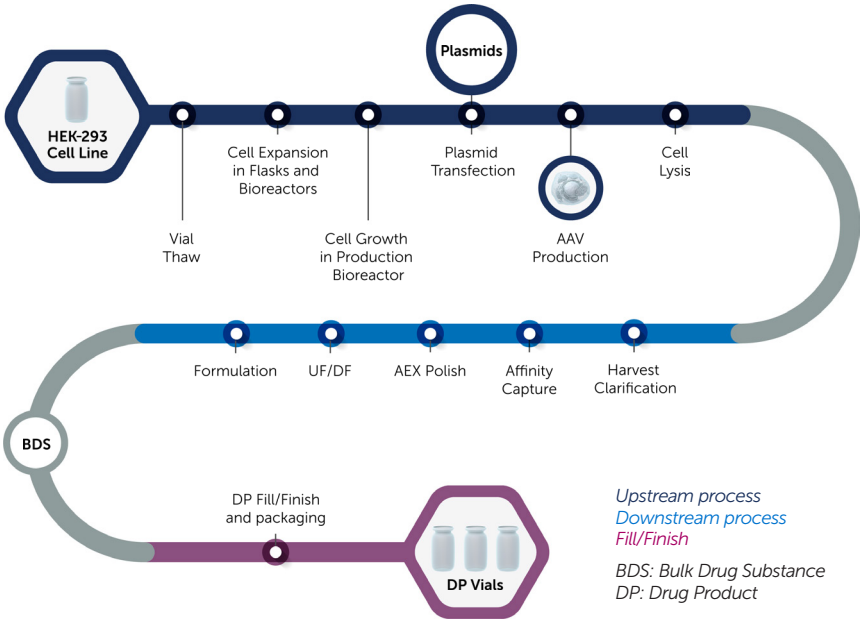
Addressing AAV Manufacturing Challenges

Oxford Biomedica

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 Oxford Biomedica'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

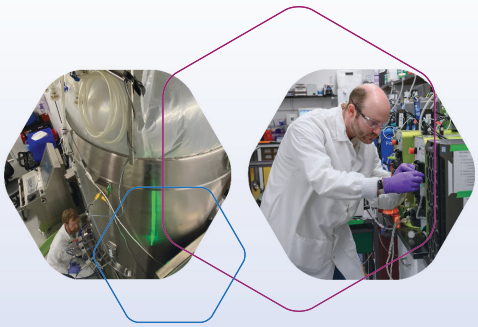
- ✓ Anion exchange chromatography (AEX) has achieved <10% empty capsids with yields as high as 75-90% (construct dependent)
- ✓ Delivers the same level of purity across other major serotypes
- ✓ Reproducible operational success at 50L, 500L, 2,000L

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™

We are a quality and innovation-led CDMO with over 25 years of experience, committed to helping our clients deliver cell and gene 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.

Let's do something life-changing together

For more information please contact:

Oxford Biomedica
+44 (0) 1865 783 000
www.oxb.com

partnering@oxb.com

Oxford Biomedica