



Clinical & Commercial Manufacturing of Lentiviral Vectors



A quality and innovation-led CDMO dedicated to making every project a success

- ✓ State-of-the-art GMP vector substance suites and vector product (fill and finish) suites
- ✓ Established serum-free suspension manufacturing process
- ✓ Perfusion process currently used in GMP
- ✓ Access to next generation technologies to drive down cost per dose
- ✓ Established and validated analytical methods
- ✓ Facilities approved by multiple regulatory agencies, including the FDA, EMA, MHRA, PDMA, and ANVISA

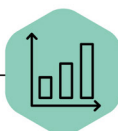
Trusted by emerging biotech and pharmaceutical companies with programmes across all development stages.

Leverage our world-class manufacturing capabilities and next generation technologies to bring your lentiviral vector-based products to market.

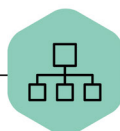
Complete end-to-end services



Construct and plasmid design



Analytical method development and validation



Process development



GMP manufacturing



QA release



Stability studies



CMC and regulatory support

Partnering with Oxford Biomedica



Process transfer, development, and optimisation

- ✓ Experienced in the transfer of processes and products from other manufacturing sites or clients' GMP facilities
- ✓ Best-in-class development and scale-up services to optimise processes prior to GMP production
- ✓ Broad range of scales (shake flask, AMBR®15, AMBR®250, and 0.5L, 5L, 50L and 200L scale)



Continuous innovation to reduce cost of goods

- ✓ Highly optimised existing serum-free fed-batch and perfusion process platforms
- ✓ Innovation in media development, upstream and downstream process, scale-up, and automation
- ✓ Proprietary technologies, such as the TetraVecta™ system and LentiStable™ producer cell lines to further enhance quality and productivity



Large manufacturing capability

- ✓ Sufficient manufacturing capacity to support large scale commercial manufacturing programmes



Process and analytical method validation

- ✓ Market-leading experience in successfully executing process validation programs for multiple lentiviral vector-based products
- ✓ Automation of analytical methods, enabling greater throughput and reduced costs
- ✓ In-house QC labs to support commercial supply



Regulatory expertise

- ✓ First commercial supplier of lentiviral vectors for a CAR-T product
- ✓ Support for regulatory activities such as IND and CTA submissions



Robust quality systems

- ✓ Multiple successful inspections of our manufacturing sites conducted by regulatory authorities including the FDA, EMA, MHRA, ANVISA and PMDA



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 CGMP manufacturing, accompanied by robust control systems, analytical methods and deep regulatory knowledge.

**Let's do something
life-changing together**

**For more information
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