Clinical & Commercial Manufacturing of Lentiviral Vectors

A global quality and innovation-led CDMO in cell and gene therapy 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**
- **Analytic method development and validation**
- **Process development**
- **GMP manufacturing**
- **QA release**
- **Stability studies**
- **CMC and regulatory support**

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Partnering with OXB

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 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.

Let's deliver life-changing therapies together

To discuss your project, please contact our team at

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