CLINICAL & COMMERCIAL MANUFACTURING OF LENTIVIRAL VECTORS

Oxford Biomedica

High-quality innovation-led CDMO dedicated to make every project a success

- ✓ State-of-the-art GMP vector substance suites (6) and vector product (fill and finish) suites (2)
- ✓ Established suspension, serum-free manufacturing process
- ✓ Perfusion process currently used in GMP
- ✓ Access to next generation technologies driving down cost per dose
- ✓ Established and validated analytical methods
- ✓ Facilities approved by multiple regulatory agencies, including FDA, EMA, MHRA, PDMA
- ✓ Expertise with different lentiviruses (HIV, SIV, EIAV) and multiple envelope glycoproteins used for pseudotyping

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

World-class manufacturing services and technologies to achieve successful commercialisation of your lentiviral vector-based products.

Complete end-to-end services

- Construct and plasmid design
- Analytical method development and validation
- Process development
- GMP manufacturing
- QA release
- Stability studies
- Regulatory support

Want to learn more?
partnering@oxb.com

Oxford Biomedica advantages

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 cGMP production
- ✓ Broad range of scales (shake flask, AMBR15, AMBR250, then 0.5L, 5L, 50L and 200L scale)

Continuous innovation to reduce costs 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 in the world
- ✓ Support 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 and PMDA

Partner of choice for lentiviral vector development and cGMP manufacture

Key partnerships for *ex vivo* and *in vivo* lentiviral vector-based products include:

ARCELLX · Bristol Myers Squibb · immatics · Cabaletta Bio · NOVARTIS · Boehringer Ingelheim · Beam THERAPEUTICS · HOMOLOGY Medicines, Inc.

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