



Your Partner for Pivotal and Commercial Manufacturing

Delivering the experience, scale and expertise needed to advance therapies towards commercial supply.

As programmes advance towards commercialisation, manufacturing must be robust, scalable and inspection-ready. OXB supports this transition through expertise in process characterisation, PPQ, regulatory submissions and commercial-scale GMP manufacturing.

30+

Years of viral
vector experience

1,000+

GMP
batches

18

GMP
suites

10

Process
characterisation
programmes
completed

100+

Regulatory
submissions supported
across multiple
product lifecycles

Up to
1,000L

Lenti and AAV
commercial-scale
capability

Why clients choose OXB for late-stage programmes

- ❧ Late-stage and commercialisation expertise
- ❧ Accelerated process characterisation capabilities
- ❧ Proven regulatory submission support
- ❧ Global manufacturing network at commercial scale
- ❧ End-to-end support from development to supply



Navigating the path to commercial supply

Process Characterisation and Analytical Method Validation

Our platform expertise and process understanding enable us to accelerate process characterisation studies to a **6 month timeline**.

PPQ and Manufacturing Readiness

Experience implementing **rolling PPQ** strategies to align manufacturing and regulatory timelines and accelerate commercial readiness.

Regulatory Support

Deep experience supporting regulatory programmes across major markets:



FDA



EMA



MHRA



PMDA



MDFS



Anvisa

17 successful registration submissions.

Manufacturing at Commercial Scale

Access scalable GMP manufacturing across our global network, which includes sites in the **UK, US and France**.

Long-term Partnership

100+ programmes supported, with long-standing client **partnerships spanning more than a decade**.

Ready to advance your late-stage programme? email partnering@oxb.com to discuss how OXB can support your journey to commercial supply.



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