Analytics

Optimised solutions to support clinical development and product commercialisation

List of key analytic methods

Platform assays:

— pH
— Residual sodium butyrate
— Endotoxin
— Bioburden
— Sterility
— Mycoplasma
— Micro BCA
Total protein
— HCP ELISA
— Residual Endonuclease
— Picogreen
Residual total DNA
— 18S
Residual host cell DNA
— KanR
Residual plasmid DNA
— VSV-G
Residual plasmid DNA
— SV40
Residual host cell DNA

Lentiviral specific assays:

Vector titre
FACS
RNA copy number
p24 ELISA
RCL
RCLCC

Product specific assays:

Potency
Vector ID

In development:

Mass spectrometry
Next-Generation Sequencing
HPLC based vector quantification

Superior analytical methods are essential to pharmaceutical product manufacturing, in both product development and quality control testing. The challenging analytical methods associated with complex products like novel lentiviral vector-based gene therapeutics require specialist knowledge, techniques and equipment.

Our analytics solution

We offer an exceptionally comprehensive suite of in-house assays, ensuring full lentiviral vector characterisation, quality control and stability testing, and preparing CMC components for regulatory filings.

We maintain our analytical assays within our in-house QC labs, allowing us to be confident in our ability to validate our methods to support clinical and commercial supply. We have an extensive clinical and commercial track record with our own and our partners' products and can advise on the optimum selection of assays. We also develop custom-made assays, such as identity and potency assays, for specific applications or types of product.

GMP manufacturing facilities

Oxford Biomedica (OXB) is one of the very few companies in the world that can offer in-house, GMP replication competent lentiviral (RCL) and RCL co-culture testing of production cells from our purpose-built category-3 labs. Our manufacturing sites are registered with the FDA and EMA and we hold regulatory authorisations for clinical trial products and commercial products.

Analytics automation

We have unique and world-leading experience in successfully developing process analytics testing for multiple lentiviral vector-based products.
Our platform analytical methods, with appropriate product-specific changes, have been validated to commercial standards, meaning that we can be confident that future programs based on our platform will be successful.
We continue to invest in extensive automation of our analytical methods, allowing for greater throughput and reduced turnaround times, as well as reduced costs.

Want to learn more?
partnering@oxb.com

Successful product development requires robust quality systems and regulatory support

Our facilities are GLP, GMP and GCP accredited and can support your clinical sample testing and CMC documentation preparation (including BLA, IND and CTA filings). We have extensive experience in interacting with regulators as a product development company with more than 10 years' experience in managing gene therapy clinical trials. The LentiVector® platform was the first to deliver an FDA approved advanced therapy gene-modified product and OXB was the first FDA-approved site for the commercial manufacture of lentiviral vectors.

We can support our partners with regulatory meetings, pre-licence inspection (PLI) preparation, clinical study design and CRO management.

Oxford Biomedica is introducing digitalisation and machine learning to its systems to improve productivity and quality

Digitalisation of data analytics will likely change the healthcare industry, from how drugs are discovered and manufactured to how patients receive treatments. Thanks to our extensive and unique experience in manufacturing lentiviral vectors, we have amassed a complex, comprehensive data set. Working in partnership with Microsoft Research's Station B, we are developing *in silico* models and novel algorithms to maximise production and improve the efficiency of our platform.

Pushing the boundaries

We continue to invest in the development of high throughput methods for increased sensitivity and capability, such as mass spectrometry to reduce turnaround times and costs as well as improve product quality.

We maintain our analytical assays within our in-house QC labs, allowing us to be confident in our ability to validate our methods to support commercial supply

Partner of choice for lentiviral vector development and cGMP manufacture

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

AXOVANT
NOVARTIS
SANOFI
Orchard therapeutics
Santen
Boehringer Ingelheim
gtx UK CYSTIC FIBROSIS GENE THERAPY CONSORTIUM

1st

- **First** to administer lentiviral vector gene therapy directly to patients
- **First** approved CAR-T therapy in the US and Europe uses Oxford Biomedica's LentiVector® platform
- **First** FDA, EMA and PDMA-approved commercial supplier of lentiviral vectors in the world

For more information please contact:

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

partnering@oxb.com

Oxford Biomedica