Analytics for Lentiviral Vectors

Oxford Biomedica

55+ in-house assays to ensure compliant GMP batch release and stability testing

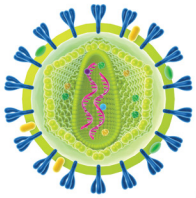
Analytical methods are key to the successful manufacture of lentiviral vector-based gene therapeutics and require specialist knowledge, techniques and equipment.

List of key analytic methods

Identity
- Vector identity
- Vector sequencing

Biological activity
- Integration titre
- Particle to infectivity ratio
- Potency
- Flow cytometry expression

Purity/ impurity
- Total protein (BCA)
- Total residual DNA
- Residual plasmid DNA
- Residual host cell DNA
- Residual host cell protein
- Residual sodium butyrate
- Residual endonuclease
- Residual PEI
- Residual SAN
- Residual SV40 DNA
- Residual E1A DNA
- Residual U1 snRNA



General
- pH
- Appearance
- Osmolality
- Sub-visible particles

Safety
- Mycoplasma
- Sterility
- Bioburden
- Endotoxin,
- *In vivo* inapparent viruses & *In vitro* extraneous agents
- Replication competent lentivirus (RCL)

Quantity
- p24
- RNA copy number

Characterisation assays

Mass spectrometry

Dynamic light scattering

Primary T cell titering

Established analytical offering

- ✓ In-house assays for full characterization, QC, and stability testing
- ✓ In-house GMP replication competent lentiviral (RCL) assay from purpose-built category-3 labs
- ✓ Routine development of custom product specific assays, such as identity and potency assays

Long track record

- ✓ 25+ years of extensive clinical and manufacturing experience including GMP manufacturing since 2014
- ✓ Analytical methods accepted by multiple regulatory agencies, including the FDA, EMA, MHRA, ANVISA and PMDA
- ✓ Analytical package used to release GMP-compliant batches for more than 15 products

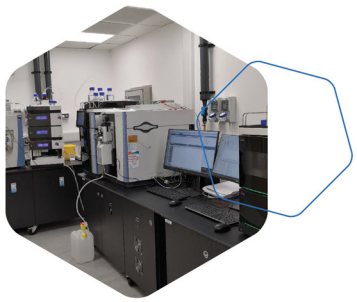
Expert regulatory support

- ✓ Support with regulatory meetings, pre-licence inspection preparation and CMC documentation preparation for regulatory filings
- ✓ Redaction of quality section for numerous IND, CTA and BLA filings
- ✓ Regulatory advice on the optimum selection of assays

Pushing the boundaries: innovation, digitalisation and automation

- ✓ High level of automation for higher throughput and cost reduction
- ✓ Development of new analytical methods to increase assay sensitivity and capability
- ✓ On-going digitalisation of comprehensive dataset to improve process productivity and quality

Cutting-edge digital and physical automated platform enabling high throughput optimisation services



State-of-the-art mass spectrometry facility for viral vector protein characterisation and residual HCP

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 please contact:

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

partnering@oxb.com