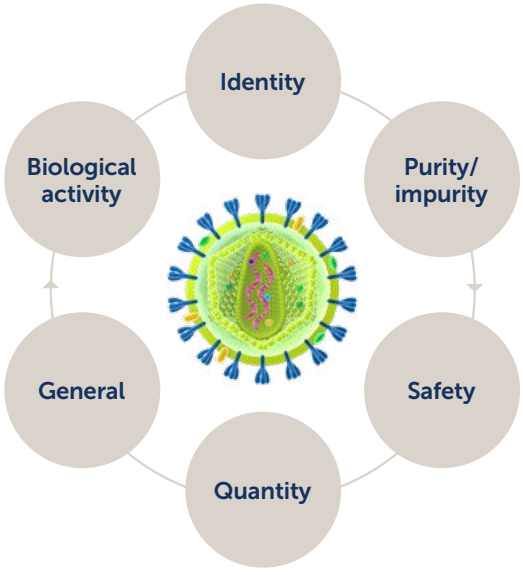
ANALYTICS FOR LENTIVIRAL VECTORS

Oxford Biomedica

More than 30 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



- Vector identity
- Vector sequencing

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

- 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

- pH
- Appearance
- Osmolality
- Sub-visible particles

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

- p24
- RNA copy number

Characterisation assays

Mass spectrometry

Dynamic light scattering

Primary T cell titering

Want to learn more?
partnering@oxb.com

Established analytical offering

- ✓ Comprehensive suite of in-house assays for full characterisation, quality control 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 and PMDA
- ✓ Analytical package used to release GMP-compliant batches for more than 15 products

Expert regulatory support

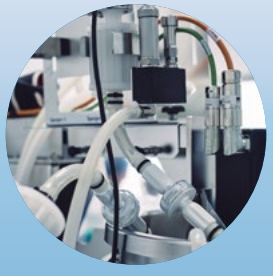
- ✓ Support with regulatory meetings, pre-licence inspection preparation and CMC documentation preparation for regulatory filings
- ✓ Redaction of quality section for numerous IND, CTA and BLA filings
- ✓ Regulatory advice on the optimum selection of assays

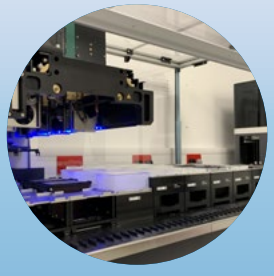
Pushing the boundaries: innovation, digitalisation and automation

- ✓ 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





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