

BioReliance

Products and Services

About BioReliance

As one of the world's foremost contract service organizations, BioReliance is relied upon by pharmaceutical, biopharmaceutical, vaccine, gene therapy, medical device and chemical companies across the globe to speed development and accelerate product time to market.

Combining broad scientific expertise and depth of regulatory knowledge, BioReliance has the skills and foresight to support client products through every phase of the testing, development and manufacturing process.

Working with state-of-the-art specialized technologies, the teams will define the best support strategies for any product. At the forefront of industry developments, BioReliance is continually pioneering new services to advance client testing and manufacturing programs.

BioReliance's industry leading experts possess the knowledge required to anticipate regulatory developments, so allowing the team to develop sound scientific and regulatory programs that steer products reliably and speedily through preclinical stages to commercialization.

BioReliance believes that it is the premier provider of specialist services to the biologics industry. This is achieved by our scientists continually monitoring and evaluating emerging technologies and developing new industry defining initiatives, often leading to collaborations with industry leaders and publications in scientific journals.

Why choose BioReliance?

World-class reputation

Quality without compromise

Pioneers in new technologies

Global facilities and technical support

Comprehensive, specialized service for your product

Rockville



Stirling



Glasgow



Heidelberg



Biologics Safety Testing

Virology

In Vitro Testing

- Assays for adventitious viruses
- Assays for specific mammalian viruses
- Assays for the presence of replication-competent gene therapy vectors
- Tumorigenicity assays
- Custom assays

In Vivo Testing

- Assays for detecting adventitious viral contaminants
- Tumorigenicity assays
- Biodistribution studies
- TSE bioassays
- Potency assays
- Custom assays

Retrovirology

Immunoassay

Lot release testing

Assay development & transfer

Microbiology

Sterility

- Bacteriostasis & fungistasis
- Isolator testing

Mycoplasma

Molecular Biology

- Quantitative PCR
- PCR
- Biodistribution
- Detection of retroviruses & endogenous retrovirus-like particles
- Detection & quantification of residual host cell DNA by Q-PCR

Cell Biology

- Electron microscopy
- Fluorescence *in situ* hybridization for genetic stability studies
- Karyology
- Histology
- Cross-reactivity testing

Viral/TSE Clearance Studies

- TSE studies by Western Blot and bioassay
- Column re-use
- Cleaning validation studies

Analytical

- Stability testing & storage
- Lot release testing
- Purposeful degradation
- Method development
- Comparability testing
- Method transfer
- Method validation
- Performance of GLP potency assays

Clinical Trial Support Services

- Detection of vector infectivity
- Detection of viral vectors by Q-PCR & RT-PCR
- Detection of expressed recombinant protein
- Detection of total & neutralizing antivector/vaccine antibodies
- Detection of cytokine response
- Immunoassay
- Assay development

Laboratory Animal Diagnostics Services (LADS)

- Comprehensive animal health services
- Rodent & rabbit serology
- Simian serology
- Diagnostic reagents
- PCR testing
- Viral isolations

Toxicology

Genetic

- Gene mutation
- Chromosome damage
- Primary DNA damage
- Assessment of hemolytic property
- Mammalian S9 microsome preparations

Mammalian

- Repeated-dose studies
- Analytical chemistry services
- Studies for nucleic acid-based therapeutics
- Transgenic carcinogenicity studies
- Contract pathology services
- Custom vaccine toxicology studies

Regulatory & Technical Services

- Regulatory information services
- Advice on regulatory strategies
- Data review & evaluations
- Expert report writing
- Preparation of documentation
- Response to authorities
- Technical support

Manufacturing

Cell Banking & Storage

- Master Cell Bank (MCB) - human, murine, CHO, insect, bacterial
- Working Cell Bank (WCB)
- End of Production Cell Bank (EPCB)

Viral Seed Stock

Production of clinical lot

- adenoviral, retroviral, vaccinia, herpes, adeno-associated viral vectors

Testing of clinical lot

Microbial Fermentation

- Active Pharmaceutical Ingredients Production (API)
- Cell banking services

Cell Line Development

- Early vector development
- Establishment of a stable cell line
- Media adaptation & optimization for growth
- Protein expression
- Scale-up
- Stability analysis

Process Development

- Cell line development
- Adaptation to serum-free media
- Media development & optimization
- Viral production & purification
- Protein production & purification
- Cell culture development
- Downstream purification
- Production batch record writing
- Assay development

Small Scale Manual Filling

- Manual close filling (up to 1000 vials per day)
- Grade A & Grade B filling suite
- Filling process validation

Clinical Manufacture of Gene Therapy, Vaccine & Cell Therapy Applicants

Custom Assay Development

to meet your unique requirements

With hundreds of protocols to test for a wide range of contaminants, the breadth of our expertise is unrivalled.

Human Viruses	Human Parvovirus	Caprine Viruses	Simian Retroviruses
Human Retroviruses	(B19 & Adeno-associated viruses)	Simian Viruses	Simian Immunodeficiency Virus
Cytomegalovirus (CMV)	Human Adenovirus	Equine Viruses	(SIV) & Simian Retrovirus (SRV)
Epstein-Barr Virus (EBV)	Rodent Viruses	Avian Viruses	Squirrel Monkey Retrovirus Virus (SMRV)
Human Herpesvirus-6 (HHV-6)	Mouse, Rat & Hamster antibody production	Feline Viruses	Other Contaminants
Human Herpesvirus-7 (HHV-7)	(MAP, RAP & HAP) tests	Bunyaviruses	Mollicutes
Human Herpesvirus-8 (HHV-8)	Murine Minute Virus (MMV)	Circoviruses	Bacteria
Herpes Simplex Virus (H-SV)	Other Species-Specific Viruses	Retroviruses	Residual Protein
Hepatitis Viruses	Bovine Viruses	Rodent Retroviruses-XC, S + L-	Fungi
Human Papillomavirus (HPV)	Porcine Viruses		



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