TECHNICAL FACT SHEET

Biosafety Services

Health Inspired, Quality Driven.

Helping bring safe and compliant medical products to the marketplace

Life-saving medicines are heavily regulated during development, manufacture, and distribution. To fulfill regulatory requirements, the biopharmaceutical industry is increasingly looking for independent service providers who can deliver comprehensive characterization solutions.

We offer a comprehensive range of integrated solutions, including biosafety testing & characterization of cell bank & virus seeds, unprocessed bulks/ viral harvests, and drug substance/ product.

SGS Health Science provide the biopharmaceutical industry with a one-stop solution for all analytical and bioanalytical requirements.

Utilizing specialist laboratories around the world, our experts provide effective and efficient testing solutions for analytical development, biologics characterization, biosafety, quality control, as well as clinical research.

Our Laboratory

Testing Laboratory For Companies Producing

- Viral vaccines
- Gene therapies
- Cell therapies
- Recombinant proteins
- Monoclonal antibodies

Equipment & Labs

- IQ, OQ, PQ on all equipment
- HVAC, positive/negative pressure isolation, BSL2
- Facility expansion to +7,000 m^2
- 72 separate BSL2 labs
- Test item and material segregation
- Client cell bank culture service
- Segregated virus culture
- Dedicated labs for virology, molecular biology, TEM, bioanalytical
- One way testing system

GMP Biosafety Testing

- Cell banks (mammalian & insect)
- Virus bank/seeds
- Bulk harvests
- Drug substance
- Final product
- Plasmids
- Raw materials

Quality & Compliance

- GLP/GMP biosafety platform with methods validated to ICH Q 2 (R1)
- Meet guidelines and regulations from EMA, FDA, ICH, WHO
- 21 CFR part 11 compliant

Online Secure Client Portal

- Validated 21 CFR part 11 compliant
- Submit test items
- Check timelines
- Access/download final reports
- Test item stock information

Our Services

Real-Time PCR

- Global experts with 25 years' experience pioneering qPCR and RT- PCR for biologics
- Validated ABI qPCR Platform
- Over 300 GMP pathogen detection/ quantitation qPCRs validated to ICH Q2 (R1)
- Highly sensitive, robust, reliable with multiple spike/ extraction controls
- Custom development, validation, method transfers
- Mycoplasma/Spiroplasma qPCR
- Mycobacterium qPCR
- Residual Host Cell/Plasmid DNA
- DNA Sizing

Identity

- DNA fingerprinting by RAPD
- Gene specific NAT
- DNA sequencing

TEM

- Negative stain and thin section techniques for the detection of adventitious agents
- Visualization and quantitation of virus particles
- Stain/Non stain penetrated capsid ratios

GMP Sanger Sequencing

- Validated ABI 3500 xL Genetic Analyzer
- Identity and sequence of plasmids, vectors, full genome
- Consensus sequence for transgene and expression cassettes in microbial and mammalian cell bank production systems
- 4 x Bi directional DNA sequencing, with a minimum of 4-fold double strand coverage on each given base

Adventitious Agents

- GMP in vitro assays with options for 14 and 28+ days using a combination of indicator cell lines and CPE, haemadsorption and haemagglutination end points
- Infectivity assay for detection of bovine/ porcine viruses to meet 9 CFR

Replication Competent Vectors

- Expert neutralisation consultancy, design, testing
- Neutralisation and Interference pre-studies
- Manufacture of neutralising antisera
- Replication competent adenovirus assay

Retrovirus

- RT activity by PERT (method designed by A Lovatt et al and recommended by FDA)
- Infectivity assays
- Mus-Dunni co-cultivation assay
- HEK 293 co-cult with F-PERT endpoint
- XC Plaque and S+L assays

Impurities

- Host Cell DNA qPCR/Protein ELISA
- Residual Benzonase ELISA
- Residual BSA ELISA
- Bacterial endotoxin kinetic chromogenic LAL

Genetic Stability

- Sequencing of mRNA DNA control regions
- Transgene copy number by qPCR
- Structural analysis by non-radioactive
- Southern Blotting
- Plasmid, viral vector, mRNA DNA sequencing

Custom Consultancy Services

- Study design, development, validation
- Custom protocols/assays with option for method transfer in/out
- Product Specific Validation including for Phase III
- Regulatory consultancy, complex testing strategies, expert report writing

Microbial Contaminants

- Mycoplasma culture EP/USP harmonized (with or without Mycoplasmastasis)
- Sterility direct inoculation EP/ USP harmonized (with or without bacteriostasis/fungistasis)
- Bioburden
- Mycobacterium culture
- Mycoplasma & Mycobacterium qPCR
- Sterility membrane filtration

Contact us

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WHEN YOU NEED TO BE SURE

SGS