LIFE SCIENCES

LIFE INSPIRED, QUALITY ASSURED

BIOSAFETY SERVICES

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 on one site.

SGS's global center of excellence for cell bank characterization & virus testing is located in the United Kingdom and provides services with ultimate reliability, highest GLP/cGMP quality & scientific expertise.

As trailblazers in the development of the biosafety testing industry, our SGS Vitrology team in Glasgow have developed and validated novel nucleic acid technologies, such as real-time PCR, RAPD, Sequencing, Non-radioactive Southern Blotting, Next Generation Sequencing (NGS). For any of your biologics, we help you comply with the global regulatory guidelines and testing requirements.

ABOUT

Established in 2007, our laboratory in Glasgow is a 2,338 m² cGMP/cGLP certified, MHRA and US FDA registered and inspected laboratory that offers biosafety testing services.

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

Our team of experienced scientists have over 15+ years experience in GMP, FDA, EP, ICH compliant validated assays.

SGS LIFE SCIENCES

SGS Life Sciences enables the medical and health innovators of the world to deliver life-changing solutions in the quickest, safest and most efficient way, helping improve the lives of many. We provide the highest quality services, reliable expertise and guidance through our network of laboratories conveniently located around the globe.

SGS

OUR LABORATORY

TESTING LABORATORY FOR COMPANIES PRODUCING

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

GMP BIOSAFETY TESTING

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

EQUIPMENT & LABS

- IQ, OQ, PQ on all equipment
- HVAC, positive/negative pressure isolation, BSL2
- Facility expansion to 2,338 m^2
- 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

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 in the 1990s
- Validated ABI qPCR Platform
- Over 250 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

SIZE	2,338 m^2
ESTABLISHED	2007
CERTIFICATION	cGLP & cGMP MHRA US FDA registered & inspected
SITE MANAGER	Dr. Archie Lovatt
QUALITY MANAGEMENT SYSTEM	GLP GMP
US FDA REGISTRATION NUMBER	3009867953

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

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

WHY CHOOSE SGS LIFE SCIENCES?

SGS Life Science Services 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 and quality control, as well as clinical research.

Global network

Rapid turnaround times

Data management and Reporting

CONTACT US

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WHEN YOU NEED TO BE SURE

SGS