LIFE SCIENCES

LIFE INSPIRED, QUALITY DRIVEN

cGMP BULK HARVEST TESTING

SGS

To satisfy Regulatory Authorities such as the US Food & Drug Administration (FDA) and the European Medicines Evaluation Agency (EMEA) all cell banks, viral banks, raw materials of animal origin, bulk harvests, and batches of clinical drug product must undergo extensive safety testing to demonstrate freedom from bacteria, fungi, mycoplasma and viruses and retroviruses.

Bulk Harvest Testing services by SGS ensure that unprocessed bulk harvest is free from contamination prior to any downstream processing.

TIMELY & ROBUST TESTING

- Virus vaccine
- Therapeutic monoclonal antibody
- r-protein biopharmaceuticals
- Gene therapy
- Cell therapy

CGMP QUALITY CONTROL ASSAYS

- Mycoplasma testing (PTC, Phar. Eur. & USP Harmonized)
- Sterility & Bio-burden (Phar. Eur. & USP)
- Adventitious agent testing by 14 and 28 day In vitro assays with a wide range of detector cell lines
- Identity testing of the vector/vaccine
- Replication Competent Adenovirus (RCA) Assays
- Infectious virus titration assays and virus particle quantification by TEM
- Over 150 viral detection QPCR assays for specific viruses (including, MVM, Vesivirus, Human, Insect, 9CFR Bovine/Porcine, and Avian/Duck viruses) and Retroviruses
- Residual host cell DNA (HCD) quantification by QPCR (CHO, Human, HEK 293, Mouse, Vero, Sf9, E. coli, MDCK, Yeast)
- Endotoxin and residual host cell protein (HCP) assays
- Customized residual plasmid DNA by QPCR
- Customized product-specific validation studies

QUALITY COMPLIANCE

- cGMP and GLP accreditation from UK MHRA
- ICH Q2 Assay Validation
- FDA, EU & Phar. Eur Guidelines
- IQ, OQ, PQ Equipment validation

ABOUT SGS

SGS provides a comprehensive range of biosafety services such as: virology, cell and molecular biology as well as microbiology and electron microscopy. Health Authorities, including the US FDA and the EMA, require companies to undergo safety testing to demonstrate that all cell banks, viral banks, raw materials of animal origin, bulk harvests, and batches of clinical drug are free of bacteria, fungi, mycoplasma, viruses and other potential contaminants.

SGS helps clients by ensuring product safety in satisfying these regulatory requirements through a large range of validated assays and develops new services in the following areas:

- Cell bank and virus seeds characterization per the major compendia, regulatory and ICH guidelines
- Raw material and bulk harvest testing (sterility, mycoplasma, viruses and other potential biological contaminants)
- Final product testing for residual DNA and other process related impurities
- Regulatory and safety consultancy services
- Custom development of assays

SGS's global centre 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 ha 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. Our team of experienced scientists have over 20+ years' experience in GMP, FDA, EP, ICH compliant validated assays.

SGS BENEFITS

- Global Network
- Rapid Turnaround time
- Data Management and Reporting

CONTACT US

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WHEN YOU NEED TO BE SURE