Biosafety & Characterisation Services – Glasgow

WHEN YOU NEED TO BE SURE

SGS

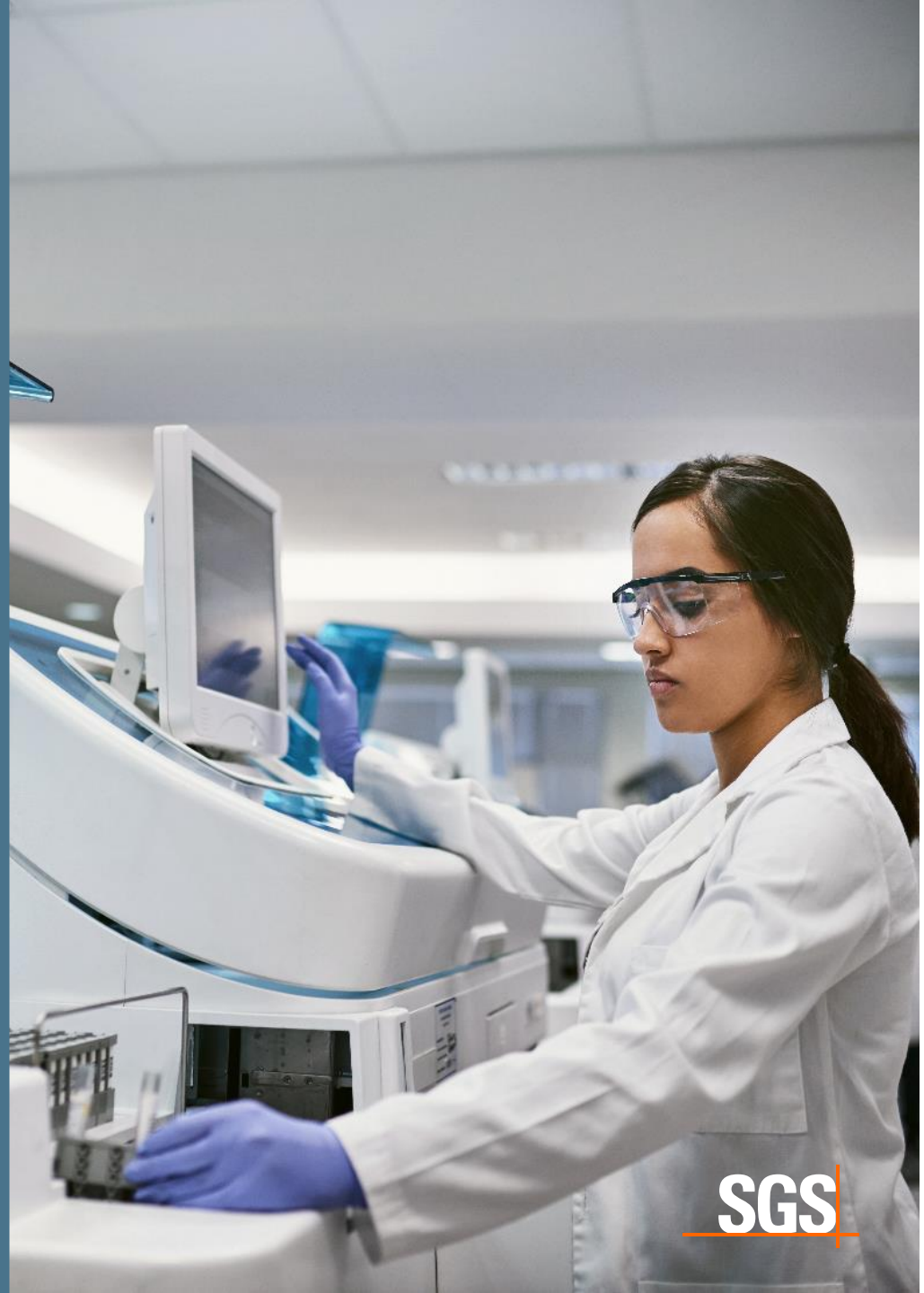
Contents

23 Laboratories

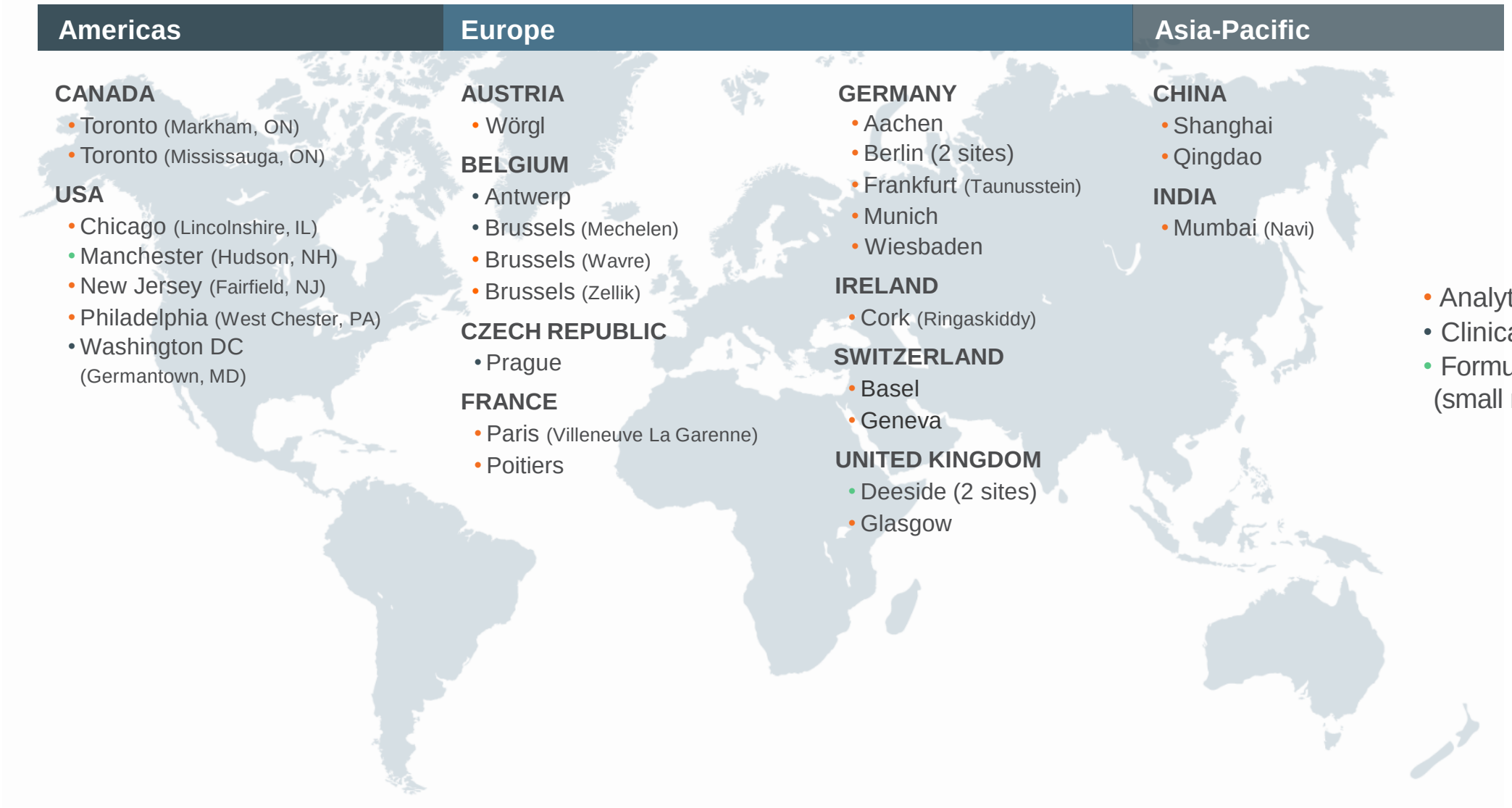
1,000+ Clinical Trials Executed

12 Countries

40+ Years of Experience



SGS HEALTH SCIENCE NETWORK



Americas

CANADA
- Toronto (Markham, ON)
- Toronto (Mississauga, ON)

USA
- Chicago (Lincolnshire, IL)
- Manchester (Hudson, NH)
- New Jersey (Fairfield, NJ)
- Philadelphia (West Chester, PA)
- Washington DC (Germantown, MD)

Europe

AUSTRIA
- Wörgl

BELGIUM
- Antwerp
- Brussels (Mechelen)
- Brussels (Wavre)
- Brussels (Zellik)

CZECH REPUBLIC
- Prague

FRANCE
- Paris (Villeneuve La Garenne)
- Poitiers

GERMANY
- Aachen
- Berlin (2 sites)
- Frankfurt (Taunusstein)
- Munich
- Wiesbaden

IRELAND
- Cork (Ringaskiddy)

SWITZERLAND
- Basel
- Geneva

UNITED KINGDOM
- Deeside (2 sites)
- Glasgow

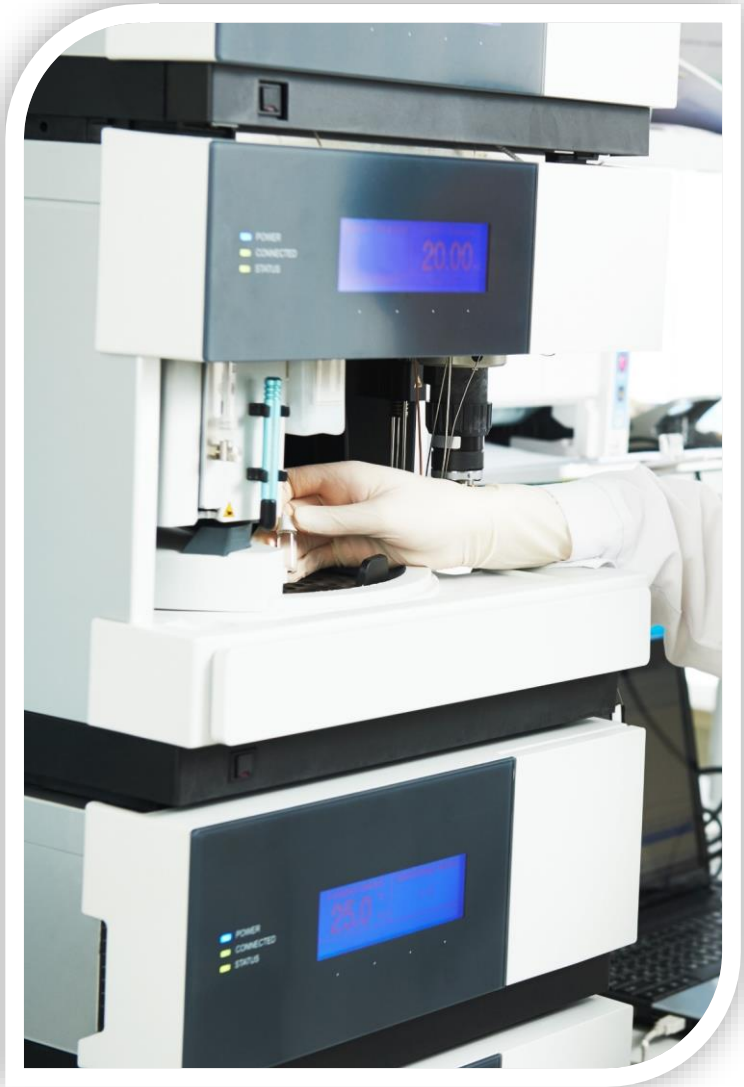
Asia-Pacific

CHINA
- Shanghai
- Qingdao

INDIA
- Mumbai (Navi)

- Analytical Testing
- Clinical Research
- Formulation & CDMO (small molecule)

LABORATORY CAPABILITIES ACROSS OUR NETWORK



CAPABILITIES	NORTH AMERICA	EUROPE	ASIA-PACIFIC
ANALYTICAL CHEMISTRY	•	•	•
MICROBIOLOGY	•	•	•
STERILITY TESTING	•	•	•
STABILITY STUDIES	•	•	•
METHOD DEVELOPMENT & VALIDATION	•	•	•
EXTRACTABLES	•	•	•
LEACHABLES	•	•	•
CONTAINER TESTING	•	•	•
BIOLOGICS METHOD DEV. & VALIDATION	•	•	-
BIOLOGICS CHARACTERIZATION	•	•	-
BIOLOGICS QC & STABILITY TESTING	•	•	-
BIOSAFETY	-	•	-
BIOANALYSIS	•	•	-
BIOLOGICAL ACTIVITY	•	•	-
MEDICAL MARIJUANA	•	-	-
IN VITRO TOXICOLOGY	•	-	-

GLOBAL CLINICAL DEVELOPMENT SERVICES

FROM STAND ALONE TO FULL SERVICES WITH THE END IN MIND

PROJECT ASSESSMENT & STUDY INITIATION		CLINICAL TRIALS		STUDY DATA EXPLOITATION
Pre Clinical	**Phase I - IIa**	**Phase II - III**	**Phase IIIb - IV**	
Drug Development Consultancy - Regulatory Affairs				
Study Feasibility				
Clinical Pharmacology Unit				
Quality Assurance/Site Auditing				
Clinical & Medical Monitoring				
International Project Management				
Pharmacovigilance / Drug Safety				
Data Management / EDC				
Statistics / PK/PD data Analysis / Secure Data Office				
Medical Writing				
Bioanalytical / Biomarkers				

GLASGOW – UK

Established	*Size:*	*Manager*	*Certifications*	
2007	3,150 m^2	Dr. Archie Lovatt	GMP / GLP	USFDA registered and inspected

Services

- Cell & Virus Bank Characterization
- Mycoplasma, Mycobacteria, Spiroplasma by qPCR
- Virology – In Vitro Adventitious Virus Assays and Cell Biology Assays
- Electron Microscopy – Virus Particle Quantification & Identification
- Retrovirus Infectivity Assays
- Virus Detection by qPCR
- Genetic Stability Testing
- Raw Material & Bulk Harvest Testing
- Batch Release (Residual Impurities)
- Cell Line Induction Studies & Virus Identity
- Sanger & Next Generation Nucleic Acid Sequencing
- RT Assays (FPERT & qPERT)
- Regulatory Consultancy Services
- Assay Development & Tech. Transfer

Contact

SGS Vitrology - 5 South Avenue, Clydebank Business Park, Glasgow, G81 2LG, UK

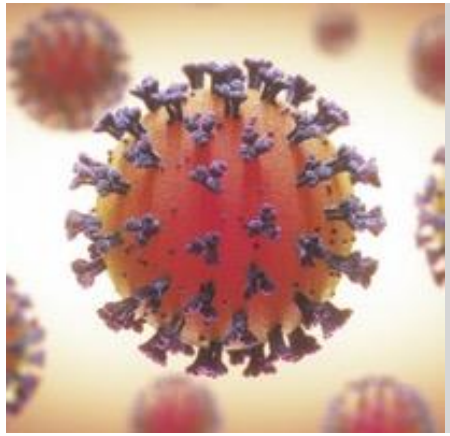
GMP COMPLIANT TESTING FOR A RANGE OF PRODUCTS / PLATFORMS

Therapeutic proteins & biosimilars

CHO, NS0, Sp2/0, BHK, HEK293…

Viral vaccines,

MRC5, Per.C6, HEK293, A549, Vero, MDCK, CHO, HeLa…



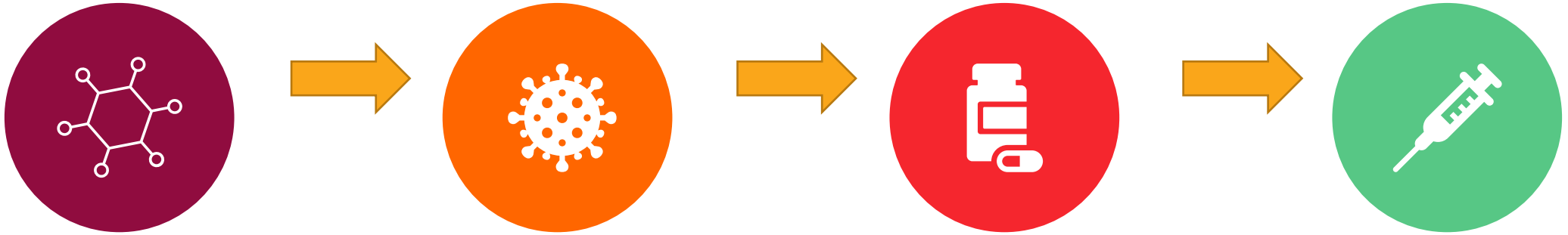
Gene Therapy

Retrovirus, lentivirus, AAV, adenovirus, baculovirus, plasmids …

Cell Therapy

Stem Cells, Islet Cells, Autologous, Allogeneic, Car-T

Support Across Every Stage



CELL / VIRUS BANK / PLASMIDS & STARTING MATERIALS

BULK HARVEST

DRUG SUBSTANCE

DRUG PRODUCT

Characterisation and Biosafety for Biologics

(FDA Vaccine 2010, USP<1050>, Phar. Eur. 5.2.3, WHO TRS 978 & ICH Q5A)
(Phar. Eur. 5.14, ICH Q5, USP<1043>)

CELL / VIRUS BANK & STARTING MATERIALS

Microbial contaminants

- Mycoplasma via culture and Quantitative Polymerase Chain Reaction (qPCR) (USP 63 Phar.Eur.2.6.7)
- Mycobacteria via culture and validated Quantitative Polymerase Chain Reaction (qPCR)
- Spiroplasma
- Sterility (<USP 71>, Phar.Eur.2.6.12)

Adventitious Virus Detection

- In vitro cell culture assay
- 9CFR 113 In vitro cell culture assay and Quantitative Polymerase Chain Reaction (qPCR)

Specific Virus Detection

- 300+ GMP Validated Virus Specific Quantitative Polymerase Chain Reaction (qPCR) Assays (USP <1126/1127>, Phar.Eur.2.6.21)
- Mouse Antibody Production (MAP)
- Hamster Antibody Production (HAP)

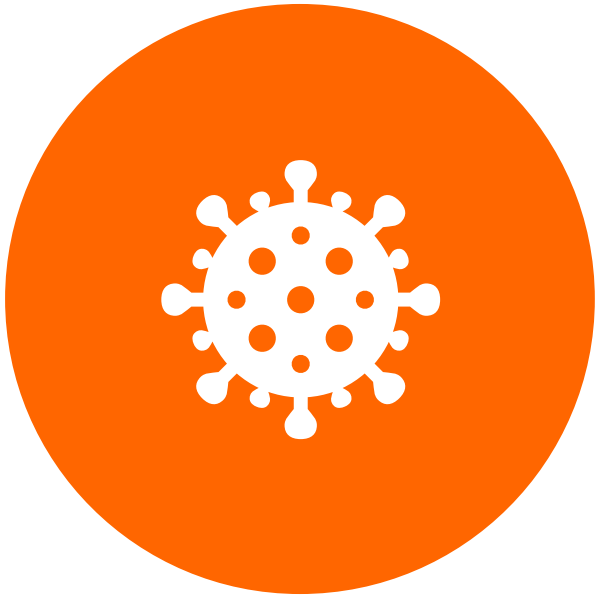
Identity & Genetic Stability Testing

- DNA Fingerprinting Identification of Cell Lines by Random Amplified Polymorphic DNA (RAPD)
- Gene-Specific Nucleic Acid Testing (NAT) for Identification
- Karyology for cell lines
- Plasmid and Viral Vector sequencing
- Vector and Integrated Expression Cassette - Gene Copy Number
- Southern Blot for Genetic Integrity

Detection of Retrovirus

- Fluorescent Product Enhanced Reverse Transcriptase (F-PERT) & Quantitative Real Time Fluorescent Product Enhanced Reverse Transcriptase (Q-PERT)
- Transmission Electron Microscopy (TEM)
- Infectivity assays
- Infectious retroviruses/Mus-Dunni/HEK293 cocultivation
- Replication Competent Retrovirus

SGS



BULK HARVEST

Microbial contaminants

- Mycoplasma via culture and Quantitative Polymerase Chain Reaction (qPCR) (USP 63 Phar.Eur.2.6.7)
- Mycobacteria via culture and validated Quantitative Polymerase Chain Reaction (qPCR)
- Spiroplasma
- Sterility

Adventitious Virus Detection

- In vitro cell culture assays
- Haemadsorption or Haemaglutination

Specific Virus Detection

- >300 GMP Validated Virus Specific Quantitative Polymerase Chain Reaction (qPCR) assays

Identity for Control Cells

- Random Amplified Polymorphic DNA (RAPD)
- Nucleic Acid Testing (NAT)

Detection of Retrovirus

- F-PERT & Q-PERT EXPAND WHOLE
- Transmission Electron Microscopy
- Infectious retroviruses/Mus-Dunni/HEK293 cocultivation

SGS

DRUG SUBSTANCE

Identity

- Sanger Sequencing - Vector Identity

Residual Impurities

- Residual Host Cell DNA/RNA (USP <1126/1127>, Pharm.Eur.2.6.21 & Pharm.Eur.2.6.35)
- Residual Host Cell Protein (USP <1126/1127>, Pharm.Eur.2.6.36)
- Residual Reagents e.g. Benzonase, Bovine Serum Albumin (BSA) etc.
- Residual Plasmid DNA
- Endotoxin (<USP 85>, Pharm.Eur.2.6.12)

Genetic Stability and Integrity

- Genetic Characterization by Southern Blot
- Nucleic Acid Sequencing (DNA & RNA) Next Generation Sequencing & Sanger Sequencing
- Gene Copy Number by Quantitative Polymerase Chain Reaction (qPCR)

Replication Competent Virus

- Replication Competent Adeno-Associated Virus (AAV)
- Replication Competent Lentivirus (RCL)
- Replication Competent Adenovirus (RCA)

Other DS Assays:

- Vector Concentration/ Infectious Particle Titre
- Infectivity / Particle Ratio
- Vector Copy Number by Quantitative Polymerase Chain Reaction (qPCR)

DRUG PRODUCT

Identity

- Vector Identity – Sanger Sequencing

Qualification Assay

- Vector Particle Concentration
- Infectious Particle Titre
- Infectivity / Particle Ratio

Batch Release Assay

- Bacterial Endotoxin
- Osmolality
- pH
- Extractable volume
- Vector Aggregates
- Sterility
- Appearance

Replication Competent Tests

- Replication Competent Adeno-Associate Virus (AAV)
- Replication competent Lentivirus (RCL)

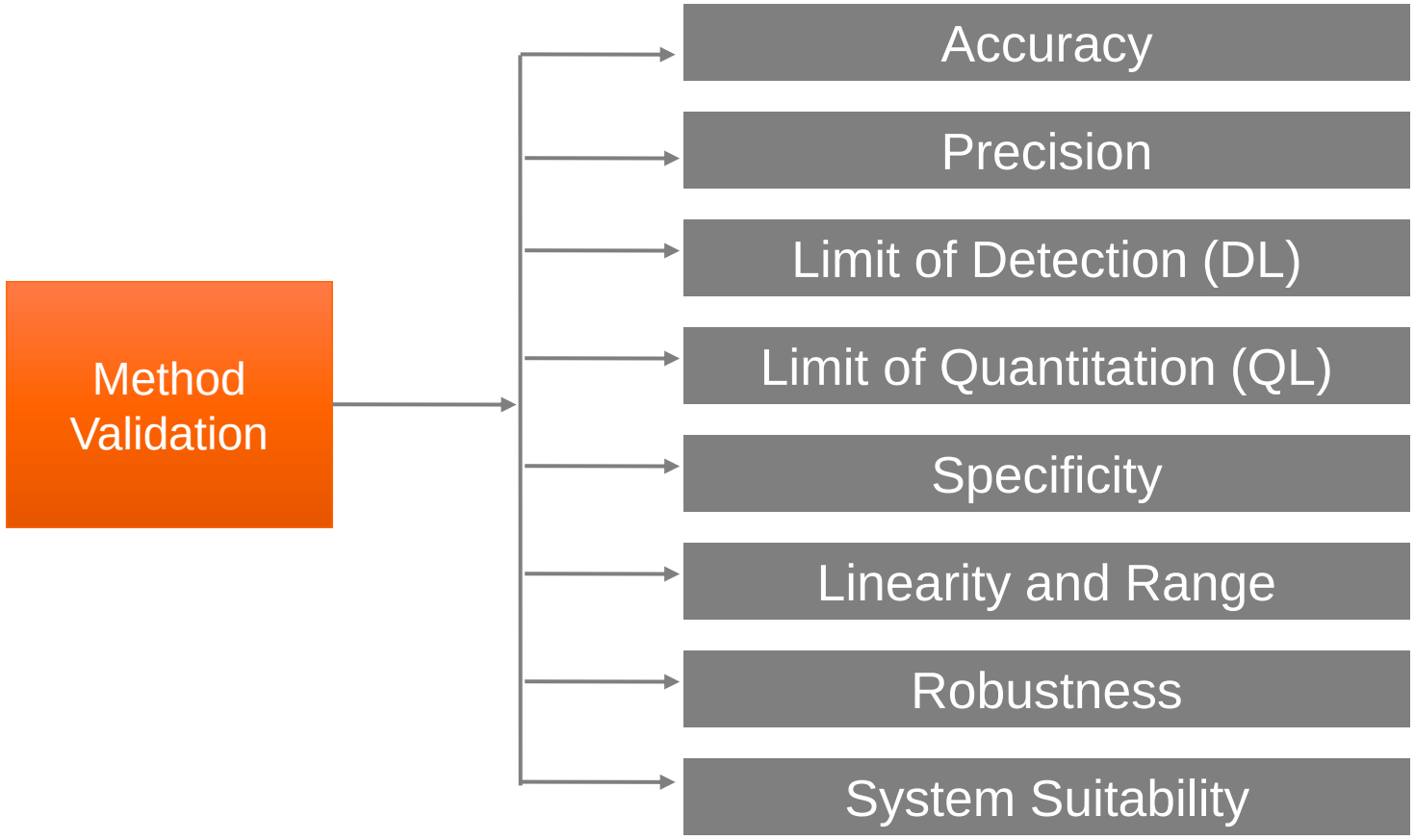
CERTIFICATES AND AUDIT HISTORY

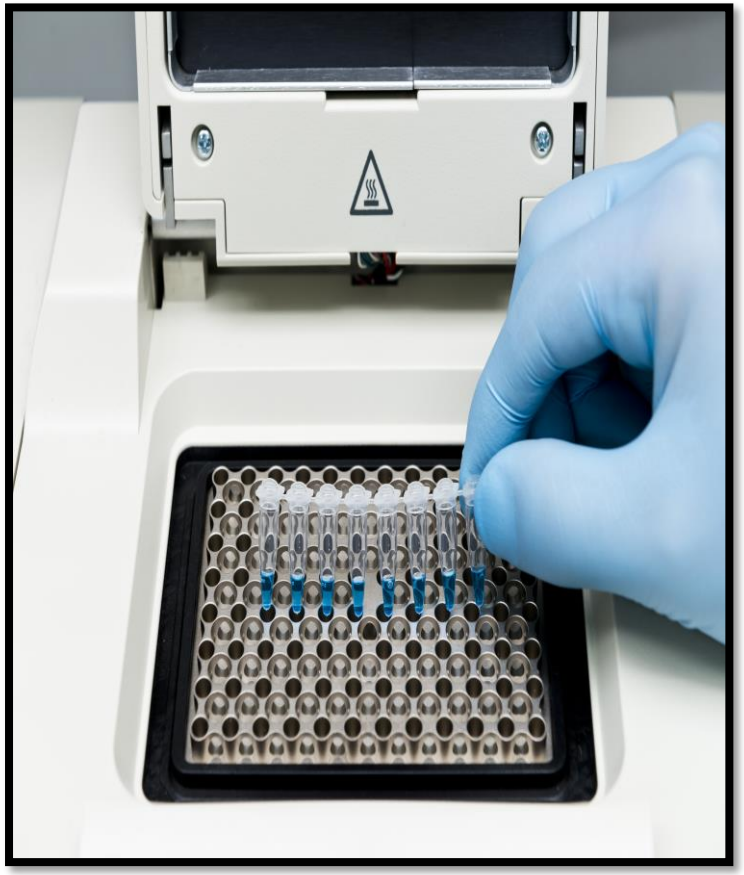
- Audited by US FDA 2015 – zero 483s
- MHRA GLP Statement of Compliance 2021
- MHRA GMP Certificate of Compliance of a Manufacturer 2022
- Software 21 CFR part 11 compliant

- MHRA GLP = 2008, 2010, 2012, 2015, 2018, 2021
- MHRA GMP = 2008, 2010, 2012, 2016, 2019, 2022
- FDA = 2015

PLATFORM OF GMP VALIDATED ASSAYS

SGS have over 300 assays developed and validated as described in the US pharmacopeia or the ICH Q2 (R1) guidelines





TEAM & SITE HISTORY

- Specialised team set up in 1996 (Q-One Biotech), to develop GMP biosafety testing technologies for vaccines, gene therapies and bio-therapeutics
- New virus detection systems - Pioneered the development of qPCR, DNA sequencing, electron microscopy, cell culture assays under GMP
- Set-up Vitrology in 2007 - Partnership with Takara Bio for CGT therapies Japan
- Acquired by SGS in 2012 - becoming part of the world's largest testing/certification company
- Swine Flu pandemic threat - emergency response to meet rapid manufacturing and biosafety testing of 100s of million doses in < 6 months
- 2019-22; Launch of SGS Centre of Excellence for Biosafety - Readiness for new viral threats/pandemic rapid testing platforms. Execution of Oxford / AZD1222 accelerated development and batch testing 2020-21. 160 FTE and growing. Supported batch release of over 4 billion doses of Covid vaccine

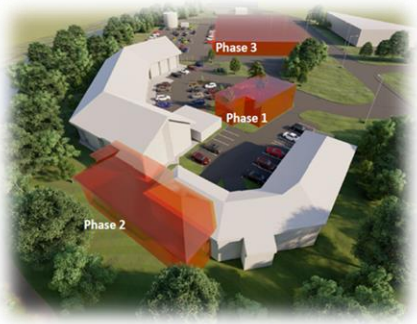
GROWTH – PEOPLE, FACILITY, EXPERTISE

SGS Vitrology (Glasgow) has grown to support release of biopharmaceuticals and viral vaccines on a Global scale…

- 2007 to 2021 grown from 17 staff to over 160 FTE
- Founders remain with over 25 years experience

- 2022 increased capacity to 3,150 m²
- Molecular Biology, Virology, TEM, Bio-analytical, Sequencing, Genetic Stability

- Highest Quality GLP/GMP Biosafety Testing Facility with 72 segregated BSL-2 labs



- £50M investment since 2007, with more confirmed for growth 2023+ up to 7,000 m²

- Expert consultancy and collaboration for all your large molecule biosafety needs

WHY WORK WITH SGS?

Scientific Expertise

- Scientists pioneered biosafety testing in 1990s
- Cohesive group with over 25 years working together developing, validating, and running GMP lot release assays

Dr Archie Lovatt- Scientific Director

- Pioneered real-time PCR and PERT technology for biologics testing.
- The Medicine Maker 2015 & 2016 – Top 100 Most Influential People in Drug Development and Manufacturing
- Scottish Life Sciences 2023 Leadership Award Winner
- US Pharm. Panel of Experts - Viral Vaccines and Cell Banking

Quality

- Multiple successful audits by large Pharma and experienced Biotechs
- GMP CoAs or Final Reports – 10+ pages providing detailed info on sample prep, method, validity criteria, results/conclusion, audit steps
- Reports are templated and carefully audited to ensure no errors

WHY WORK WITH SGS?

Sample management

- Flexible to client requirements on TAT
- PM team offering regular updates for pro-active sample submission and TAT management
- Shipment support
- Cell expansion service
- Manage subcontractors

Communication

- Dedicated PMs
- Email at sample receipt, lab end (study director), final report
- Direct communication with the study directors
- Free access to our validated secure online client portal
- Consultation on next steps within 48 hours of any issue affecting the final result of an assay

Digitalization

- Audits
- Video conference calls with sales, technical, quality, PM teams
- Best-in-class data integrity

EXPERT SAMPLE SHIPMENT SUPPORT

Dedicated to serving the life science industries for three decades

- **Highly-trained drivers** who are qualified to (un)pack consignments on site
- Provision of validated **temperature-controlled packaging** and temperature loggers (where required)
- **Completion of all paperwork** (where legally allowed)
- A **dedicated project management team** lead by one of our experienced Account Managers
- **Investigator liaison and protocol support and guidance** (where required)
- Assistance in obtaining **required import and export permits**
- Hold **SGS import permits** for wide range of sample types
- Swift customs **clearance**
- Full customized management **reporting**

Contact us

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