# Monoclonal Antibodies (mAbs) Testing Services

Health Inspired,
Quality Driven.

SGS

# Testing along the mAb process

CELL LINE GENERATION → PROCESS OPTIMIZATION → ENGINEERING RUN → GMP MANUFACTURING → FORMULATION (FILL & FINISH) → PK/PD BIOANALYSIS → CLINICAL STUDIES

monoclonal antibody development process

SGS

Our clients can rely on SGS global analytical capabilities and dedicated expertise to accelerate their mAbs project

**CELL BANK TESTING**
- Microbiological
- Identity
- Viral safety testing
- Genetic stability

**ANALYTICAL DEVELOPMENT**
- Methods to monitor critical Quality Attributes

**ANALYTICAL DEVELOPMENT**
- Methods in line with ICH Q14

**GMP VALIDATION**
- Methods in line with ICH Q2(R2)

**STABILITY TRIALS**
- Drug Substance
- Drug Product

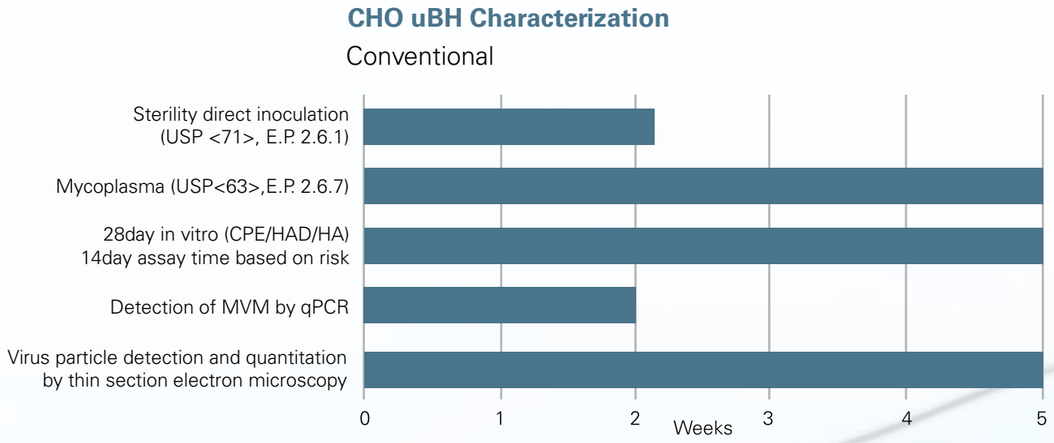
**TRIAL PHASES I, II & III**
- Biomarker development
- Validation of bioanalytical methods

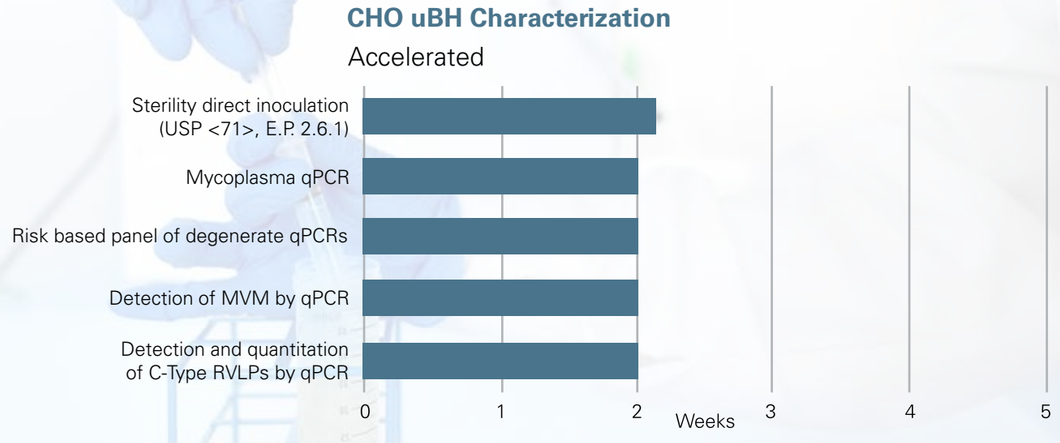
**BIOSAFETY**

*In vitro* adventitious virus assays • Endotoxins • specified pathogen PCR's • TEM • Retroviruses detection assays
Mycoplasma (culture + qPCR) • Sterility / Bioburden

Engage SGS experts early in your monoclonal antibody program. From discovery through to market entry, we simplify complexity, minimize technical and communication barriers, and significantly accelerate regulatory approval.

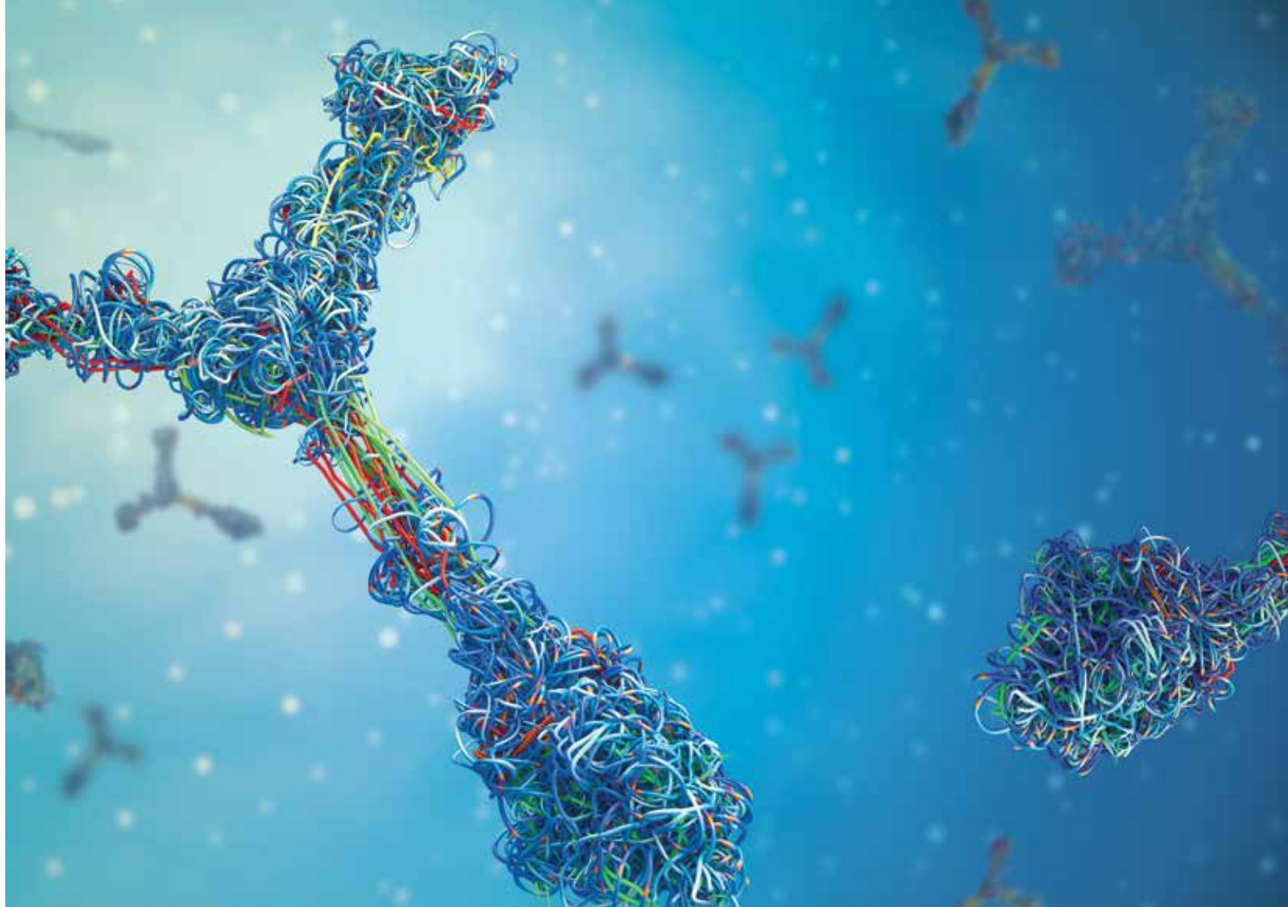
# Testing for CHO biologics



# Biosafety testing of CHO biologics

- Rapid targeted NAT - a fast, ICH Q2-validated alternative to traditional in-vitro assays, accelerating CHO-based biologics manufacturing
- Covers 39 qPCR targets across 15+ high-risk viral families (Hsu et al., 2024) for comprehensive detection
- Uses TaqMan® chemistry with degenerate primers/probes for broad and specific viral identification, contamination-free and highly sensitive
- Fully aligned with ICH Q5A(R2) guidelines; NGS options available for in-vivo replacement and cell bank testing
- Risk-based panel design enabling faster, confident batch release and shorter time to patient



# Expert guidance for your analytical strategy

## Identify attributes

- Identification of attributes
- Product knowledge
- Forced degradation

## Develop method

- Adequate selection of technology and instrument
- Proof of concept study to confirm methodology

## Fit-for-purpose

- Assessment of analytical procedure performance
- Documentation of analytical procedure (including control strategy)

## Validate methods

- In line with ICH Q2(R2) validation of methods applied to critical Quality Attributes (batch release, stability studies)

## Trending

- Monitoring of method performance
- Monitoring of product attributes along its lifecycle

# Why SGS: Complete mAbs Project Support

## Characterization

STRUCTURAL CHARACTERIZATION
- Composition, sequencing, PTMs

HIGHER ORDER STRUCTURE
- Secondary, tertiary and aggregates

FUNCTIONAL CHARACTERIZATION
- Ligand binding and cell-based technologies

IMPURITY IDENTIFICATION
- Product- & process-related impurities

## QC & stability (DS, DP, raw materials)

RELEASE TESTING
- Compendial, bespoke ID tests
- Potency and function

MICROBIOLOGY
- Sterility, bioburden, endotoxin

QUANTITATIVE IMPURITY ANALYSES
- Product- and process-related impurities

STABILITY TESTING
- Accelerated, standard

## Biosafety

VIRUS DETECTION ASSAYS
- In-vitro, qPCR, TEM

CELL IDENTITY & CHARACTERIZATION
- DNA fingerprinting, Sanger sequencing

GENETIC STABILITY
- Southern blot, DNA sequencing (NGS)

## Bioanalysis and clinical

ACROSS DRUG DEVELOPMENT PROCESS
- From discovery pharmacology to late clinical stages

REGULATORY TOXICOLOGY PRECLINICAL AND CLINICAL
- Pharmacokinetics (PK)
- Immunogenicity (ADA, Nab)
- Pharmacodynamics (Cellular/Soluble Biomarkers)

# Expertise for mAbs Producers

SGS Laboratories

## Method development, transfer and validation

<4 WEEKS FAST-TRACK METHOD TRANSFER OF EIGHT BIOASSAYS

We are experienced in developing complex assays and fast-tracking method transfer

## Characterization studies

>50 CHARACTERIZATION PROJECTS TO US FDA & EMA GUIDELINES

We applied ICH Q6B across diverse studies from insulin to complex biotherapeutic modalities, ensuring compliance with biologics guidelines

## Biosafety testing

+200 TESTS PER DRUG PER YEAR
>95% ON TIME DELIVERY

Highest quality GMP biosafety testing facility with 72 segregated BSL-2 labs

## Batch release testing

>1200 PHYSICOCHEMICAL TESTS PER YEAR
>200 BATCHES TESTED PER YEAR

Our routine batch release and stability studies include physicochemical, potency, purity, microbiological tests

# Our expertise in BA/BE

## Lab capabilities

### 6 LABORATORIES
(EUROPE, NORTH AMERICA, CHINA)

> 600 Projects conducted per year
> 2500 Assays developed & validated
> 300k Samples analyzed per year
> 250 Experts

## Expertise & technologies

### ALL MODALITIES
(NCE, NBE, ADCS, BIOSIMILARS, CGT)

- Immuno Assays
- Cell-Based Assays
- Molecular Biology
- LC-MS/MS & LC-UV-Vis/Fluorescence
- Robotics (TECAN, Waters, Biotage)

## Clinical analytics

### ANALYTICAL AND SAMPLE PREPARATION SERVICES FOR CLINICAL TRIALS

- Safety lab testing (24/7)
- Biomarkers
- PBMC / BMMC isolation, cryo-preservation, and analysis
- Flow Cytometry, Cell culture and ELISA
- Genotyping
- IVD Instrument Studies for EMA/ FDA approval

## Regulatory

### GXP & CFR PART 11 COMPLIANT

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- UK Medicines and Healthcare products Regulatory Agency (MHRA)

# Monoclonal Antibodies (mAbs) Testing Services

## Health Inspired, Quality Driven.




## Contact us

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SGS

When you need to be sure