# SGS expertise in cell-based and binding bioassays

## Health Inspired, Quality Driven.

### Cell-based potency assays for biologics development

*Advanced functional characterization for biologics and biosimilars, including antibody-drug conjugates (ADCs)*

As biologics and biosimilars continue to increase in complexity, robust demonstrations of biological activity and well-defined mechanisms of action (MoA) are essential to support product development, comparability and regulatory approval. Our science- and quality-driven cell-based potency assays provide biologically relevant, actionable insights to support analytical characterization, biosimilarity assessment, process consistency and life cycle management.

### SGS solution

Our global network of bioassay laboratories operates across three locations: Canada, Switzerland and Belgium.

In Canada, the Mississauga team, with more than two decades of experience in biologics, plays a key role in delivering reliable, high quality cell based potency data from early development through quality control (QC) and release testing.

A comprehensive functional characterization toolkit enables integrated, MoA-aligned bioassay solutions tailored for monoclonal antibodies, biosimilars, recombinant proteins, fusion proteins, multispecifics and ADCs. We combine fit-for-purpose cell-based and binding assay platforms to deliver reproducible and quantitative data aligned with regulatory expectations. Our deep platform expertise, optimized assay strategies and experienced scientific teams help reduce development timelines, enabling faster progression from early characterization through validation and QC implementation.

## CORE CAPABILITIES INCLUDE:

- Binding and interaction analysis – ELISA, SPR, BLI and flow cytometry to evaluate target engagement, binding kinetics and receptor interactions
- Functional potency assays – ADCC, CDC, ADCP, neutralization and receptor activation assays aligned with product MoA
- Cell signaling and pathway analysis – reporter gene assays, signal transduction and pathway-specific functional models
- Cell growth and viability assessments – proliferation, viability, cytotoxicity and apoptosis-based assays for functional characterization

## Cell-based assay expertise

All laboratories are equipped with advanced platforms such as flow cytometry, PCR/qPCR, ddPCR and immunoassay technologies, enabling scalable solutions from early development throug QC and release testing.

Experienced scientific teams contribute extensive hands-on experience in developing, optimizing and transferring complex cell-based assays for biologics and biosimilars, with a strong focus on assay robustness, reproducibility and regulatory relevance. A rigorous, fit-for-purpose approach is applied to assay design, balancing biological relevance with regulatory efficiency to support comparability, characterization and potency evaluation across all stages of development. Expertise across diverse MoA and challenging biologics enables accelerated troubleshooting, reduced development timelines and improved assay reliability.

## Integrated biologics support

Cell-based potency testing is supported by our broader analytical capabilities, including physicochemical characterization, impurity analysis and quality control testing.

This integrated approach ensures alignment with the key regulatory attributes of safety, potency, quality, purity and identity (SISPQ), supporting consistent product performance and regulatory readiness.

## Advantages

- MoA-driven assay design
- Broad modality coverage across advanced therapeutics
- Scalable from early development to QC environments
- Integrated analytical and regulatory support
- Proven expertise in complex biologics

## Our experts

Our team combines deep scientific expertise with more than two decades of biologics experience, delivering reliable, high-quality data to support development, validation and regulatory success.

To learn more about our cell-based potency assay capabilities,  please contact [insert email].



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When you need to be sure