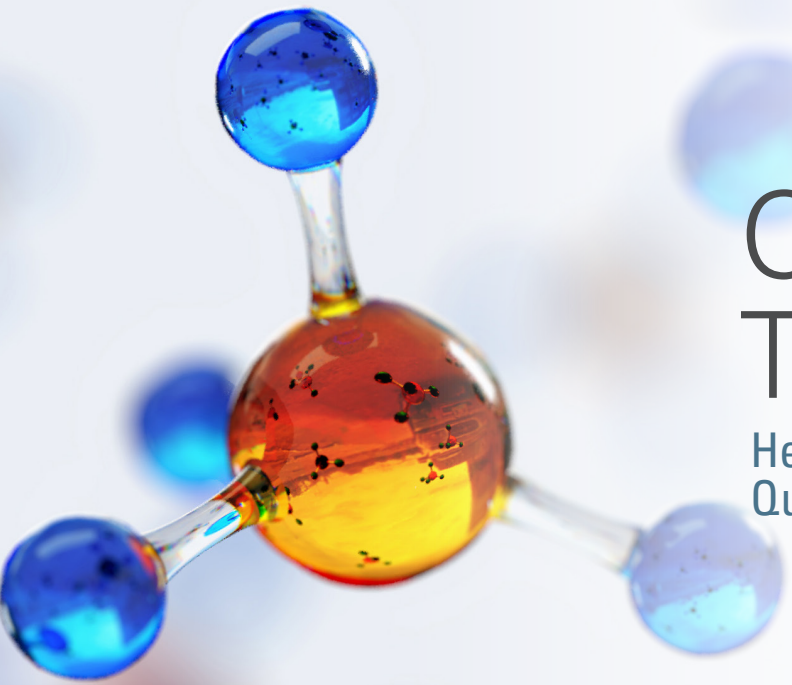


Cell and Gene Therapies

Health Inspired,
Quality Driven.

SGS

Supporting C&GT Product Manufacturers

Industry-leading solutions for every stage of the C&GT development process.

Safeguarding people's health requires bringing safe, high-quality, affordable and effective medicines to market. SGS boasts a wealth of Cell and Gene Therapy (C&GT) expertise. Our global team of specialists, working in cutting-edge facilities, provide much-needed support to leading manufacturers of C&GT products whether a viral vector or RNA product.

The exceptional testing portfolio of SGS – underpinned by our key biopharmaceutical pillars of biosafety, characterization, bioanalysis and quality control– makes us the ideal partner for all your C&GT outsourcing needs.

SGS provides a range of testing solutions to help C&GT product manufacturers with:

- Identification/design of the therapeutic vector and its structural characterization
- Ensuring product safety and stability
- Confirming quality and product consistency including support for raw and ancillary material analytics
- Analyzing key purity markers
- Verifying potency and therapeutic activity
- Solutions to help organizations bring safe, effective products to market.

Creating an Effective Therapeutic Vector

Identification of the therapeutic vector and its structural characterization

Therapeutic vectors function as transport vehicles, protecting and delivering genetic material to the targeted cells. Creating an effective therapeutic vector is therefore nearly as important as developing the working gene itself.

C&GT product manufacturers must identify the appropriate therapeutic vector and precisely define specific structural characteristics. SGS has a great deal of experience in this area, using techniques such as:

- Analytical ultracentrifugation (AUC) to conduct quantitative analyses of the C&GT product's macromolecules
- Nanoparticle tracking analysis (NTA) to visualize vector particle size and contraction
- Resistive pulse sensing (RPS) to detect and measure the size of particles in fluid

The experienced C&GT specialists at SGS work in leading-edge, internationally accredited facilities. They provide a wealth of customized solutions to help characterize your therapeutic vector and study it in detail, assuring the quality and consistency of your final product.

Ensuring Product Safety

Adopt a safety-first approach

C&GT product manufacturers face a major challenge in making sure their products are completely free from any harmful contaminants. SGS provide a range of services to address this critical safety issue, including:

- Bioburden analysis
- Quantitation of endotoxin and identification of any potentially harmful or adventitious agents.
- Restriction enzyme analysis to confirm your solution's viral genome integrity.

SGS will work tirelessly to ensure that when you do bring a product to market, it is safe. Rest easy in the knowledge that you can focus on your core business activity while the experts at SGS leverage their broad analytical portfolio and unparalleled knowledge to safeguard the quality of the final product.

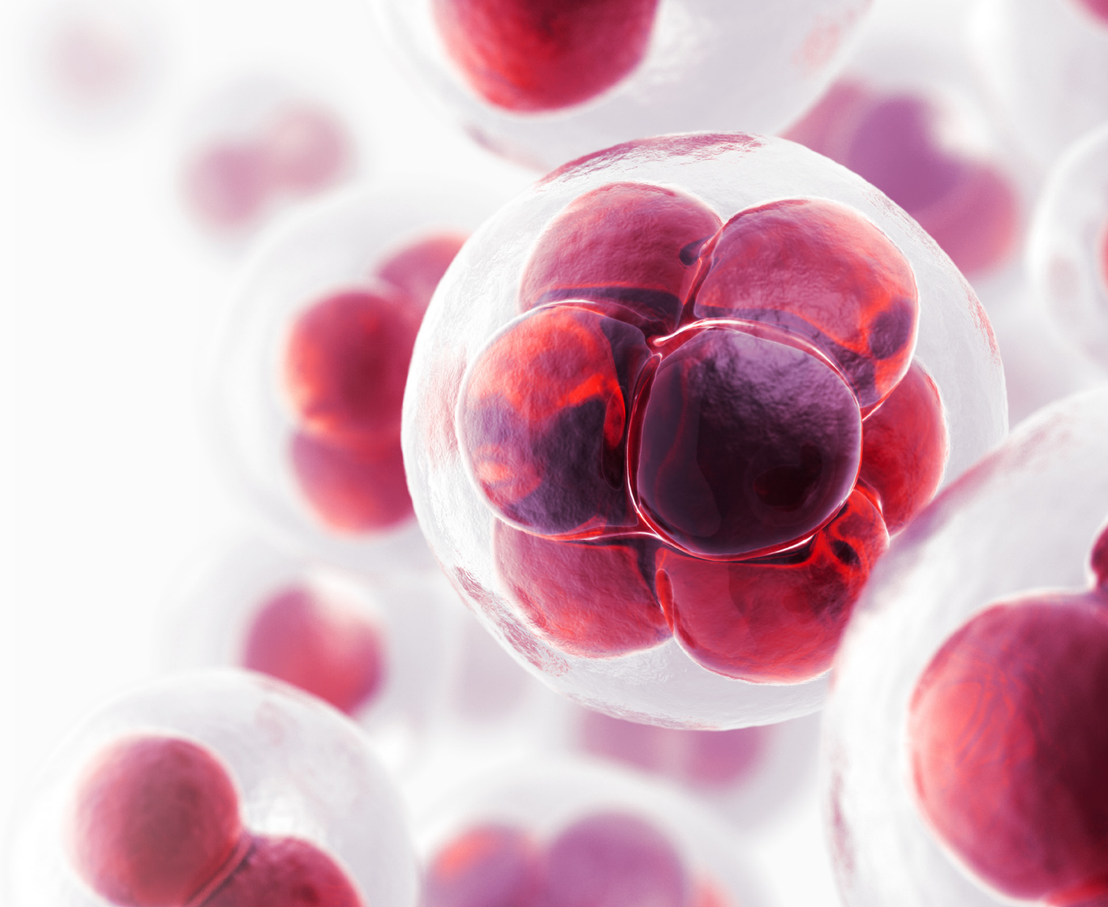
Confirming Quality and Product Consistency

Maintain exceptional standards at all times

Ensuring product consistency can often be difficult, but it's even more challenging when manufacturing C&GT products. These are highly engineered biological products that require the same quality of product at commercial-scale production as in the early clinical manufacturing stage. Fortunately, SGS can aid manufacturers in confirming quality and product consistency throughout all stages of development by providing a broad range of services including:

- Development of potency assays (MTS) to assess cell proliferation, cell viability, and cytotoxicity.
- Development of titer assays to determine the concentration of viral particles.
- Assess appearance (clarity, color, and particulate analysis) and physicochemical characteristics such as osmolality and pH for both viral and non-viral mediated therapies.

SGS specialists will act as safeguards, ensuring that your products always meet the necessary quality and consistency parameters. With these experts by your side, you can outsource the entire end-to-end process of confirming the ongoing quality and product consistency.



Analyzing Key Purity Markers

Identify potential contamination

C&GT products must be free from all process and product-related biological and chemical contamination. SGS provides innovative solutions to identify any harmful contaminants which can highlight areas where product purity needs to be improved. SGS has a wealth of experience in techniques such as:

- Detection of residual host cell DNA, RNA, and host cell proteins.
- Advanced and sensitive chromatographic and mass spectrometry (MS) methods for the detection of process and product contaminants, including immature and defective viral particles that might affect product purity and efficacy.
- Next-generation sequencing (NGS).

Our array of testing solutions will evaluate your product's purity, underscoring issues that need to be addressed. They will also help you ensure it is free from extraneous material before it is assessed by regulators – and before it hits the market.

Verifying Potency and Therapeutic Activity

Confirm your product's efficacy

C&GT products need to have the desired therapeutic effect. In vitro potency verification reveals the product's therapeutic activity, demonstrating the impact that it will have when administered to a patient.

SGS can help manufacturers easily assess their products' true potency with a range of industry-leading services, including:

- Manual or automated cell counting to verify the TNC count.
- Flow cytometry to assess and quantitate antigen expression on cells.
- Fluorescence and microscopy methods to detect viral antigens and visualize focal areas of infection.

Our innovative solutions, provided by experienced specialists working in state-of-the-art laboratories, allow the potency of your product to be accurately measured. Our trusted experts are up to date with the latest regulatory standards and industry best practices – making them the ideal partner for all your potency testing requirements.

Let’s Build a Healthier Future

We are SGS – the world’s leading testing, inspection, and certification company, with decades of experience in the health and nutrition sector. SGS Health Science has one core mission: improving patient health by safeguarding the quality and efficacy of medicines.

SGS Health Science delivers industry-leading contract development and manufacturing (CDMO) and analytical development and testing to support you every step of the way as you deliver first-class, fully compliant biopharmaceutical and pharmaceutical drugs, clinical research, and medical devices.

We are customer-centric, working hand-in-hand with our clients and providing services tailored to their specific needs.

By choosing SGS, you will be working with leading experts who will collaborate with you throughout every stage of your C&GT product’s development. You can leverage our industry-leading, fully accredited facilities featuring state-of-the-art equipment, and consult our knowledgeable specialists throughout the product development process.

Health Science

Health Inspired,
Quality Driven.

Contact us

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WHEN YOU NEED TO BE SURE

SGS