Analytical Solutions for Cell & Gene Therapies

Sophisticated analysis for advanced therapies

- Extensive CGT characterization services
- Release and Stability Testing for Viral Vectors
- Method Development, Transfer, and Validation
- TLA-based Genetic QC Solutions

solvias

Cell and gene therapies (**CGT**) are complex and technically demanding to manufacture. Solvias helps you overcome every challenge in CGT analytical testing in a **cGMP-compliant environment**.

Broad capabilities covering a variety of modalities

- ✓ **Viral vectors**
- ✓ **Cell-Based Therapies**
- ✓ **Gene Edited Therapies**
- ✓ **mRNA**

Characterization

Extensive expertise in CGT characterization, including raw material testing, cell culture media-specific analysis, and oligonucleotide analytics and vector characterization, all in a regulated cGMP environment.

Genetic QC

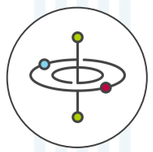
Our proprietary Target Locus Amplification (TLA) technology accurately determines gene editing outcomes, supporting our QC solutions for cell line development, viral vectors, genetically engineered models, and ATMPs.

Impurities

With comprehensive capabilities for impurity testing and contamination control, we have solutions from initial profiling to commercial control across modalities and dosage forms.

Release Testing

A complete suite of identity, purity, potency, and safety tests including physical, chemical, cellular, and functional QC testing. With expertise in bioassay potency testing and cGMP compliant analytical ultra centrifugation (AUC) for vector payload analysis.



Stability

We offer stability studies for every clinical phase. Capabilities include forced degradation, photo stability, freeze-thaw testing, and a range of temperature and humidity options. >80 m^3 on-site storage.

Biosafety

Sterile and non-sterile product testing including rapid methods, organism identification, pyrogen & endotoxin testing, and container closure integrity testing (CCIT).

Bring **your innovation** to its destination

Meet every **challenge** with a Solvias **solution**

Novel Assays

The development of novel therapeutics often requires testing methods designed and optimized to address novel therapeutic attributes. Scientific sophistication is needed to deliver the appropriate solutions.

Cutting-edge Technology

Solvias uses an array of advanced technologies, including UPLC, LC-MS, CE-MS, bio-spectroscopy, capillary electrophoresis, amino acid analytics, cGMP-compliant AUC, and next-gen sequencing. We tailor testing programs using a comprehensive range of orthogonal analytical methods.

Compliance

The innovative nature of these therapies often places us in uncharted compliance territory. Despite several guidelines from various agencies, clear paths for compliance are not always evident.

Unparalleled Expertise

Solvias supports CGT developers from early stage to commercialization, navigating the regulatory requirements to bring your innovation to its destination. Our scientists are well-versed in the ever-changing regulatory landscape for CGTs, employing risk-based strategy to ensure compliance even in the absence of detailed product-specific guidelines.

On-Time Delivery

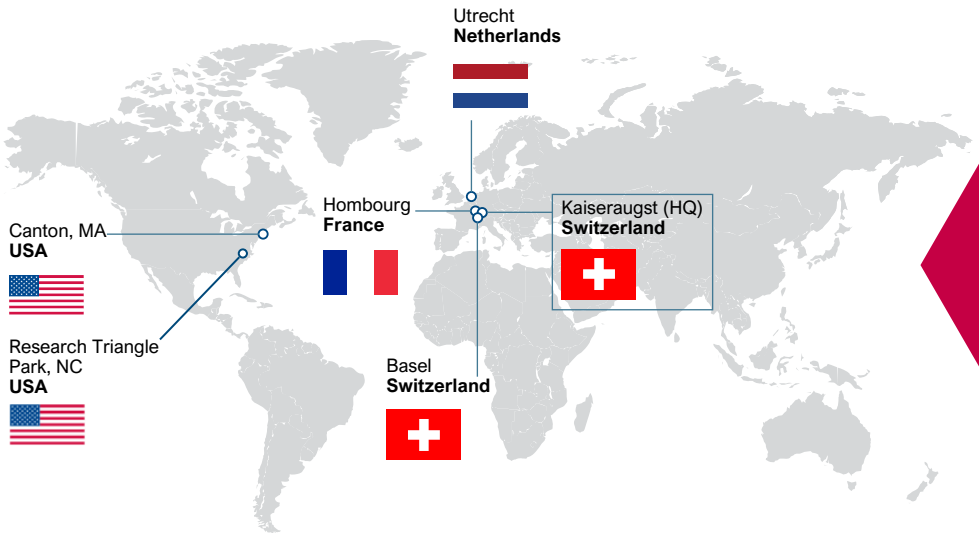
Staying on schedule is critical for the development of cell and gene therapies. For companies scaling up, rising production volumes heighten the challenge of meeting tight deadlines.

Efficiency & Experience

We deliver customized solutions rapidly, accelerating the delivery of data and achieving “right first time” results.

Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 6 centers of excellence



Contact us to speak with an expert: info@solvias.com

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