Unmatched Genetic QC Solutions for CGT

Cergentis services from Solvias - Complete genetic QC

- Confirm on-target genetic alterations
- Complete (trans)gene sequencing to detect sequence and structural variants
- Map exact transgene insertion sites
- Assess heterogeneity of genome-edited cell pools

solvias

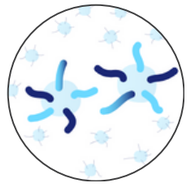
Cell and gene therapy (CGT) is a revolutionary and rapidly growing field that opens up untapped therapeutic avenues for remedies against devastating and debilitating diseases. **The EMA and FDA require you to demonstrate and guarantee the safety of your ATMPs.** Therefore, implementing the **right genetic QC tools** early in the development process is essential to ensure the success of your manufactured products.

How does TLA work?

Our proprietary Targeted Locus Amplification (TLA) platform detects genetic variations **in and around the gene of interest**, offering unrivaled genetic insights as a cost-effective and time-efficient alternative to conventional QC approaches. Unlike most conventional technologies, our approach does not require a prior hypothesis or detailed locus information: it selects regions based on physical proximity. This **hypothesis-neutral** approach can uncover new genetic interactions and structural variations that impact on gene expression and function.

1) Crosslinking

Chemical bonds between spatially close DNA molecules are induced.

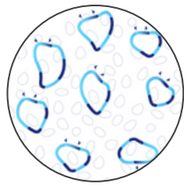


2) Fragmentation

The crosslinked DNA is cut it into smaller, more manageable fragments.

3) Circularization

Sequences that were originally close in the genome are ligated into the same molecule.

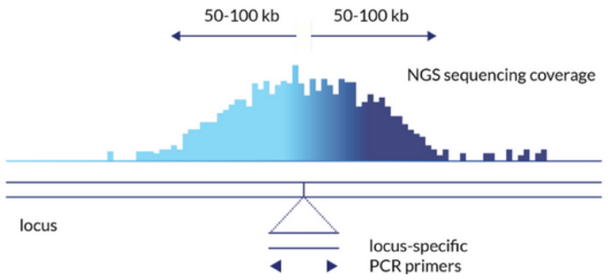


4) Amplification

Stochastic reshuffling and amplification of circularized DNA.

A single platform to evaluate all relevant genetic characteristics

With TLA, we achieve deep and broad sequence coverage across any (trans)gene of interest, mapping exact transgene insertion sites and detecting both sequential and structural variations. The method is extensively described in peer-reviewed publications, which have in turn warranted world-class partnerships and established us as a globally trusted partner for genetic analysis of ATMPs.



	Characteristics	TLA + NGS
Vector/ GOI Integrity	Integration sites	✓
	Structural variants	✓
	Co-integrations	✓
	SNVs	✓
	Indels	✓
	Rearrangements	✓
	Concatemers	✓
	Copy number	✓ (ddPCR)

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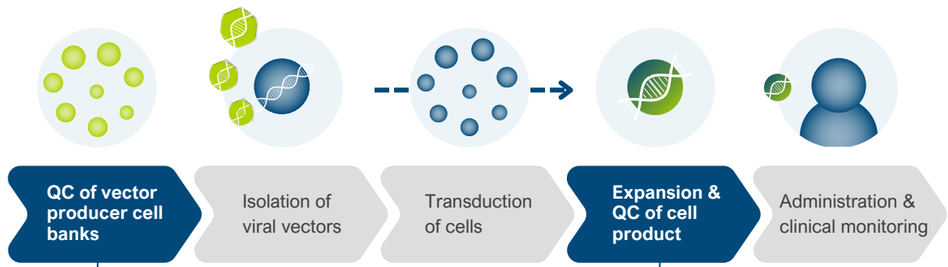
Bring **your innovation** to its destination

TLA-based solutions in CGT manufacturing

Our genetic QC solutions provide reliable genomic evidence to mitigate risk in R&D decisions and accelerate time to clinic. We can help you ensure safety and quality by unambiguously demonstrating desired genetic modifications, such as excluding off-target integration or assessing the genetic consequences of gene editing or random viral vector integration.



De-risk R&D decisions and minimize time-to-clinic

- ✓ Genetic stability of modified cells
- ✓ Identify sequence variants in integrated vectors and insertion sites
- ✓ Analysis of transgene integration and monitoring of CAR-T cell stability
- ✓ ATMP characterization

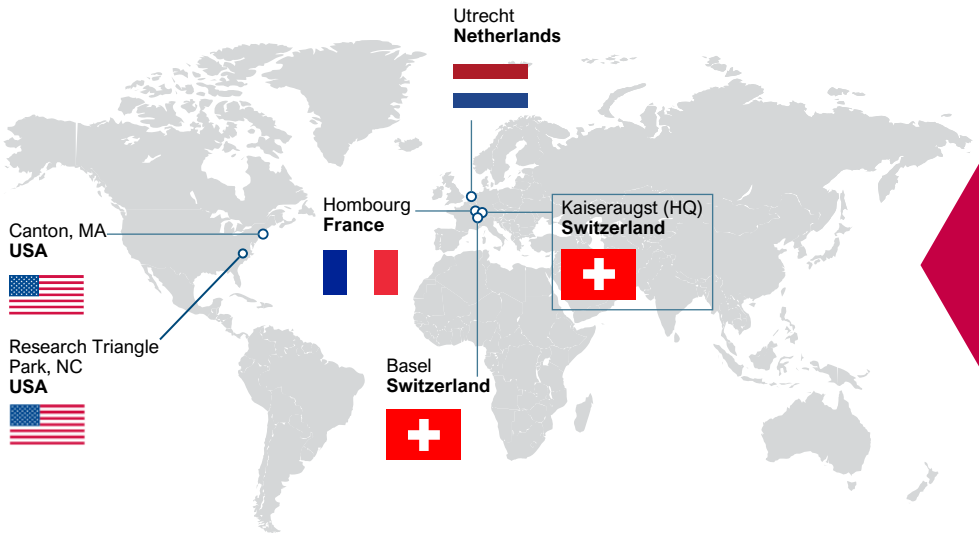
Comply with FDA/EMA requirements

TLA offers unmatched genetic insights to help you satisfy the stringent genetic characterization requirements for transfected and transduced cells. FDA and EMA guidelines require thorough interrogation of:

- ✓ Viral vector integration sites and the potential for insertional mutagenesis
- ✓ Genomic integrity - including inserted sequence, chromosomal rearrangements and large insertions or deletions
- ✓ Genetic stability of modified cells
- ✓ Vector copy number

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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