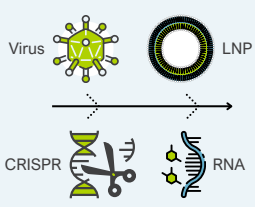
Cell & Gene Therapies

Cell Therapy is the transfer of a specific cell type(s) into a patient to treat or prevent disease. The cells can be from the patient (autologous) or a healthy donor (allogeneic). A common example is CAR T cell therapies, a type of immunotherapy for cancer.

Gene Therapy is the use of genetic material to treat or prevent disease. It can be used to reduce levels of a disease-causing protein, increase production of disease-fighting proteins, or to produce new/modified proteins. Gene therapies can be delivered *in vivo* or *ex vivo*.

Cell and Gene Therapies (CGTs) are often combined:



Gene can be packaged into a vector

Genetic material modifies the cell

Cells are delivered to patient

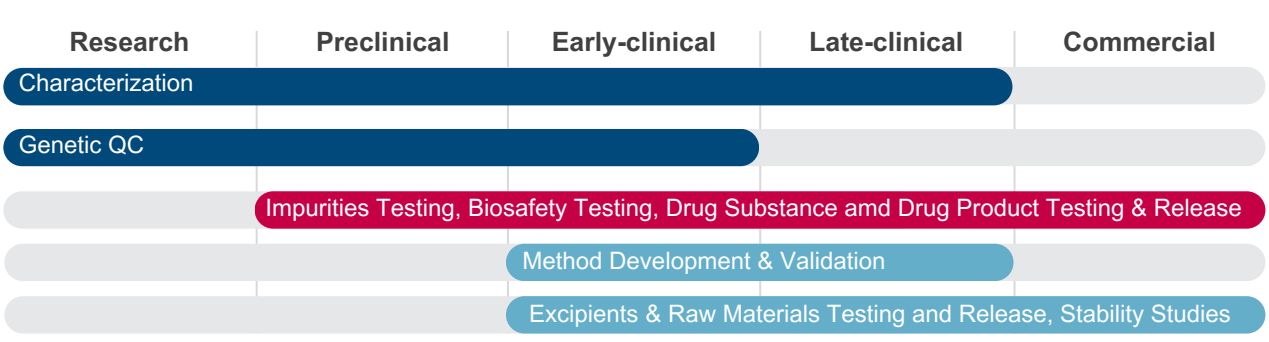
Evaluating critical quality attributes of CGTs requires a range of analytical tests for identity, purity, potency, safety, and stability. However, several factor make developing, validating, and implementing these methods very challenging, often placing us in uncharted territory:

Variability of raw materials, lack of reference standards, and complex modes of action

Despite regulatory guidelines, compliance paths are often unclear

For companies scaling up, higher production volumes make meeting deadlines more challenging.

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 and a range of orthogonal analytical methods to ensure compliance even in the absence of detailed product-specific guidelines. We deliver customized solutions rapidly, accelerating the delivery of data and achieving “right first time” results.



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

IMPURITIES

Broad capabilities for impurity testing and contamination control, from initial profiling to E&L and commercial control across modalities and dosage forms.

BIOSAFETY

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

GMP DS AND DP TESTING & RELEASE

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.

METHOD DEVELOPMENT & VALIDATION

Cell-based bioassays, ELISA, Western blotting, residual DNA (threshold analysis, qPCR), rodent parvoviruses, surface plasmon resonance, RNA and DNA sequencing, bioburden, endotoxin, sterility, viral safety, cell biology methods and potency assays.

EXCIPIENTS & RAW MATERIALS

Confirm identity, assess impurities, and ensure genetic makeup through PCR, chromatography, mass spectrometry, electrophoresis, titration, NGS, and Sanger.

STABILITY

Forced degradation, photo stability, freeze-thaw testing, and a range of temperature and humidity options, including ICH recommended and custom conditions.

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

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