Expanding into North America

Solvias **Biologics and Cell and Gene Therapy** Center of Excellence in Research Triangle Park, North Carolina

- Cell-Based Bioassays
- Analytical Chemistry
- Cell Banking
- Thaw-and-Go Solution

solvias

Solvias newest facility in **Research Triangle Park**, North Carolina, will expand upon our testing services for **cell and gene therapies** and other novel modalities while reinforcing **mAb** testing capabilities from **preclinical to commercial** release.

Bring **your innovation** to its destination

Cell-Based Bioassay Expertise

From day one, the RTP center will focus on one of the most critical challenges in CGT: developing robust cell-based bioassays, particularly for potency testing, which is a leading cause of clinical holds. Our new center is designed to help clients overcome these obstacles and bring their innovation to its destination.

Applications

- **Potency Testing:** Determine the strength or activity of a therapy to ensure it performs as intended
- **Immunogenicity Studies:** Determine whether a therapy induces an immune response (e.g., anti-drug antibodies or cytokine production).
- **Antigenicity Studies:** Determine whether a molecule is recognized as an antigen by the immune system.
- **Function Studies:** Determine the specific biological activity of a therapy
- **Mechanism of Action Studies:** Determine the biological pathways or processes a therapy engages to achieve its effect.

Assay Types

- Binding Assays
- Programed Cell Death
- Gene Expression
- Cell Proliferation
- Cell Signaling Assays
- Reporter Assays

Detection Methods

- ELISA – UV vis, fluorescence, ultra-sensitive luminescence
- AlphaLISA
- Flow Cytometry – FACS Lyric
- Electrochemiluminescence – MSD
- Capillary Electrophoresis – Maurice CE

Cell Banking

We work with customer-supplied research cells, culturing and preparing Master Cell Banks (MCB) and Working Cell Banks (WCB). The MCB is cryopreserved after thorough characterization and testing for purity, identity, and stability, serving as a reliable primary source for future use. With our Thaw-and-Go solution, these pre-optimized frozen cell banks are ready for immediate use in assays without the need for recovery or additional preparation, reducing turnaround times and ensuring consistent, reproducible results across experiments.

Analytical Chemistry

At RTP, we complement our bioassay services with advanced analytical chemistry capabilities, including USP compendial methods and characterization services.

- ✓ Osmolarity
- ✓ pH
- ✓ Particle size
- ✓ USP certificates for particle sizes
- ✓ HIAC
- ✓ Turbidity
- ✓ CE - Maurice
- ✓ HPLC - Agilent 1260 w/ FLD & DAD
- ✓ HPLC - Agilent 1290 w/ UV & FLD
- ✓ SCIEX - PA 800 + CE-SDS, CGE & IVTRNA

Expansion Phases

I

Phase I: Opening in January 2025

Our first 20,000 sq. ft. space is on track for completion by January 2025 and will focus on delivering cutting-edge analytical chemistry and cell-based bioassay services

II

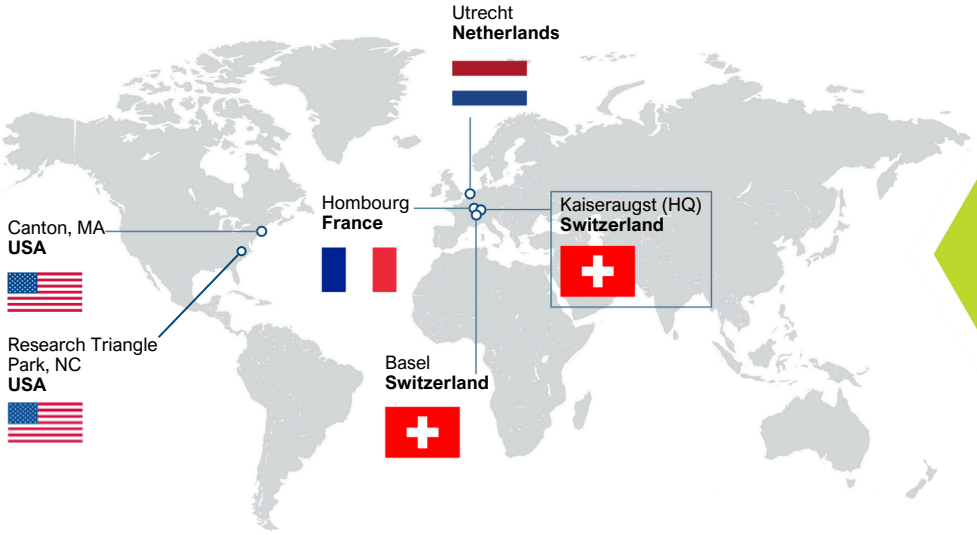
Phase II: Slated for completion by July 2025

The second phase will add 30,000 sq. ft. of advanced laboratory space, significantly broadening our service portfolio to include:

- Microbiology: Featuring rapid sterility testing and other microbiological services.
- Molecular Biology: Enhanced capabilities with automation for faster and more efficient workflows.
- Virology: Comprehensive viral testing services to support biologics and advanced therapies.
- Transmission Electron Microscopy (TEM): Providing high-resolution imaging for in-depth structural analysis.
- Lentivirus Suite: Dedicated facilities for the safe and efficient handling of lentiviral vectors.

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

solvias.com

solvias

A050124