Expanding into North America

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

- Viral Vectors
- Cell-Based Therapies
- RNA-Based Modalities
- Monoclonal Antibodies

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Solvias newest facility in Research Triangle Park, North Carolina, will expand upon our GMP 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

Therapeutic Modalities

Viral Vectors	Build out phase I	Build out phase II
AAV Drug Substance Release Testing	• Pharmacopoeia compendial • Next generation Sequencing • TCID50 • rcAAV • Copy Number by ddPCR • ID by Sequencing • Host Cell Protein • Residual Host Cell DNA	• Residual PE • Residual Benzonase • Endotoxins • Bioburden
AAV Drug Product Release Testing	• Pharmacopoeial compendial assays • TCID50 • rcAAV • Copy Number by ddPCR • ID by Sequencing	• Extractable Volume • Sub-visible Particles • Endotoxins • Sterility
Additional Capabilities	• Cell-based Bioassays • Serotype Titration by ELISA • Cell Line Characterization • Genetic Stability	• Intact Mass of VPs for ID, Purity, Ratio and PTMs • Peptide Mapping of Capsid Proteins

RNA-based Tx	Build out phase I	Build out phase II
CRISPR-Type Assays	• Manipulated Cells Characterization • Cell-Based Bioassay	• Guide RNA Characterization • Cas9 and Cas9-Like Complexes • Delivery System Analysis (Liposomes, LNPs, Vesicles, Exosomes)
Plasmid DNA	• ID by Sequencing • Immunoassay of Transgene • Residual Host Cell DNA/RNA	• Plasmid and Vector Integrity
mRNA Drug Substance	• ID by Sequencing • Cell-Based Bioassay • dsRNA Detection • Residual DNA • Residual Protein • In Vitro Translation	• Length • Poly(A) Tail Length and Distribution • Capping Efficiency
mRNA Drug Product	• ID by Sequencing • Encapsulation Efficiency • Cell-Based Bioassay	• LNP and Lipid Content and Characterization • Adduct Characterization • Particle Sizing and Polydispersity

Cell-based Tx	Build out phase I	Build out phase II
Allogeneic and Autologous	• Cell Counting and Viability • Vector-Related Contaminants by qPCR • Phenotypic Characterization by Flow Cytometry • Mycoplasma testing by PCR • Adventitious virus detection by NGS	• Rapid Sterility • Lentivirus testing • Cat 3 testing laboratory
Additional Capabilities	• Recombinant Protein Expression (Flow, ELISA) • Potency Assays • Transgene Characterization • Clonogenicity Assays • Cell Differentiation and Characterization • Cell-Mediated Killing Assays	• Recombinant protein expression by chromatography methods

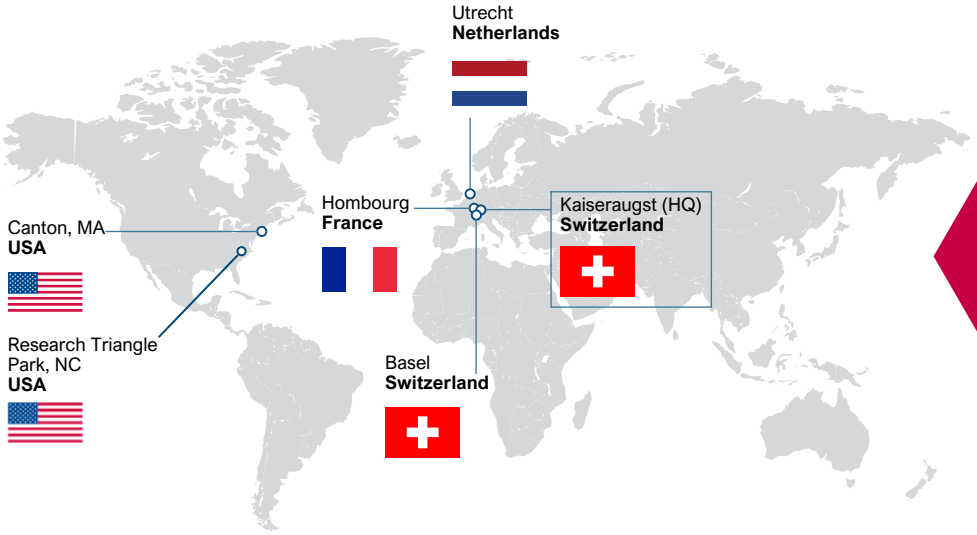
mAbs	Build out phase I	Build out phase II
mAb Drug Substance	• Appearance • pH • Color and Clarity • Protein Content (UV) • Binding Assay • Residual Host Cell DNA • Residual Host Cell Protein • Residual Protein A	• Purity by CE-SDS • SEC-UPLC • Bioburden
mAb Drug Product	• Appearance • pH • Osmolality • Protein Content (UV) • Binding Assay	• Extractable Volume • Sub-visible Particles • Purity by CE-SDS • SEC-UPLC • Sterility
Additional Capabilities	• Cell-based Bioassays • Cell Line Characterization • Genetic Stability	

Expansion Phases

Phase I: initial launch focused on cGMP release testing including cell-based potency and molecular assays.
Phase II: planned expansion to include additional capacity and capabilities like stability chambers and complex biophysical characterization.

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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