

# Monoclonal Antibodies & Antibody-Drug Conjugates

From Lab to Life-changing Therapies

Characterization and comparability

Method Development and Validation

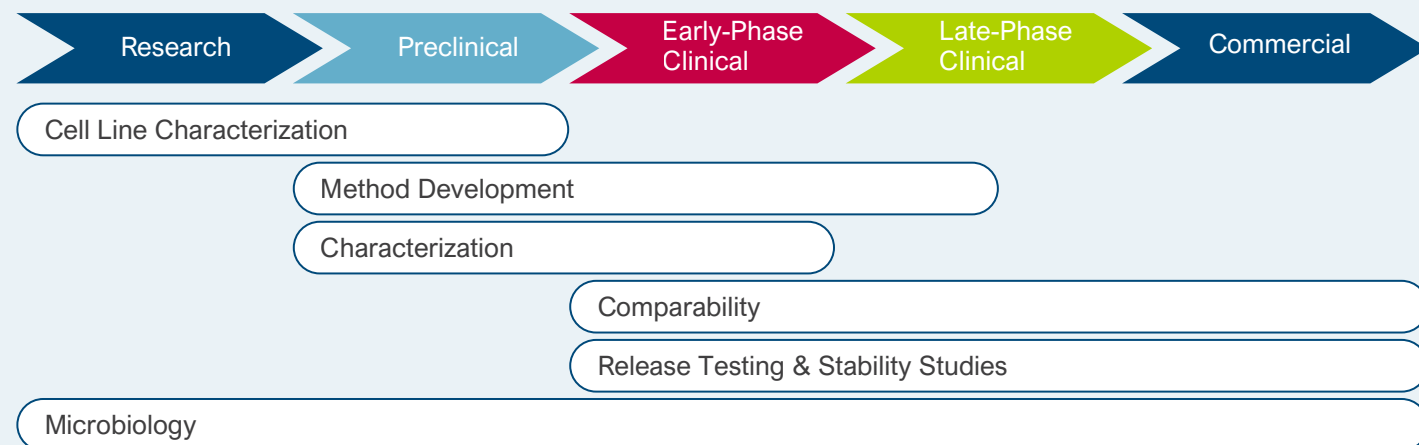
Comprehensive stability testing portfolio

Drug Substance & Drug Product Release Testing

**solvias** 

Navigate the complexity of mAbs and ADCs with Solvias' comprehensive array of innovative **testing solutions** to ensure the quality, safety, and effectiveness of your product.

### Solutions from Lab to Launch



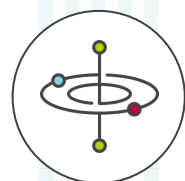
### Method Development and Validation

- ✓ Customizable analytical methods for flexibility and risk reduction.
- ✓ Orthogonal approaches for robustness.



### Genetic QC of CHO Cell Lines

- ✓ Cell Line Characterization: Ensure correct coding sequence.
- ✓ Monoclonality: Assure monoclonal derivation of MCB.
- ✓ Genetic Stability: Monitor genetic drift during production.



### Stability

- ✓ Stability-indicating methods validated for phase-appropriate testing.
- ✓ Comprehensive stability testing, including long-term and accelerated studies.



### Biosafety

- ✓ Sterile and non-sterile raw materials, cell bank, bulk harvest and product testing.



### Characterization and Comparability

<b>Primary Structure</b> <ul style="list-style-type: none"> <li>• PepMap</li> <li>• AAA (including extinction coefficient)</li> <li>• N-Terminal Sequencing</li> </ul>	<b>Higher Order Structure</b> <ul style="list-style-type: none"> <li>• CD (2nd structure)</li> <li>• DSC (thermal stability)</li> <li>• HDX</li> </ul>
<b>Heterogeneity and PTMs</b> <ul style="list-style-type: none"> <li>• PepMap PTM</li> <li>• Disulfide Mapping</li> <li>• Free Thiol</li> <li>• Carbohydrate Structure (N-/O-Glycans)</li> <li>• Conjugation Confirmation (site specific)</li> </ul>	<b>Charge heterogeneity</b> <ul style="list-style-type: none"> <li>• IEX</li> <li>• cIEF and cIEF-MS</li> <li>• CZE</li> </ul>
<b>Size heterogeneity</b> <ul style="list-style-type: none"> <li>• SEC or SEC-MALS (or AF4-MALS)</li> <li>• Intact Mass (incl. DAR ratio)</li> <li>• CE-SDS</li> <li>• AUC</li> </ul>	<b>Functionality</b> <ul style="list-style-type: none"> <li>• Cell-Based Bioassay</li> <li>• ELISA</li> <li>• SPR</li> </ul>
	<b>Purity</b> <ul style="list-style-type: none"> <li>• SEC</li> <li>• RP</li> </ul>

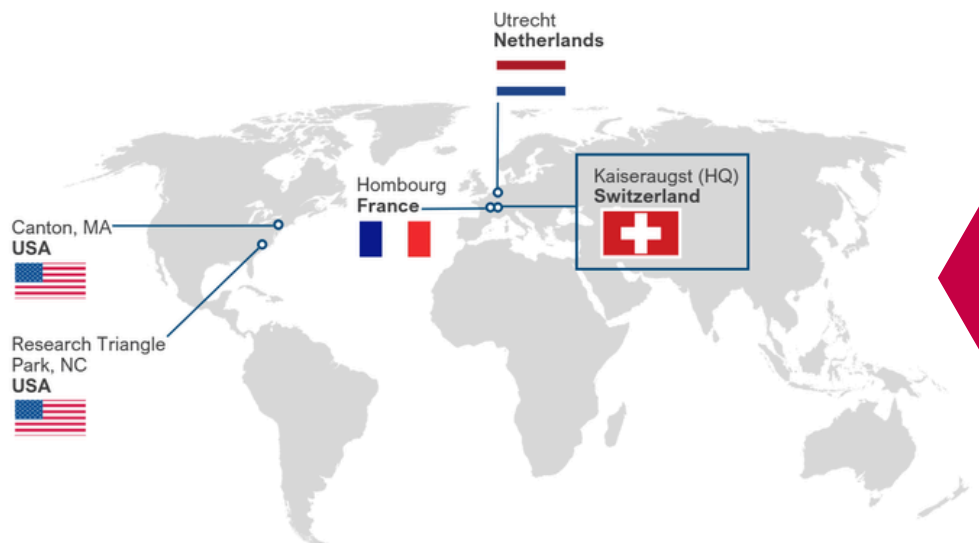


### Release Testing

<b>Identity</b> <ul style="list-style-type: none"> <li>• Sequence: PepMap</li> <li>• Charge: cIEF, CZE, IEX</li> <li>• Size: SEC, CE-SDS</li> </ul>	<b>Impurities &amp; Excipients</b> <ul style="list-style-type: none"> <li>• rProt. A by ELISA</li> <li>• rHCP by ELISA</li> <li>• rHC-DNA by qPCR</li> <li>• Elemental Impurities</li> <li>• Extractable &amp; Leachables</li> <li>• Tween</li> <li>• Antifoam / PDMS</li> <li>• Na+, Cl-</li> </ul>
<b>Potency</b> <ul style="list-style-type: none"> <li>• Binding ELISA</li> <li>• Cell-Based Bioassay</li> <li>• SPR</li> </ul>	
<b>Biosafety &amp; Microbiology</b> <ul style="list-style-type: none"> <li>• Bacterial Endotoxins</li> <li>• Bioburden</li> <li>• Sterility</li> </ul>	<b>Description</b> <ul style="list-style-type: none"> <li>• pH potentiometry</li> <li>• Conductivity</li> <li>• Degree of Coloration</li> <li>• Turbidity</li> <li>• Osmolality</li> <li>• Sub-Visible Particles (LO, MFI)</li> <li>• Visible Particles</li> </ul>
<b>Drug Antibody Ratio</b> <ul style="list-style-type: none"> <li>• HIC</li> <li>• LC-MS</li> </ul>	
<b>Primary Packaging</b> <ul style="list-style-type: none"> <li>• CCIT</li> <li>• Appearance of Container</li> </ul>	<b>Purity</b> <ul style="list-style-type: none"> <li>• Deamidation/Oxidation: gPepMap (UV/MS)</li> <li>• Charge: cIEF, CZE, IEX</li> <li>• Size: SEC, CE-SDS</li> <li>• Toxin: Free Toxin RPC</li> </ul>

## Why partner with us?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m<sup>2</sup> of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



Contact us to speak with  
an expert: [info@solvias.com](mailto:info@solvias.com)

  [solvias.com](https://www.solvias.com)

