

# Monoclonal Antibodies: From Lab to Life-changing Therapies

Deep expertise in monoclonal antibodies (mAbs) and antibody-drug conjugates (ADC) CMC testing from preclinical to commercial

Characterization and  
comparability

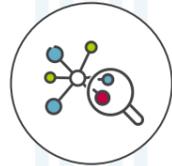
Method Development and  
Validation

Comprehensive stability  
testing portfolio

Drug Substance & Drug  
Product Release Testing

**solvias** 

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



### Characterization and Comparability

Our orthogonal approach to **structural analysis** enables the identification of potential issues in even the smallest changes. Our experts are also skilled in **PTM characterization**, charge variant identification, and cell-based phase-appropriate **potency assays**.

- ✓ Antibody-drug-conjugate (**ADC**) **characterization**: state-of-the-art LC-MS and workflows for accurate determination of the drug-to-antibody ratio (DAR), site of drug conjugation, drug characterization and protein conformation of your ADCs.



### Genetic QC of CHO Cell Lines

Ensure your CHO cell lines produce consistent and predictable expression of the therapeutic gene. Monitor whether genetic drift has occurred during production, determine vector copy number by ddPCR, and assess the probability of monoclonal derivation of your MCB.



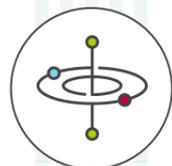
### Method Development and Validation

Broad tool kit of customizable, in-house developed analytical platform methods with an orthogonal approach for flexibility and risk reduction.



### Release Testing

Analytical testing for drug substance and drug product with a robust quality system ensuring late-stage and commercial release compliance. Our efficient processes enable a rapid turnaround time of as little as 10 weeks, helping eliminate supply chain bottlenecks.



### Stability

Comprehensive stability testing portfolio with ready capacity and E&L capabilities covering all major dosage forms and complex delivery systems.



### Biosafety

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

# Bring **your innovation** to its destination

## Unique Challenges of mAbs Development

The success of mAb therapies relies on their targeting precision, an element tied to structural and chemical integrity. However, the journey from lab to patient is fraught with stability challenges, spotlighting the critical role of advanced characterization and quality control. Solvias provides a comprehensive suite of **cGMP-compliant biologics CMC testing** services. Our unique blend of biological and physical-chemical testing paired with specialized services enables us to apply our deep expertise to the fastest-growing areas of biologics development.

## Cutting-Edge Technology

Solvias is at the forefront of mAb analytical services, keeping pace with the constantly evolving landscape of regulatory demands. Our commitment to excellence is demonstrated through our ongoing investment in cutting-edge analytical technology. This enables us to provide mAb data that is highly sensitive, accurate, and within the strict framework of cGMP compliance. Leveraging advanced techniques and our profound expertise, we offer best-in-class analytics, enabling our customers to ensure the safety and effectiveness of their drugs.

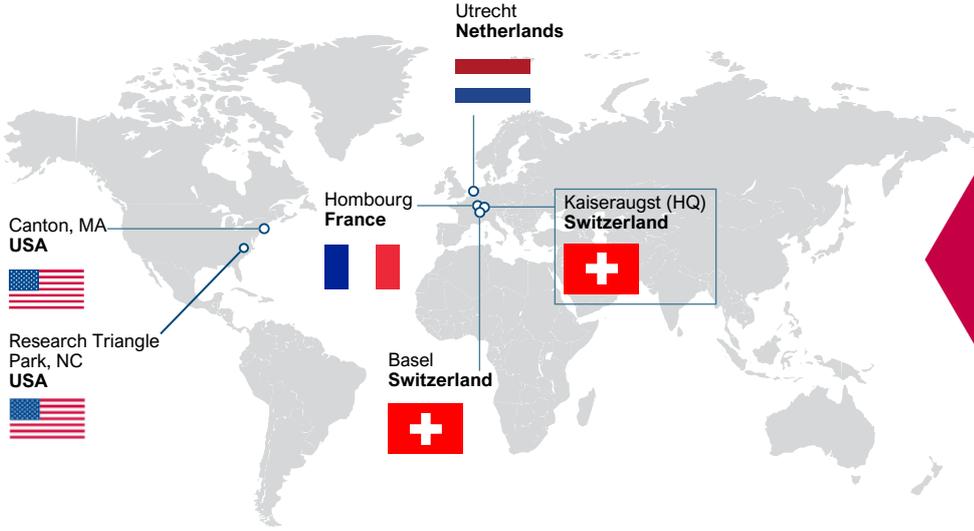
## Unparalleled Expertise

Our CMC testing offerings are rooted in a deep understanding of the critical quality attributes that impact biologics development, ensuring reliable, cost-effective solutions. You enjoy direct access to our subject matter experts and project managers. By keeping technology and testing capabilities in-house, we're able to provide accurate results rapidly, helping avoid costly program delays.



## 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](mailto:info@solvias.com)

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

