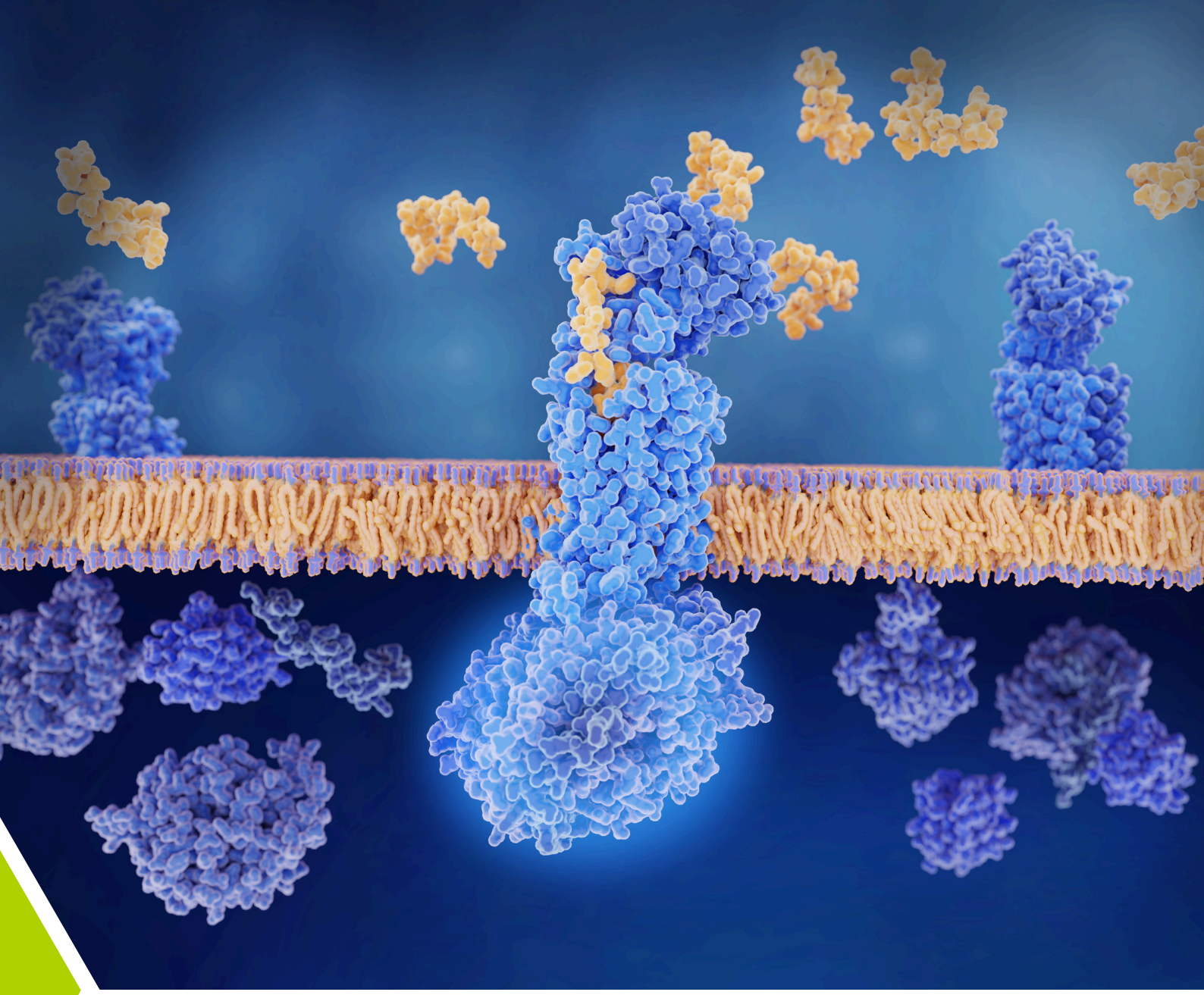


Analysis of Protein Biopharmaceuticals

cGMP-compliant CMC testing services to navigate biologics development challenges from preclinical to commercial stages

- Characterization and comparability
- Method Development and Validation
- Comprehensive stability testing portfolio
- Drug Substance & Drug Product Release Testing

solvias

Broad capabilities covering a variety of modalities

- ✓ **Monoclonal antibodies (mAbs)**
- ✓ **Antibody-drug conjugates (ADC)**
- ✓ **Protein conjugates (PEG)**
- ✓ **Recombinant proteins and glycoproteins**
- ✓ **Bispecifics**
- ✓ **Peptides**

Characterization and Comparability

Expert characterization team proficient in **primary and higher-order** structures, post-translational modifications (**PTMs**), charge variant identification, and phase-appropriate **potency assays**. Our orthogonal approach to structural analysis enables the identification of potential issues in even the smallest changes.

Method Development and Validation

Broad tool kit of customizable, in-house developed analytical platform methods with an orthogonal approach for flexibility and risk reduction. We document each method in SOPs for seamless execution at Solvias and easy transferability. Our validations, adhering to cGMP and ICH guidelines, cover critical parameters such as sensitivity, accuracy, linearity, and stability.

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 turnaround times as fast as 10 weeks. We also address requests from regulatory bodies during IND/BLA, using an orthogonal technology to confirm analytical data or to provide additional data.

Stability

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

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.

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

Meet every **challenge** with a Solvias **solution**

Cutting-Edge Technology

High-Resolution Mass Spectrometry (HRMS)

Essential for in-depth primary protein structure analysis, this advanced technology enables detailed primary protein structure analysis, including **peptide mapping** and precise identification of **site-specific disulfides and free thiols**. HRMS also precisely identifies a **wide range of post-translational modifications**, such as deamidation, oxidation, glycation, glycosylation, isomerization, single amino acid exchanges (SAAE), phosphorylation, and alterations in disulfide bridges, as well as truncations and modifications at the N- and C-terminals.

- ✓ **LC-MS:** Orbitrap, qTOF, Triple Quad
- ✓ **CE-MS:** cIEF-qTOF-MS, CZE-qTOF-MS
- ✓ **HDX-MS:** LEAP-PAL, Orbitrap-MS

Spectroscopy

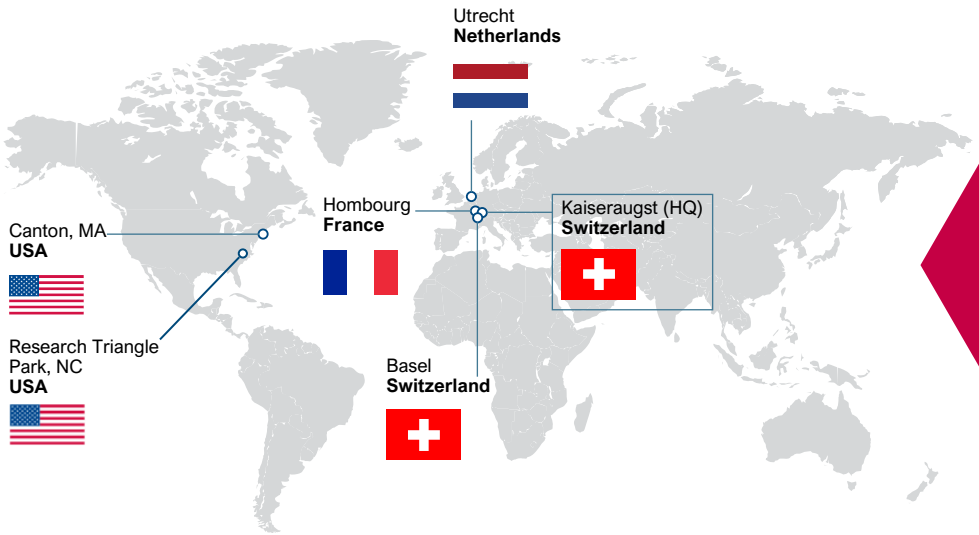
- ✓ CD
- ✓ FT-IR
- ✓ NMR
- ✓ DLS
- ✓ nDSC
- ✓ AUC
- ✓ SoloVPE UV
- ✓ Fluorescence Spectroscopy
- ✓ (SEC-/AF4-) MALS

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

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