

Monoclonal Antibodies & Antibody-Drug Conjugates

From Lab to Life-changing Therapies

Characterization and comparability

Method Development and Validation

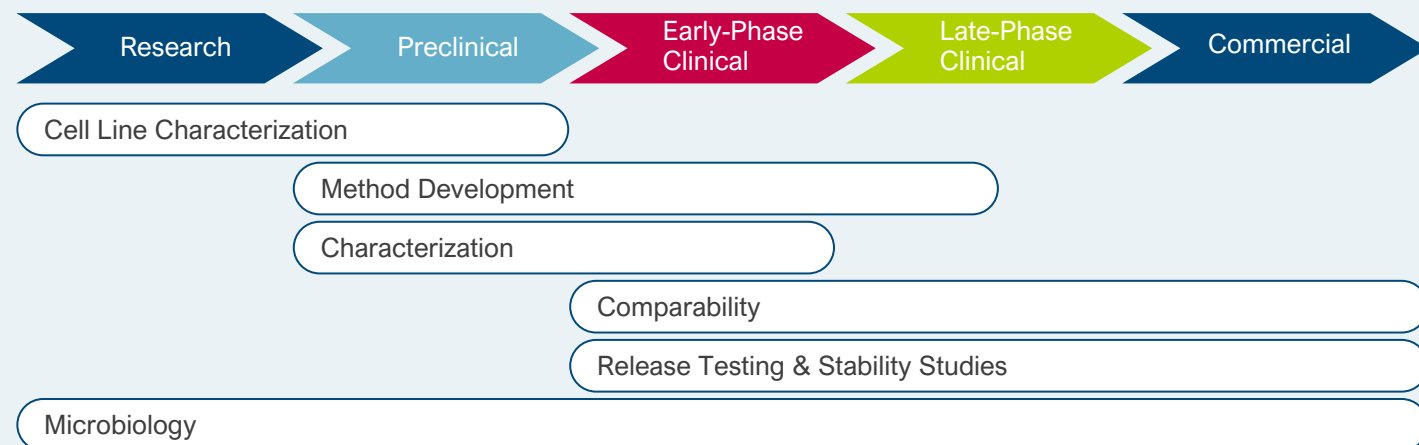
Comprehensive stability testing portfolio

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



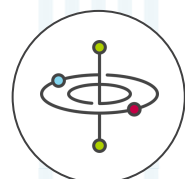
Method Development and Validation

- ✓ 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.



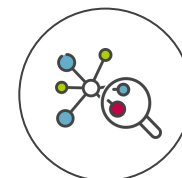
Stability

- ✓ 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

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



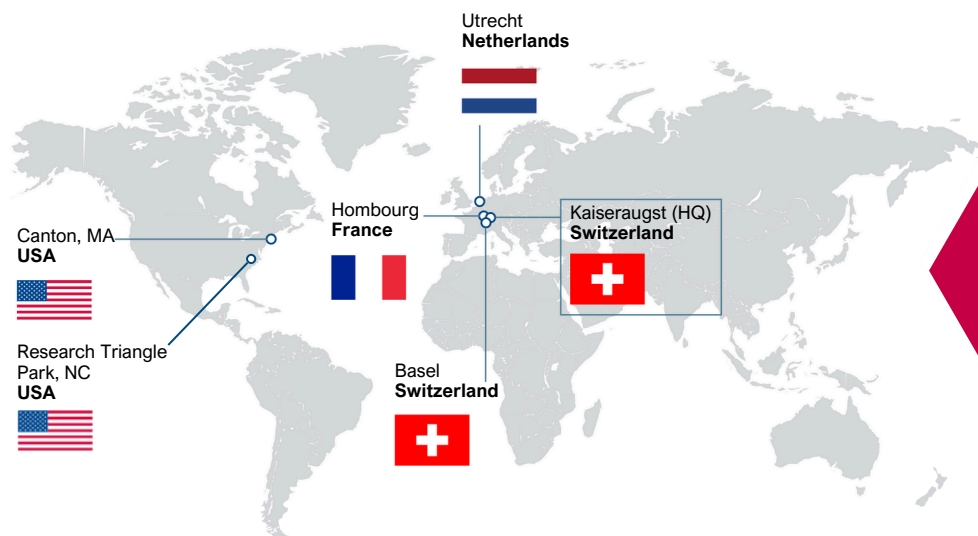
Release Testing

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



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- 175+ PhD-level scientists
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