

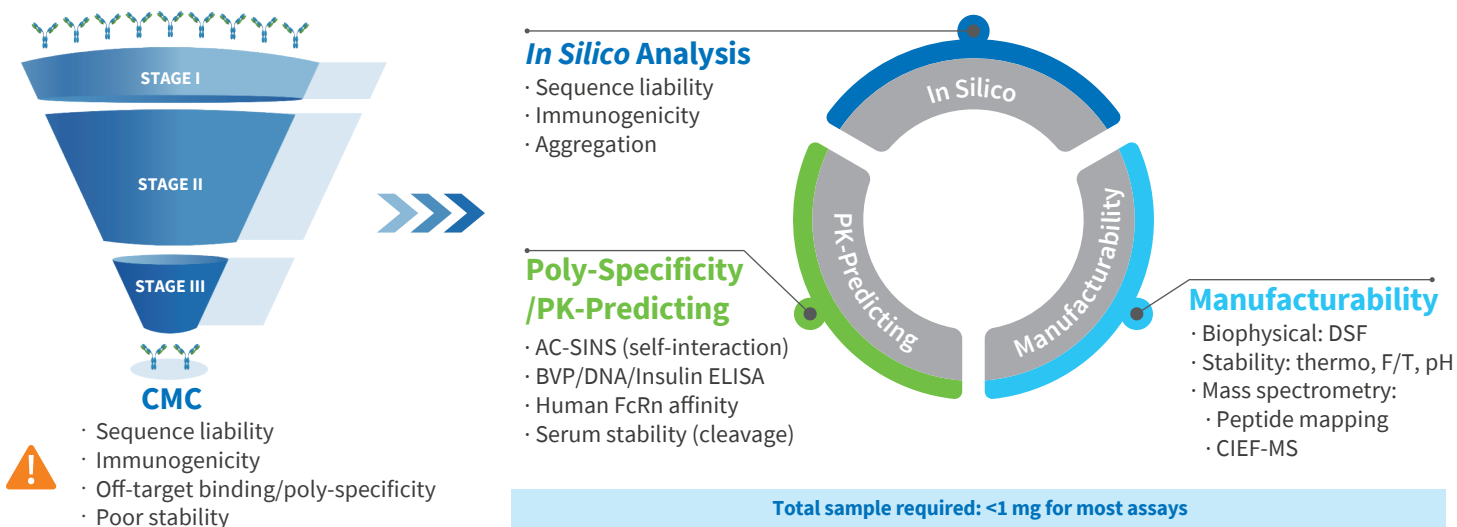
Early-Stage Developability Assessments for Lead Optimization

- *In Silico* Analysis
- Off-Target/PK-Assessment
- Mass Spec
- Biophysical
- Forced Degradation Studies

WuXi Biologics' Micro Developability Platform is specially designed to support early- to mid-stages of drug discovery, offering a suite of high-throughput (HTP), low-sample-consumption assays that can evaluate biophysical properties, PK, and manufacturability.

Developability is a Key Criteria

Early-stage screening for therapeutic antibodies often prioritizes binding affinity and function, while critical developability factors are frequently overlooked, leading to CMC and clinical challenges. WuXi Biologics has developed the Micro Developability platform, a HTP analytical suite that requires less than 1 mg of antibody. This platform utilizes HTP *in silico* screening and early-stage developability testing to assess biophysical properties, PK, and manufacturability. By analyzing critical developability aspects with expert interpretation, these early assessments help optimize leads, mitigate downstream risks, and facilitate a seamless transition to CMC development.



Features and Applications

Key Features of the Platform:

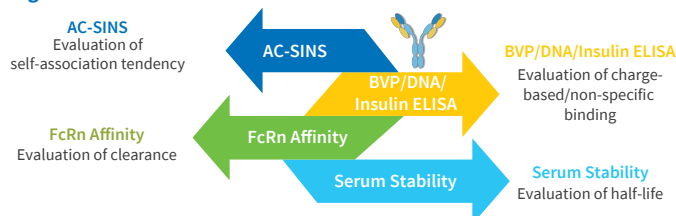
- Early stability assessments
- *In silico* analysis (Figure 1)
- Off-target/PK-assessment assays (Figure 2)
- Biophysical characterization
- Mass Spec analysis
- <1 mg protein needed
- HTP evaluation of many molecules at research stage

Figure 1

Liability	Aggregation	Immunogenicity
• Post-translational modification • CDR hotspots • Free cysteine • Fc mutation • Amino acid usage frequency	• Structure prediction • Hydrophobicity based • Free cysteine based	• Sequence similarity based • MHC based • Humanization

Sequence liability and CDR hotspot, aggregation, and immunogenicity

Figure 2

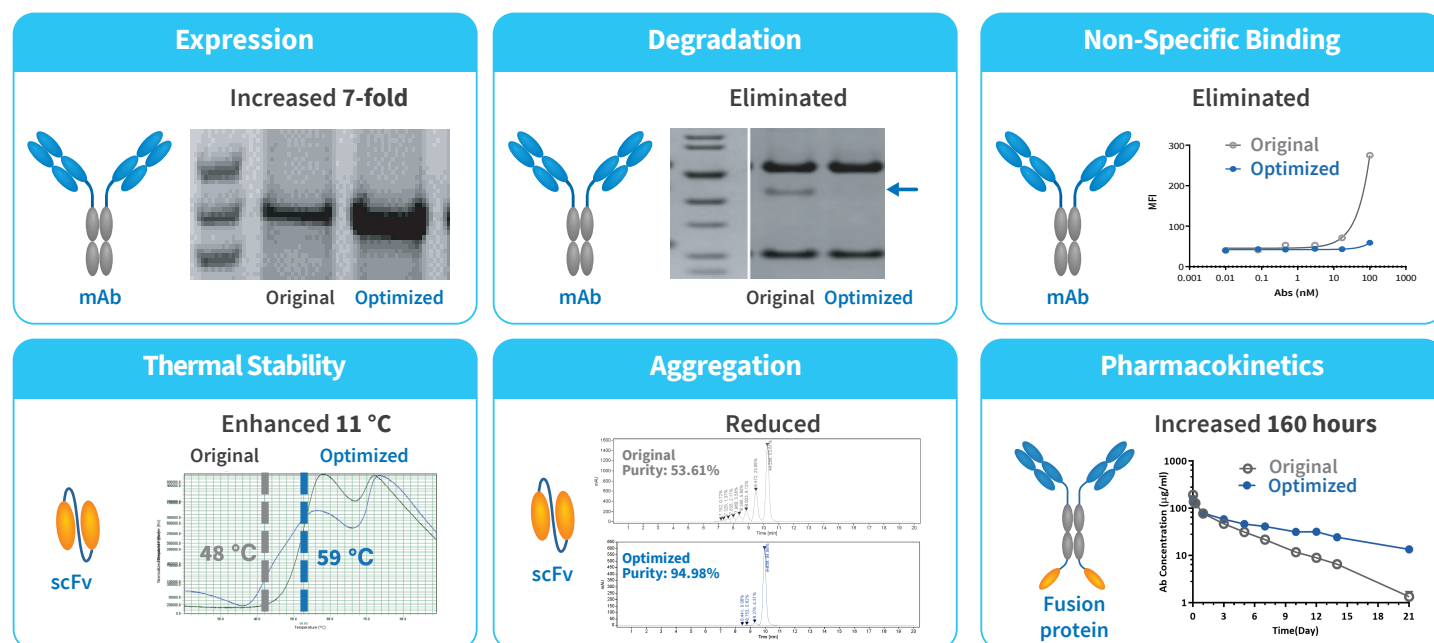


Micro Developability Evaluation Overview

Category	Method	Purpose / Analytical Focus
<i>In Silico</i> Analysis	Liability	Identifies potential liabilities such as PTMs, CDR hotspots, free cysteines, Fc mutations, and amino acid usage frequency
	Immunogenicity	Predicts immunogenic risk based on structural, hydrophobicity, and free cysteine-related factors
	Aggregation	Assesses aggregation risk based on sequence similarity, MHC binding, and humanization
Off-Target/PK-Assessment	AC-SINS and HIC	Measures self-interaction tendency
	BVP/DNA/Insulin ELISA	Evaluates charge-based/non-specific binding
	Human FcRn (BLI)	Assesses antibody clearance
	Serum susceptibility	Assesses serum stability and molecules' half-life
Biophysical	DSF/T _{agg}	Detects T _m , T _{agg}
	Solubility/Viscosity	For high-concentration molecules
	DLS	Measures particle size and polydispersity
Mass Spec	Intact Mass	Analyzes clipping variants
	CE-MS	Determines charge variants and heterogeneity
	Peptide mapping	Identifies PTMs
	Disulfide/Glycan	Characterizes disulfide bond and glycan profiles
Forced Degradation Studies	SEC	Monitors thermal stress, low pH, freeze/thaw stability
	iCIEF	Monitors thermal stress, low pH, freeze/thaw stability
	CE-SDS (NR/R)	Monitors thermal stress, low pH, freeze/thaw stability
	Peptide mapping	Monitors thermal stress, low pH, freeze/thaw stability
	SPR	Monitors thermal stress, low pH, freeze/thaw stability

Antibody Developability Optimization

With multiple successful cases, our team excels in developability optimization of challenging molecules. Below are select examples showcasing how our experts resolve early developability issues to enable optimal molecular properties for CMC development.



About WuXi Biologics CRO Services

WuXi Biologics is a leading global CRDMO, with the R represented by our premium-quality CRO Services. With expertise in diverse drug modalities, we deliver comprehensive research services, including antibody discovery, protein production and engineering, and *in vitro/in vivo* testing, to seamlessly advance our clients' molecules from concept to CMC development.

Drug Development Expertise Empowering Research Services for Biologics

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