

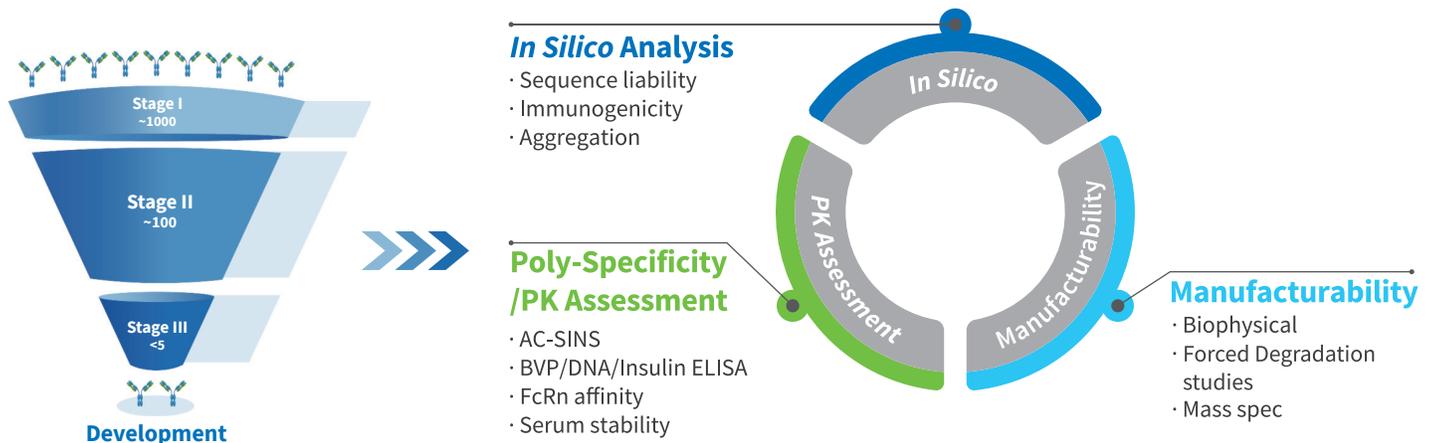
## Early-Stage Developability Assessments for Lead Optimization

- *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.



<1 mg of antibody for most assays in 2 weeks

### Features and Applications

#### Key Features of the Platform:

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

Figure 1

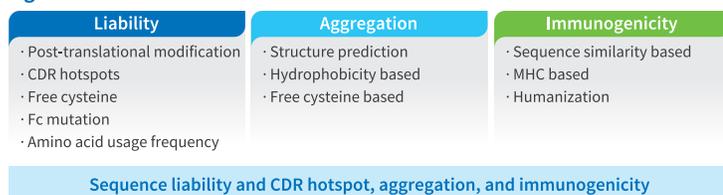
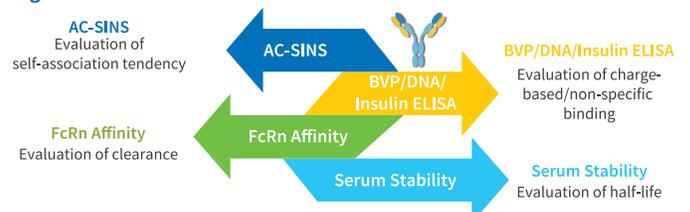


Figure 2

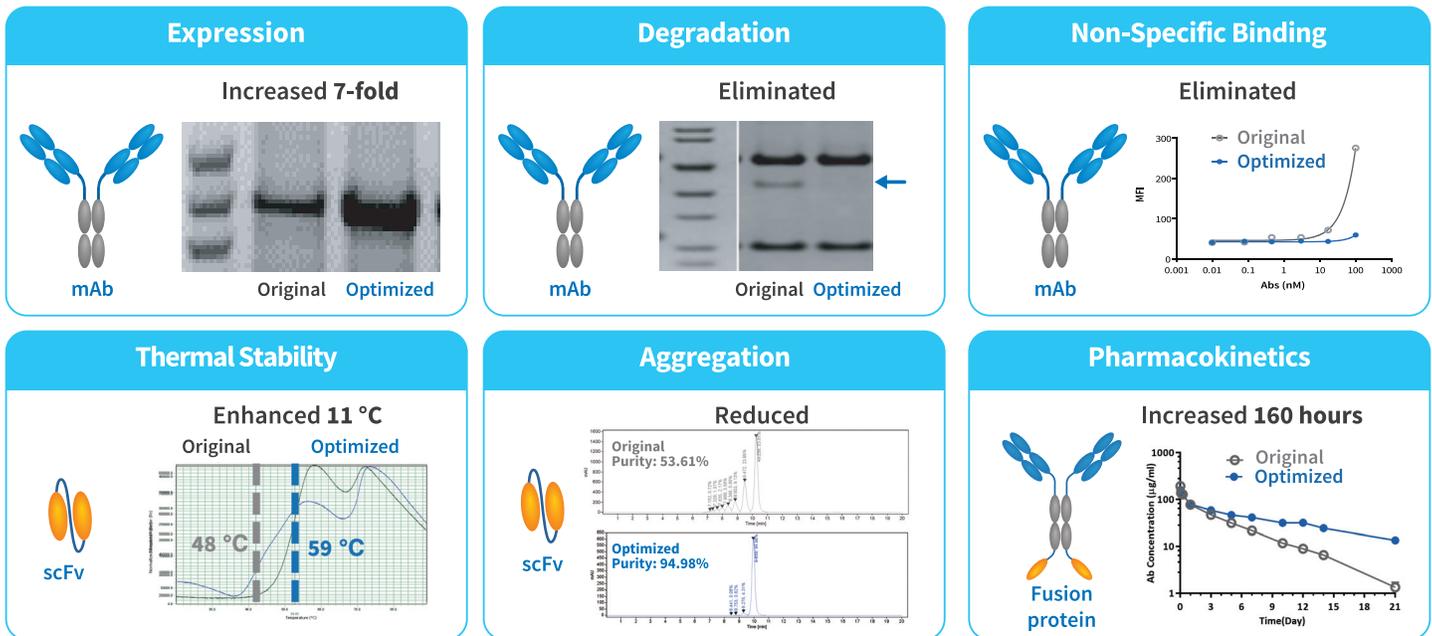


## Micro Developability Evaluation Overview

Category		Method	Purpose / Analytical Focus
In Silico Analysis		Liability	Identifies potential liabilities such as PTMs, CDR hotspots, free cysteines, Fc mutations, and amino acid usage frequency
		Aggregation	Predicts aggregation risk based on structural, hydrophobicity, and free cysteine-related factors
		Immunogenicity	Assesses immunogenic risk based on sequence similarity, MHC binding, and humanization
Poly-Specificity /PK-Assessment Assays		AC-SINS and HIC	Measures self-interaction tendency
		BVP/DNA/Insulin ELISA	Evaluates charge-based/non-specific binding
		FcRn affinity	Assesses antibody clearance
		Serum stability	Assesses serum stability and molecules' half-life
Manufacturability Assessment	Biophysical Characterization	DSF/T <sub>agg</sub>	Detects T <sub>m</sub> , T <sub>agg</sub>
		Solubility/Viscosity	For high-concentration molecules
		DLS	Measures particle size and polydispersity
	Mass Spectrometry	Intact MS	Analyzes clipping variants
		CIEF-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 Experience Empowering Research Services for Biologics

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