

Developability and Analytics

Industry-leading risk assessment data to enable effective clinical strategies

Despite widespread success in biologics development, there are significant challenges associated with therapeutics development, especially when liabilities are "discovered" during late-stage activities.

The developability of a drug protein candidate is a strong indicator whether it can be successfully developed into a viable drug. Since developability challenges can adversely impact production consistency, shipping and handling excursions, and long-term storage, it is increasingly important to perform developability assessment studies to overcome these risks and mitigate the risk of costly late-stage failures.



Aragen's expertise

Aragen's developability assessment expertise helps identify the physical and chemical properties of drug candidates, such as aggregation, post-translational modifications, stability and solubility that can negatively impact the safety, efficacy, manufacturability and ultimately the success of clinical candidates. Our approach combines in silico modelling, stress, stability and concentration tests.

Aragen's focus for developability is on:

- Efficient workflows, rigorous analyses and accelerated understanding of structure/function relationships
- Early risk assessment and mitigation
- Upstream and downstream alignment with modern platform processes

Aragen's developability process

Aragen's developability service enables data-driven decisions with methods that shed light onto structure/function relationships and potential critical quality attributes. Early assessment of risk allows for mitigation through reengineering or establishing control processes.



IMW: Intact molecular weight, SEC: Size exclusion chrom, CE: Capillary Electrophoresis, cIEF: Capillary Isoelectric focusing, DLS: Dynamic Light Scattering

With a broad range of analytical services and capabilities, we provide our clients the tools and understanding to achieve successful biologics characterization and process development in a phase-appropriate manner.

Analytical Characterization process

 Target research
(Target validation)
 Hit and lead
generation
"Candidate
source
 Lead optimization
"Candidate
Engineering"
 Pre-clinical
enabling
"Initiation of
Manufacturing"
 IND and
Clinic

Let's begin the conversation

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