

# Streamlining Analytical Development with LabZient™



## Innovative Analytical Development Platform for Complex Biologics & Bioconjugates

Abzena's LabZient™ analytical platform represents a pioneering approach in the field of analytical development, particularly for complex biologics such as immunoglobulins. Leveraging decades of analytical expertise, Abzena's new platform utilizes a series of optimized procedures, tailored to evaluate critical quality attributes (CQAs) across a wide spectrum of IgG1 and IgG4 subclass immunoglobulins.

## Expediting the Path to IND Through Advanced Methodologies

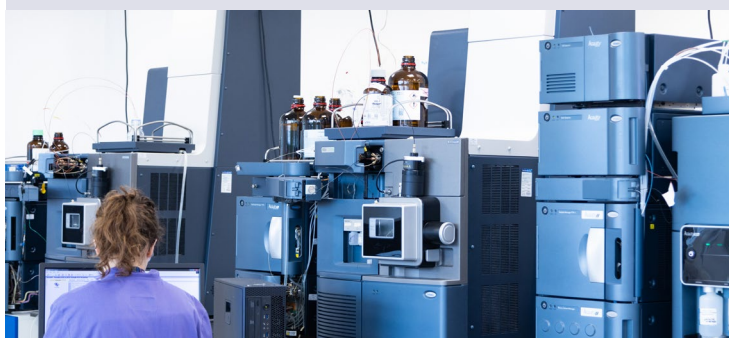
The LabZient™ platform enables a rapid path to Investigational New Drug (IND) applications by reducing the extensive testing traditionally necessary to demonstrate an analytical method's suitability. Leveraging the latest International Council for Harmonization (ICH) guidelines, LabZient™ focuses on multi-product methods, allowing for testing of various products without significant changes to operational conditions, system suitability, or reporting structure. This alignment with ICHQ2(R2) and ICHQ14 guidelines significantly reduces the need for extensive validation testing.

## Cutting-Edge Analytical Techniques Employed by LabZient™

LabZient™ incorporates advanced analytical techniques such as:

1. Size Exclusion High-Pressure Liquid Chromatography (SEHPLC) for protein aggregation detection.
2. Capillary Electrophoresis Sodium Dodecyl Sulfate Reduced and Non-Reduced (CESDSR and NR) for purity and identity assessments.
3. Imaged Capillary Isoelectric Focusing (icIEF) for purity, identity, and charge variant measurements.

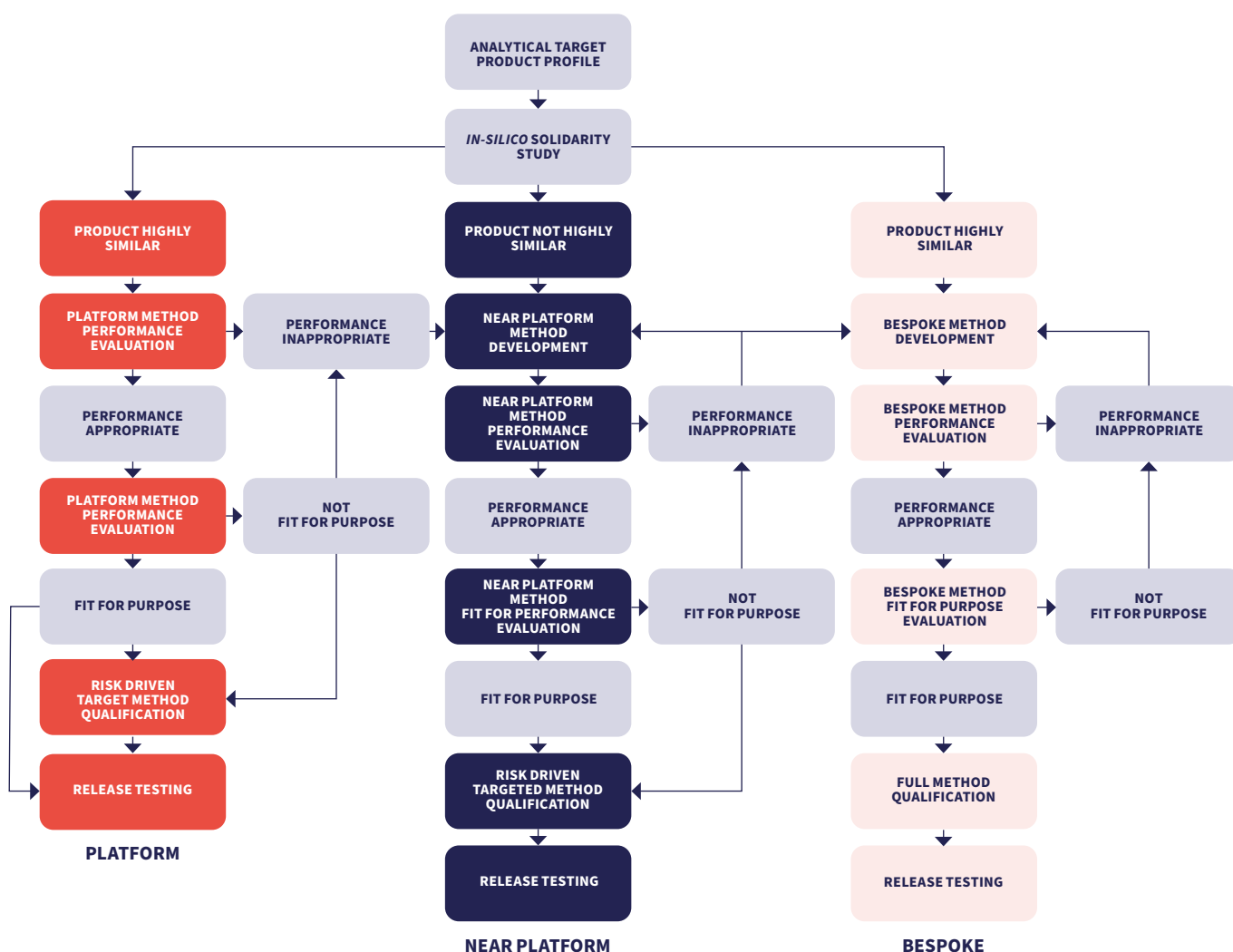
These methods have been validated with certified IgG standards, ensuring compliance with quality control standards and enabling an expedited analytical workflow.



## Operational Activities and Risk Mitigation

The platform begins with the technical transfer of pre-existing product-specific analytical data, if available. An Analytical Target Profile (ATP) is then drafted, outlining the desired performance of the analytical procedure and defining product-specific CQAs. This process includes a rigorous *in-silico* similarity assessment to compare the structural and physicochemical properties of the test antibody with previously validated IgG1/4 molecules, ensuring that the method is fit for purpose.

When the *in-silico* assessment indicates that the molecules under study differ significantly from the standard, or if the existing methods prove inadequate, we pivot to a more customized approach. This progression (illustrated in Figure 1) may involve tweaking existing methods or, when necessary, creating entirely new methods from the ground up to meet the unique requirements of the product. This flexible strategy ensures that our analytical methods are precisely tailored for the molecules they're intended to analyze, even when they deviate from the norm.



**Figure 1: LabZient™ Operational Workflow Chart.** This chart illustrates the operational workflow facilitated by the LabZient™ Analytical Platform. **Platform:** For products highly similar to standards, leading to a performance evaluation and potential fit-for-purpose qualification with minimal adjustments required. **Near Platform:** For products not highly similar, necessitating near-platform method development with more extensive evaluation and modification to methods. **Bespoke:** For products highly dissimilar, requiring bespoke method development and comprehensive method qualification.

Initial method performance evaluations are conducted with available test materials, followed by more comprehensive evaluations with scaled-up materials. This two-stage evaluation process provides an early understanding of method performance and a thorough fit-for-purpose assessment.

# Summary



LabZient™ by Abzena presents a breakthrough in analytical development for complex biologics, offering a cost-effective, efficient, and scientifically sound path to clinical trial readiness. By minimizing development time and streamlining the qualification and verification processes, LabZient™ sets a new standard in the field of biopharmaceutical analysis.

**Connect with our team of experts today to discover how LabZient™ can help streamline and de-risk your biopharmaceuticals' path to the clinic at [info@abzena.com](mailto:info@abzena.com) or [abzena.com](http://abzena.com).**

