

# Prolytix Biosimilar Services

The analytical assay requirements for a biosimilar are crucial to demonstrate its similarity to the reference biologic. These assays are designed to assess the physicochemical, biological, and functional characteristics of the biosimilar to ensure that it matches the reference product in terms of quality, safety, and efficacy. The key analytical assay requirements typically include:

**Biological Activity and Functional Assays**  
**Physicochemical Characterization**  
**Immunogenicity Assessment**  
**PK and PD Comparative Studies**  
**Stability Testing**  
**Comparison to the Originator**



## Why Chose Prolytix for Biosimilar Services?

- › **Comprehensive Testing Solutions**
- › **Regulatory Alignment and Collaboration**
- › **Unmatched Expertise**

## Comprehensive Bioanalytical and GMP Testing

- › **Advantage:** With 35+ years of protein chemistry experience, Prolytix is well-equipped to deliver in-depth analytical characterization, including structural, functional, and purity analysis, to demonstrate biosimilarity to reference biologics.
- › **Unique Value:** Phase-appropriate methods ensure compliance with regulatory expectations throughout the biosimilar lifecycle.

## Tailored Method Development and Validation

- › **Advantage:** Prolytix offers bespoke assay development tailored to biosimilar requirements, ensuring precise assessment of critical quality attributes (CQAs) such as potency, glycosylation, and aggregation.
- › **Unique Value:** Customized solutions reduce development timelines and risks while ensuring high-quality data for regulatory submissions.

## Immunogenicity Assessment Expertise

- › **Advantage:** Prolytix develops assays to detect anti-drug antibodies (ADA) and evaluate biosimilar immunogenicity, a critical component of regulatory approval.
- › **Unique Value:** End-to-end assay development ensures robust immunogenicity evaluation, reducing clinical risks.

## Support for Comparability and Interchangeability Studies

- › **Advantage:** Prolytix excels in comparability assessments to confirm biosimilarity and provides data for regulatory designation of interchangeability.
- › **Unique Value:** Expertise in regulatory guidance ensures alignment with FDA, EMA, and other global standards.

## Agile and Collaborative Approach

- › **Advantage:** Prolytix's consultative approach ensures close collaboration with clients to address specific biosimilar challenges.
- › **Unique Value:** Flexibility and responsiveness streamline decision-making and accelerate development timelines.

## Proven Expertise in Protein Characterization

- › **Advantage:** With 35+ years of protein chemistry experience, Prolytix is well-equipped to deliver in-depth analytical characterization, including structural, functional, and purity analysis, to demonstrate biosimilarity to reference biologics.
- › **Unique Value:** Phase-appropriate methods ensure compliance with regulatory expectations throughout the biosimilar lifecycle.

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