

Process Development, Analytical Development, & GMP Testing and Release Services

Choosing the appropriate analytical and bioanalytical CRO partner is critical to the success of your biotherapeutic drug development program. Selecting the wrong partner could delay timelines and increase costs, putting your innovation at risk. For large molecule and protein chemistry expertise to accelerate your drug development, go with the pro — Prolytix.

Release & Stability Testing

Prolytix provides GMP release and stability testing services in our FDA-inspected facility.

> Method Transfer and Validation

Ensure you demonstrate compliance through comprehensive validation studies aligned with your intended use for results that inform better decisions.

> Release Testing

Make confident decisions informed by robust methods, providing high-quality results on time.

> Life Cycle Management of Critical Reagents

Rely on uninterrupted testing of your biotherapeutics with critical reagents developed and maintained for the duration of your program.

Stability Testing and Storage

Manage your stability program from development through product approval with a wide range of ICH storage conditions and efficient sample management.

Why Prolytix?

As a boutique service provider, we focus on the unique needs of your project regardless of the stage of development. Our fully collaborative partnerships offer tailored solutions and quality data that help you efficiently bring safe and effective biotherapeutics to patients. At Prolytix, we understand the urgency to find solutions for patient populations hoping for lifesaving therapies. That is why we take great pride in delivering projects on time and within budget. At Prolytix, success is measured in customer satisfaction.

- > 35 years of experience
- > Agile, informed solutions
- > Protein chemistry expertise
- > Seamless in-house services
- A belief in transparency and collaboration
- An appreciation for urgency without sacrificing quality



Large Molecule Drug Discovery & Development Services

Prolytix advances the development of your product from discovery through GMP release with the agile support of our in-house scientists.

- Product Characterization
 Gain extensive insight into your protein with our suite of analytical and bioanalytical services using fast, accurate techniques, including HRMS.
- Determination of Critical Quality Attributes
 Efficiently take your product through preclinical and clinical trials with robust, rapid testing for critical quality attributes.

- Analytical Method Development
 Ensure the most appropriate analytical
 methods are developed to measure the
 attributes determined to be critical with the
 help of our scientific team.
- CMC Support Services
 (including Process
 Development Optimization)
 Isolate, purify, concentrate, and prepare for transfer and scale-up with a wide range of process development services.

Bioanalytical Method Development & Validation

Prolytix provides expert phase-appropriate services supporting preclinical and clinical activities.

- > Thrombin generation assays
- Neutralizing antibody assays
- > Relative potency

- > Anti-drug antibody assays
- > Pharmacokinetics



