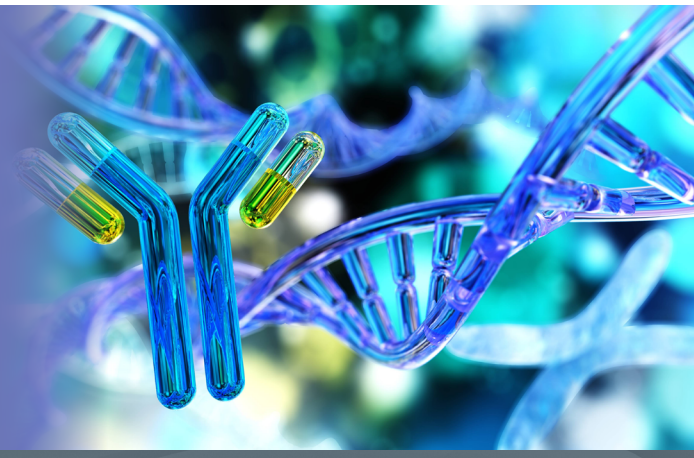
Clinical and Bioanalytical Biologics Experience & Expertise



Biologic therapies, such as antibodies, proteins and peptides as well as oligonucleotides, have far greater specificity than small molecule drugs. Their introduction as innovative drug modalities has led to significant advancements in the treatment of chronic conditions and have the potential to treat numerous human diseases that cannot be adequately treated with small molecule drugs.

Understanding the role biologic drugs can play in patient care, Celerion's team of clinical and bioanalytical experts can help optimize and expedite biologics studies to get your product to the market faster.

Clinical Experience

Celerion's clinical team have extensive ***experience with a broad range of biologics products***:

- Fusion proteins
- Monoclonal and polyclonal antibodies
- Oligonucleotides
- Peptides
- Polysaccharide derivative
- Recombinant proteins
- Vaccines

Our experience not only includes healthy volunteer studies but also extends to clinical pharmacology studies evaluating drug pharmacokinetics (PK) in specific populations, including older adults, participants with overweight/obesity, and patients with renal & hepatic impairment.

Celerion Differentiators:

Experience:

- Over 150 studies conducted with biologic therapies since 2010
- Healthy volunteer and special population study experience with a wide range of biologics

Expertise:

- Breadth of scientific biologics experience across clinical and bioanalytical personnel
- First-in-human and clinical pharmacology study support for biologic drug development

Efficiencies:

- State-of-the-art clinical and bioanalytical facilities in the US, UK and Europe
- Turnkey clinical and bioanalytical solutions for a wide range of biosimilar products

Bioanalytical Expertise

Celerion's state-of-the-art bioanalytical laboratories in Lincoln, NE, and Zurich, CH, are ***the most automated in the industry***.

Our approach is the strategic incorporation and use of bioanalytical laboratory automation to achieve controlled and error-free assays with improved accuracy, efficiency, and throughput. Our highly automated bioanalysis laboratories deliver:

- Enhanced consistency and data quality
- Higher sample throughput
- Real-time sample verification

Advantages of Our Clinical Pharmacology Unit and Co-Located Bioanalytical Lab

Immediate PBMC Processing and Analysis

– Optimized methods for high yields, viability and recovery
– Rapid assessment to support receptor occupancy analysis

Speedy Sample Analysis

– PK data availability to support dose escalation decisions
– Seamless and error-free data transfer via integrated computerized systems

Cost Savings

– No sample shipping fees
– Carbon-friendly option

Turnkey Biosimilar Development Solutions

Celerion can also support biosimilar drug development, leveraging our extensive biologics and innovator product experience for PK and pharmacodynamic (PD) studies.

Clinical Advantage for PK/PD Studies	Robust Assay Development	Scientific & Regulatory Support
✔ Highly-controlled Clinical Pharmacology Unit (CPU) using large cohorts to keep study variability to a minimum ✔ 650-bed capacity across our 3 CPUs in Belfast (UK), Lincoln (NE) and Phoenix (AZ) ✔ Uniform SOPs	✔ PK assays ✔ Anti-drug antibody (ADA) assays ✔ Neutralizing antibody assays (nAb) ✔ Cell-based assays	✔ Experienced team of pharmacokineticists, statisticians, Principal Investigators, medical writers and regulatory professionals ✔ Expertise in optimizing design to evaluate similarity that meet regulatory requirements

RESOURCES:

Key Clinical Pharmacology Studies to Support Biologic Drug Regulatory Submission

Clinical and Bioanaltyical Support for Monoclonal Antibody Drugs

Peptide Drugs: Clinical and Bioanalytical Drug Development

Clinical and Bioanalytical Oligonucleotide Experience and Expertise