

# Bioanalytical Sciences

Celerion is a global leader in regulated bioanalysis with a track record of over 40 years of scientific excellence in both of our sites. Our laboratories in Lincoln, Nebraska and Zürich, Switzerland support all phases of drug development with unmatched integration between clinical pharmacology units and bioanalytical laboratories. Our mission is simple: Deliver exceptional science with a proven record of regulatory compliance, and industry leading speed to accelerate our client's drug development and get drugs to patients faster.

- Insightful bioanalysis for pharmacokinetics and pharmacodynamics (PK/PD)
- Multi-tier immunogenicity testing experience
- Faster decisions with biomarkers
- Proven approaches in biosimilars
- Cell & gene therapy expertise
- Established strategies for complex small molecules
- Experience across all modern drug modalities
- Metabolite identification & profiling
- Fully automated workflows, implemented over 15 years



## WHAT SETS CELERION APART

### Speed with Accuracy

Fully integrated automated workflows, with barcode tracking, liquid handling and electronic laboratory notebooks (Labnotes) reduce human error and shorten timelines.

### Clinic-to-Lab Synergy

Co-located clinics and bioanalytical labs ensure rapid sample processing—critical for many PK, PD and flow cytometry timepoints.

### Fit-For-Purpose Biomarker Validation

From exploratory to full validation, our approach meets regulatory expectations while staying cost-effective and meeting intended context of use.

### Deep Scientific Expertise from the Entire Team

Every team member takes personal ownership of projects, acting as an extension of the in-house lab.

### Client Process Integration

Regular communication and project tracking are supported at every step through an integrated platform that provides accessible information on demand.

### Proven Regulatory Compliance

GLP/GCP-compliant and CLIA-certified facilities with a history of successful audits by global health authorities.

## CAPABILITIES & SERVICES

Celerion provides all possible bioanalytical services and requirements under one roof. From high-throughput PK analysis to personalized medicine assays, Celerion offers comprehensive bioanalytical solutions that support every stage of development, from pre-clinical studies to late-phase research.

### Pharmacokinetics

- Small & large molecule LC-MS/MS and Ligand Binding Assays (including radioimmunoassay, RIA)
- 40+ mass spectrometers, including SCIEX 7500+
- Cellular kinetics for cell therapies, using flow cytometry and qPCR

### Immunogenicity Assessment

- ADA assays (phase appropriate tiered testing)
- Cell-based and ligand-binding neutralization assays (NAb)
- Seroconversion, titer, competitive ligand binding, isotyping

### Biomarker Support

- Pharmacodynamic characterization assays and exploratory biomarkers
- Multiplex biomarker panels (MSD, Luminex, Simoa)
- Validation designed to meet the context of use
- CLIA certification for development of Laboratory Developed Tests (LDT)

### Bioanalytical Molecular and Cell Biology

- Flow cytometry (BD Fortessa)
- qPCR for protein expression, viral load and genotyping
- PBMC isolation network, ELISpot, T-cell immune response
- Ex-vivo stimulation for efficacy assays
- Receptor occupancy assays

### Metabolite Profiling & ID

- High Resolution MS with TripleTOF 6600+ systems
- Full service radiolabeled ADME studies

### Oligonucleotide & Peptide Bioanalysis

- Hybrid LBA-LC-MS/MS methods
- Hybridization Ligand Binding Assays
- Super sensitive quantitation of siRNA, ASOs, peptides
- Innovative assays for novel modalities

### Dose Formulation Analysis

- HPLC / PDA dose confirmatory analysis
- Radiometric detection for ADME studies
- Dose sterility and osmolality assessment



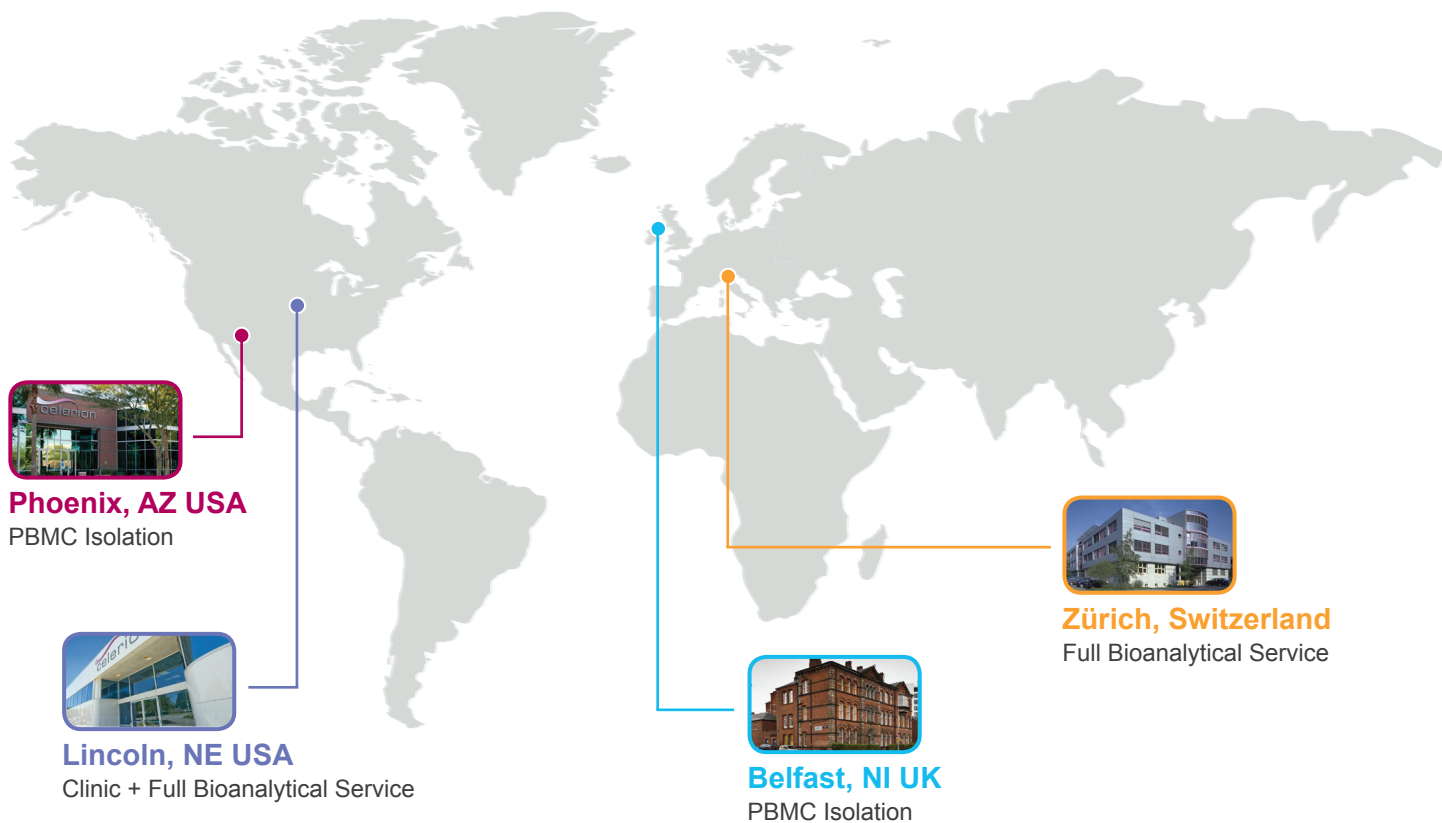
## ENABLING TECHNOLOGY

### Automation Platforms

- Hamilton Star/Starlet, Tecan Freedom EVO, Caliper Sciclone
- Fully integrated with Watson LIMS and Labnotes Electronic Laboratory Notebook (ELN)

### Instrumentation

- LC-MS/MS: SCIEX 7500+, 6500(+), 5500, 5000, 4000 with Waters Acquity UPLC
- Immunoassay: MSD, Gyros xPand, Simoa, AlphaLISA and ELISA
- Flow Cytometry: BD Fortessa (18 colors)
- qPCR: QuantStudio 5
- ELIspot: CTL Immunospot, BIOSYS Bioreader 4000



## GLOBAL LAB NETWORK

- **Lincoln, NE** – Global HQ | Co-located clinic + full service Bioanalytical Laboratory
- **Zürich, CH** – European Hub | full service Bioanalytical Laboratory
- **Belfast, UK & Phoenix, AZ** – Clinic + PBMC isolation sites and advanced sample processing

All locations use harmonized SOPs, LIMS (Watson), and Electronic Laboratory Notebook (LabsForm).

All labs are aligned through harmonized SOPs, shared training programs, validated LIMS and independent centralized QA.

## SPECIALTY EXPERIENCE AND THERAPEUTIC AREA HIGHLIGHTS

### Oncology

Expertise in antibody-drug conjugates (ADCs) with all needed bioanalytical platforms co-located for seamless, integrated support.

### Rare Diseases

Flexible, cost-conscious bioanalytical solutions designed for studies with limited patient populations.

### Infectious Diseases

BSL-2 facilities with experienced staff ensure safe handling and rapid turnaround for pathogen-related assays.

### Immunology

A long-standing partner in the evolution of immunological therapies—from early development to regulatory submission.

### Gene & Cell Therapy

End-to-end assay coverage including flow cytometry, ELISpot, qPCR, and molecular analysis tailored to complex modalities.

### Respiratory Disease

Close collaborations with specialized clinics enable access to hard-to-reach populations and disease-specific insights.

### Diabetes

Robust analytical platforms including LC-MS/MS and LBA (including RIA) support precise quantification of insulin and related biomarkers.

### Obesity

Extensive track record supporting the top obesity therapeutics with full bioanalytical coverage from discovery through approval.

### Renal & Hepatic Impairment

Established access to impaired populations through clinic networks and experience in complex matrix handling.

### Biosimilars

Proven support across many biosimilar programs with ADA, PK, and biomarker endpoints.

### Vaccines

Automated, high-throughput workflows under BSL-2 enable rapid, reliable immunogenicity and potency testing.

### Patient Centric Sampling

Proven expertise implementing patient centric sampling in clinical trials while maintaining analytical integrity.

## GET STARTED

Let our experts help accelerate your next study. With Celerion Science®, you gain a strategic partner who delivers both insight and execution.

### Celerion Science®

Personal scientific attention with a customized bioanalytical approach to rapidly deliver high-quality data.



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