

ANALYTICAL DEVELOPMENT & TESTING

Comprehensive Analytical Services to Accelerate Your Therapy to Market

Center for Breakthrough Medicines (CBM) is an advanced therapy CDMO dedicated to delivering life-changing treatments with our customers for the patients that need them. Our experienced team ensures safety, potency, purity, stability, and identity throughout product development and manufacturing, to meet key Regulatory requirements and ensure patient safety. Clients can leverage our testing capabilities as standalone services or integrated with manufacturing services on one campus without having to outsource to additional vendors. Services include analytical method development, method transfers, qualification, and validation.

INTEGRATED TESTING ON OUR SINGLE SITE

**100+**

Analytical Assays

**200,000+**

sq ft of Lab Space

**4**

Dedicated Lab Buildings

TESTING SERVICES

- Analytical Development, Method Qualification & Validation
- Compendial Testing & Environmental Monitoring
- Cell-Based Bioassays
- Molecular Biology
- Rapid Release Programs
- GMP Characterization, In-Process & Lot Release Testing
- Process Development and R&D Testing
- Sequencing
- Virology
- Stability Programs

THE CBM DIFFERENCE

Advanced Analytical Techniques

We offer next-generation sequencing, mass spectrometry, droplet digital PCR and digital PCR, measurement and characterization of empty, full, and partial capsids, and bioassays and potency packages.

Integrated Manufacturing & Testing

Testing capabilities support clinical and commercial programs from process development through drug substance manufacturing and drug product filling.

Customized Release Testing

Product release analytical testing panels are customized for each vector, nucleic acid, and cell therapy program.

Bioassays & Potency Package

We offer cell-based bioassays across multiple cell lines to measure infectivity and potency, including custom development of both expression and mechanism of action-based potency methods.

Expert Team & Partners

The CBM team has direct, hands-on experience bringing the first cell and gene therapies to market at top-tier innovators and CDMOs, and our academic partners are pioneers in the field.

Flexible Ways of Working

We are willing to put skin in the game with flexible capacity usage and milestone-based arrangements.