KBI BIOPHARMA

The world's most innovative biopharma companies count on KBI Biopharma to develop and manufacture their life-changing biologics.

Corporate Overview

Global CDMO service provider since 2004

500+ Clients serving biotech and pharma

8 Locations across the US and Europe

AWARD-WINNING CDMO SERVICES

We operate four high-growth CDMO business units, impacting the lives of millions of patients:

Analytics **Mammalian** **Microbial** **Cell Therapy**

KBI offers 18 years of pressure-tested quality systems and regulatory compliance. Our global cGMP quality system supports clinical and commercial biologics with our team of experts manufacturing and releasing hundreds of cGMP product lots.

MAMMALIAN CLD, PD, AND MANUFACTURING

KBI and Selexis provide cell line transfection through cGMP drug manufacturing with Selexis' specialized high-titer mammalian cell line development technologies and services and KBI's cGMP bulk drug manufacturing for clinical and commercial requirements.

Established track record of success

- 60+ fully integrated clinical development programs
- 190+ PD programs
- 200+ cGMP batches
- 15+ annual INDs supported

Single-use production trains

- 12x2000L

SELEXIS®

KBI BIOPHARMA

PIONEERING GLOBAL ANALYTICAL SERVICES

As the industry-leader in protein analytics, we emphasize high-value analytics across our entire offering.

Extensive formulation experience on more than 100 unique molecules with concentration ranges from 1-300 mg/ml

3300+ projects completed

Industry-leading large molecule particle characterization capabilities

MICROBIAL PD & MANUFACTURING

Our team's unique expertise enables the expression of "difficult-to-refold" products.

- **Two existing commercial programs**
- **Full program development from CLD to tox material generation**
- **Clinical supply**
- **Process Characterization/ PPQ**
- **Licensed by FDA and PMDA for commercial production**
- **Multiple scales available**
  - 2000L stainless steel
  - 300L single-use technologies
  - 100L stainless steel
- **Capacity available**

CELL THERAPY HIGHLIGHTS

Our extensive immunotherapy experience and industry-leading analytical characterization capabilities deliver robust processes to advance cell therapies into the clinic.

- **We offer comprehensive services for autologous and allogeneic cell therapy products:**
  - Process and analytical development
  - Ph I/II cGMP manufacturing capabilities
  - Clinical specimen logistics
  - Regulatory support for IND and CMC
  - Cell-based assay development

USA, COLORADO

BOULDER, Microbial

- Strain Development
- Process & Analytical Development
- cGMP Manufacturing & QC Services
- Analytical, Formulation, Stability
- Particle Characterization Core
- Modeling and Simulation

LOUISVILLE, Analytical

- Analytical Technologies
- Leading Biophysical Characterization

USA, NORTH CAROLINA

CORPORATE HQ, Mammalian

- Clinical and Commercial cGMP Manufacturing
- Analytical, Formulation, Stability & QC Mass Spec Core Facility
- Dedicated Cell-Based Assay Labs

VENTURE CENTER, Mammalian

- Process & Analytical Development
- Process Characterization DOE
- Cell Line Development-Including SURE*technology*™

PATRIOT PARK, Mammalian, Commercial Manufacturing Facility

- Mammalian cGMP Manufacturing
- 6x2k Flexible Process Trains for Campaign Production

EUROPE, BELGIUM

LEUVEN, Analytical

- Analytical, Formulation & QC Services for cGMP & non-cGMP Product Testing
- Cell-Based Assay Lab

USA, TEXAS

THE WOODLANDS, Cell Therapy

- Process & Analytical Development
- cGMP Manufacturing & Testing
- Cell-Based Assays

EUROPE, SWITZERLAND

GENEVA, Mammalian
Co-located with SELEXIS®

- Selexis Cell Line Development: Best-in-class CHO-M SURE*technology*™
- Process Development
- Clinical cGMP Manufacturing
- Drug Product Stability Testing

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