KBI BIOPHARMA

KBI Analytics and Formulation Sciences, A Partner That Grows with You

Your Program. Faster. Simpler. Smarter.

Accelerate Your Progress with Proven Scientific Expertise

When your program demands precise answers, our over two decades of experience tackling complex challenges deliver rapid, dependable results powered by profound scientific expertise.

Your analytical challenges demand comprehensive lifecycle support with customized solutions. Whether addressing complex analytical problems or minimizing regulatory risk, our established history—including successful regulatory inspections—bolsters your confidence to move forward.

25%

More than 25% of our team hold advanced degrees (Master's and PhD), and specialize in formulation development, mass spectrometry, biophysical characterization, cell-based assays, protein binding, and particle forensics.

50%

Notably, **over 50%** of the top ten CDMOs rely on us for specialized support.

Streamline your workflow with our secure online portal, allowing you to request quotes, ship samples, track progress, and access results within days to weeks, with expedited testing available for urgent needs.

U.S. Based Facilities with Proven Regulatory Excellence

Gain confidence in compliance with our industry-leading regulatory expertise ensuring inspection-ready operations. Work with a trusted provider operating in 5 U.S. based facilities and one in Geneva, Switzerland.

Mi

Microbial Regulatory Expertise:
Secured product approval and site licensure for two commercial products. Successfully navigated four FDA Inspections, one MHRA (UK) Inspection, and one PMDA (Japan) Inspection. Support 8-10 INDs annually.

Ma

Mammalian Regulatory Expertise:
Achieved product approval and site licensure for one commercial product with two additional molecules in PPQ for 2025. Completed seven FDA inspections, one PMDA (Japan) Inspection, one MFDS (Korea), and three EMA inspections. Support 10-15 INDs annually.

Empower your decision making, and watch your ideas grow with our Secure Online Portal

Drive informed decisions and accelerate your program's success through our intuitive online portal to explore tailored solutions, from rapid testing to full-scale characterization, all designed to meet your project needs with precision and efficiency.

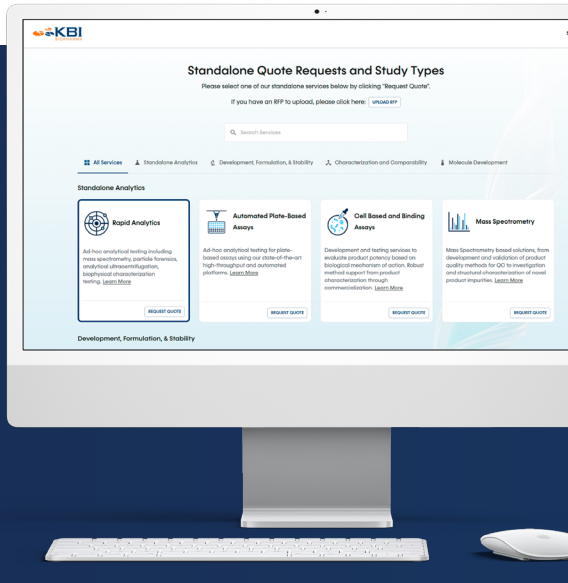
- Testing and full characterization of large molecule biologics, peptides, oligonucleotides, and AAVs.
- Developability and manufacturability assessments.
- Pre-formulation/formulation development.
- Clinical in use/ Pharmacy manual studies.
- Non-GMP and GMP release and stability including reference material, bulk drug substance (BDS), and drug product (DP).
- IND and BLA enabling characterization such as elucidation of structure and evaluation of criticality of attributes, degradation pathways and mechanism of action evaluation.
- Particle forensic analysis within 24 hours for critical insights.
- GMP AUC services, Binding technologies (Biacore, Octet).
- Polysorbate degradation studies (utilizing MS, ELSD or CAD) for precise analysis.
- Innovative Mass Spectrometry: Host cell protein (HCP) identification and quantification, process reagent clearance, and spent media analysis.

Automation and Innovation:

- Streamlined non-GMP testing platform.
- LIMS and ELN Software: Enhanced data management and traceability.
- Sciex Biophase 8800: High-throughput capillary electrophoresis.
- Advanced Analytical Tools: digital PCR, automated ELISA, oligosaccharide mapping, sialic acid and monosaccharide composition analysis.
- High-Throughput Platforms: Plate-based assays and HPLC with fully automated liquid handling for reliable, reproducible data.
- Extensive stability services at customizable and ICH-compliant studies, with shelf-life determination and trending.
- Establishment of QTPP and analytical control strategy.
- Cell-Based Assay (CBA) Lab: BSL-2 compliant, with expertise in assay development, optimization, qualification, validation, and stability testing. Equipped with detectors including Spectramax-L, FACS Lyric, Cytoflex, M3, M2, i3x, and MSD plate readers.
- ADC Testing: Comprehensive suite for antibody-drug conjugates.
- Lyophilization Development: Pre-formulation and cycle optimization for enhanced product stability.

Clarity Drives Confidence

True confidence stems from transparency and control. Our secure online portal centralizes all tools and data, ensuring you stay informed and empowered throughout your project. Fewer emails. No guesswork. **A faster, simpler, smarter way to move your program forward.**



Get In Touch

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