ABC Laboratories, Inc.

Analytical Bio-Chemistry (ABC) Laboratories, Inc.
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NUMBER OF EMPLOYEES
420

DATE FOUNDED
1968

CORPORATE CAPABILITIES

Corporate Description
Analytical Bio-Chemistry (ABC) Laboratories, Inc. is a privately held Contract Research Organization that provides expert development and analytical testing services to the pharmaceutical, biotech, animal health and chemical industries. The company supports all stages of large and small molecule drug development with a broad range of analytical support, custom synthesis and radiolabeling, environmental assessments and expert development consulting services. ABC employs more than 400 scientists and support personnel in three locations, and has its headquarters in Columbia, Missouri.

Markets served
Pharmaceutical and bio-pharmaceutical companies, animal health and medical devices

Major Products/Services
Biotech Services (Large Molecule)
- Pre-IND immunoassay method optimization and validation
- Biomarker analytical development and validation
- IND and clinical bioanalytical support
- Method feasibility, development, validation and transfer
- ICH Stability testing of bulk and finished products for IND/CTA/NDA submissions
- Biopharmaceutical product characterization
- Biopharmaceutical product testing
- Batch release testing
- Forced degradation studies
- CMC support for regulatory submissions

Pre-Clinical Development Services
- In-vitro and in-vivo DMPK
- Metabolite ID and quantification
- Toxicology dose formulation analysis
- Method development & validation
- Toxicokinetics
- Pharmacokinetic & bioavailability studies

Clinical Development
- Method development and validation
- Human mass balance
- Dose formulation and bioanalytical testing/sample analysis Phase I–IV
- Bioequivalency testing
- Drug interference testing
- Clinical supply kits

Chemistry, Manufacturing & Controls
- Analytical method development
- Method validation
- Impurity ID & characterization
- Analytical support reformulation/formulation
- Raw material, component testing/COAs
- Reference standard qualification
- ICH stability programs
- Extractables/leachables programs
- Batch release testing
- Bioequivalency testing

Custom Synthesis & Radiolabeling
- Custom synthesis (API)
- Radio-label synthesis (CGMP and non-CGMP)
- Stable-label synthesis
- Reference standard synthesis and CoAs

Environmental Assessments

Facilities
ABC Laboratories operates in a modern 90,000 square foot pharmaceutical development facility located in the Discovery Ridge Research Park in Columbia, Missouri. The facility was designed for optimal sample flow, operational efficiency, safety and regulatory compliance.

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