

Pharmalytica Services

POWERFUL SOLUTIONS

Pharmalytica Services
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Vital Statistics

Year Founded: 2000

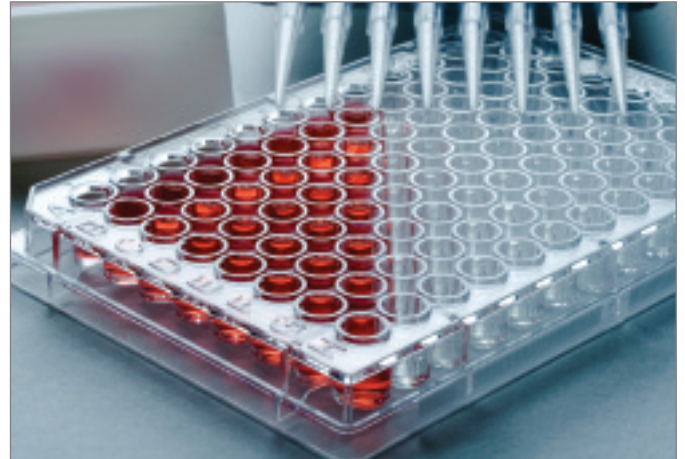
Key Personnel: James R. Scull, Ph.D., executive director and managing member; Richard C. Wedlich, MS, vice president, quality assurance; David Z. Chen, Ph.D., vice president, analytical R&D; Kurt L. Moyer, Ph.D., Director, Analytical and Bioanalysis.

Who We Are

PHARMALYTICA SERVICES, LLC is a GLP & GMP compliant contract analytical laboratory that provides testing and consulting to the pharmaceutical industry. Our company is founded on the principles of conducting rigorous science under the highest standards of quality and compliance. The members of our leadership team offer a wide array of experience in pharmaceutical development. We are dedicated to using that experience and expertise to partner with our clients to offer powerful solutions to their most challenging problems.

Major Markets

PHARMALYTICA'S CLIENT BASE INCLUDES small and mid-sized pharmaceutical, targeted therapeutic/diagnostic and medical device companies throughout North America and Europe. Our focus is on providing complete IND and NDA CMC Submission packages for those clients seeking FDA and global approval. Our facility, located near Hartford, CT, is equipped with state-of-the-art instrumentation and a staff of scientific professionals dedicated to the success of our clients' projects. Our facility is also DEA licensed to store and test controlled substances Class I thru V.



Services Offered

PHARMALYTICA IS AN FDA-REGISTERED, DEA-licensed, GLP & GMP compliant analytical laboratory offering method development and validation, full drug characterization, extractables/leachables testing, dissolution, particle size determination and excipient release testing. Our stability storage and testing programs offer the full range of FDA & ICH conditions and are designed to meet global submission requirements.

Our GLP analytical and bioanalysis laboratory offers GLP test article characterization, formulation stability and concentration verification, parent and metabolite ID and quantitation, metabolic pathway elucidation, as well as, method development and validation in support of both clinical and non-clinical studies.

Pharmalytica also provides GLP/GMP training and consulting services.

www.pharmalytica.com

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Visit Us at These Conferences

Meet Us

- CMC Analytical Services**
 - Method Development and Validation
 - Stability Storage and Testing
 - Subsistence & Leachables
 - Drug Characterization
 - Parent Material Testing
- Clinical Services**
 - Clinical Trial Services
- Pre-Clinical GLP Services**
 - IND/ANDA IND/ANDAs/INDs
 - Pharmacokinetic Analysis
 - Bioanalysis
 - Pre-Clinical Formulation Development
- EDC GLP Services**
 - EDC Facility Services
 - Subsistence Characterization
 - Pre-Clinical Formulation Development
- Consulting & Training**
 - Regulatory Consulting
 - CMC Consulting & Training
 - GLP Consulting & Training

GLP and GMP Compliant Laboratories
FDA-Registered and DEA-Licensed

About Pharmalytica Services

Pharmalytica Services provides accurate, timely, safe and cost-efficient contract analytical and manufacturing services to pharmaceutical and chemical industry clients. Our laboratories operate under full GLP and GMP compliance, are FDA registered and inspected and are DEA licensed to handle, store and test Controlled Substances (Schedule I thru V).

• Oligonucleotide & Assay Analysis

We are a single source provider for your Drug Substance CMC section of your IND/CTA, NDANMA, DMF or ANDA; we provide a full range of CMC analytical services, including global stability programs, method development and validation, new material release, drug substance and impurity characterization. In addition, we are a single source analytical provider for your Drug Product CMC section of your IND/CTA, NDANMA, or ANDA.

We offer both PAK-to-human and Biobioequivalency clinical