



Labshire, LLC Profile

Overview

- » We excel in delivering laboratory expertise in design, development, safety and operations- Boston based but global reach: Offices in Boston, MA (US); Melbourne, Australia (APAC)
- » Our clients include pre-clinical, emerging, established, and multinational companies
- » We help companies achieve important objectives by bridging the gap between sound strategy and reliable execution
- » We assist clients with the transition from scientific and technical excellence to business and commercial success

Our Clients Benefit From...

Extensive Expertise

- Benefit from the collective knowledge, experience, and judgment of our consultants

Direct Access to Decision-makers

- Engage directly with our leadership and senior consultants, ensuring personalized attention

Commitment to Excellence

- We are dedicated to delivering superior services, consistently aiming to exceed your expectations

Economical Execution

- Cost-effective solutions without compromising quality

We Are Your Partner in Excellence...

Strategic and Tactical Laboratory Services

- Laboratory strategic road map
- Assessment of regulatory requirements for current and future operations
- Quality system implementation and remediation
- Internal audits
- Test methodology and instrument assessment
- Determination of space requirements
- Optimization of workflow and personnel requirements
- Design of laboratory floor plans and work flows
- Relocation and start-up site assessment
- User Requirement Specifications (URS) for facility, instrumentation, and IT
- Contracting negotiations and vendor oversight
- Procurement and logistics

Technical

- Physical, Chemical, and Biohazard risk assessment
- BSL, 1, 2, 3 compliance
- Permitting
- Hazardous chemical storage and management
- Hazardous waste storage and management
- Information Technology assessment and design
 - Infrastructure planning covering cloud, on-premise, and hybrid solutions
 - Laboratory Information Management Systems [LIMS/LIS]

Laboratory Development

- Laboratory review and redesign to achieve operational and technical optimization
- Design, construction, and start-up oversight of your new laboratory
- Strategic planning from initial technology review through feasibility studies to final plans
- Risk assessments of your operation and for safety

Operational and Functional Support

- Integration and optimization of risk, quality, and utility Management activities
- Systems and process mapping to standardize and optimize your laboratory's operations.
- Integration of facility, equipment, materials, and supply management
- Design, Installation, Operational, and Performance Qualification of laboratory instruments
- Personnel training, education, and competency testing
- Asset and inventory management
- Document management and templates
- Development of policies, procedures, and forms

Regulatory Compliance

- Laboratory developed test (LDT compliance and gap assessment)
- Gap and risk assessments and remediation
- Title 42 CFR Part 493 for CLIA; 21 CFR Part 58: GLP for Non-Clinical Laboratory Studies. 21 CFR Part 11: Electronic Records; Electronic Signatures
- ISO15189: Medical laboratories – Requirements for quality and competence
- HIPPA

Why go it alone?

Our team is ready to assist you at any stage and prepared to tackle the most challenging demands!