



Lab Insights, LLC

Bringing insights to your laboratory

Your trusted partner in all aspects of the Clinical Lab

Small and medium sized clinical laboratories confront all sorts of challenges. From laboratory operations and quality management to IT infrastructure and laboratory information systems, your lab can benefit from having on-demand expertise without the overhead of additional senior management employees.



Lab Insights, LLC provides business analysis, training, and data management services, just to name a few. We also partner with a select list of trusted experts in the industry to provide even more services at a reasonable cost, delivering value to our customers.

To learn more, visit us at www.labinsightsllc/contact or email jessenia@labinsightsllc.com.



We help companies of all sizes establish and improve Quality Management Systems based on:

CLIA

CLSI

COLA

ISO 9001

College of American Pathologists (CAP)

FDA Medical Devices



Additionally, we provide an assessment of your compliance program based on Office of Inspector General (OIG) and Department of Justice (DOJ) guidance.

We can teach your organization how to utilize the latest technologies to design dynamic, innovative solutions built to scale with your business, while limiting the need for additional resources. Our risk-based approach to quality management and compliance has a proven track record for success.

We are committed to being your laboratory's long-term partner for quality and compliance-related services. Our staff is detail-oriented, and create high-quality and professional documentation. Below is list of some of our long-term services.

QMS Analysis

CLIA and State Application Documentation

Auditing and Monitoring Program Establishment

Assay Development and Validation

Training Program Guidance

Process Improvement Analysis

CLIA/CAP/COLA/NY State Inspection Readiness Audits

Document Control and Training Assessment Process Development

Board Of Directors and Compliance Committee Report Design

Compliance Reporting Mechanisms and Exclusion Checks Development

SOP Creation and Revisions

Incident Management Establishment



We perform on-site physical and technical audits and provide training to ensure compliance to latest Health Insurance Portability and Accountability Act (HIPAA) regulations. This includes compliance with the [Privacy Rule](#) and [Security Rule](#), the [Breach Notification Rule](#), and the [Enforcement Rule \(HITECH\)](#).

On-site and remote training are also available for the following subjects:

Individual Security and Privacy Competency

Individual Security and Privacy Awareness

Organizational Security and Privacy

Advanced Training for Security and Privacy Officers

Breach Notification

Business Associate

