CovarsaDx®
Advancing Clinical Research

# QUALITY SERVICES

Whether you're entering the U.S. market, expanding manufacturing, or preparing for clinical trials, having the right quality systems in place is essential. But navigating the U.S. regulatory environment isn't easy. FDA processes are complex, inspections are routine, and even minor gaps in Good Clinical, Laboratory, or Manufacturing Practices can stall your progress.

Many teams run into the same pitfalls: assuming ISO certification is enough, delaying quality planning until it's too late, or operating with incomplete systems that don't meet FDA requirements.

That's where CovarsaDx® comes in. We partner with diagnostic and medical device innovators to build, maintain, and monitor quality systems that are inspection-ready at every stage.


QUALITY ISN'T JUST ABOUT COMPLIANCE.

**IT'S HOW YOU MOVE FORWARD.**

## SUPPORT AT EVERY STAGE OF THE PRODUCT LIFECYCLE

### SET-UP | LAY THE GROUNDWORK FOR REGULATORY SUCCESS

- FDA-compliant Quality Management System (QMS)design, gap analysis, and SOP development
- Digital QMS support, including eQMS selection and setup
- Team training on FDA, ISO, and EU quality standards

### SUSTAINMENT | KEEP YOUR SYSTEMS STRONG AND AUDIT-READY

- Internal audits, mock inspections, and CAPA tracking
- Validation of equipment, processes, software, and cleaning
- Supplier qualification, monitoring, and document control

### POST-APPROVAL MONITORING & COMPLIANCE | SUPPORT BEYOND LAUNCH

- FDA inspection prep, response, and remediation
- Complaint handling, medical device reporting/adverse event reporting, and recalls
- Post-market surveillance, CLIA QMS support, and ongoing improvement

**LET'S CONNECT**

**SCAN THE QR CODE TO LEARN MORE OR EMAIL US AT STUDIES@COVARSADX.COM**

**Your work is important. Let's make sure it's moving in the right direction—with quality built in from the start.**

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