

Rigor, velocity, and readiness for life sciences.

Qualiss Solutions · Pharmaceutical & Life Sciences Advisory

Strategic consultancy for complex operating environments

LOGY
INSTITUTE





ABOUT QUALISS SOLUTIONS

Built for the realities of modern pharma

We help life-science organizations make complex work more rigorous, efficient, and ready for what comes next.

As pharmaceutical development accelerates and global compliance mandates evolve, organizations need more than high-level advice. Qualiss Solutions brings hands-on senior expertise to strengthen quality architectures, de-risk regulatory pathways, and build operating foundations that endure inspection and scale.

Pragmatic advisory · Senior oversight · Inspection readiness

CAPABILITIES

Four pillars of specialized advisory

REGULATORY

Regulatory & Quality Strategy

GXP compliance frameworks, inspection readiness audits, submission roadmaps, and proactive risk remediation across global health authorities.

CLINICAL

Clinical & Pharmacovigilance

Safety surveillance design, signal management, clinical trial quality assurance, and trial sponsor oversight protocols that withstand audit.

OPERATIONS

Operational Readiness & Process

Lean laboratory workflows, tech transfer acceleration, Deviation/CAPA cycle-time reduction, and scalable commercial launch readiness.

DIGITAL

Technology & Compliance Data

Validation of computerized systems (CSV/CSA), data integrity governance, QMS modernization, and digital transformation for audit trails.

PRACTICE LEADERSHIP

Senior expertise across the product lifecycle



[Leader Name]

Managing Partner · Quality & GXP

20+ years steering global QMS architecture, FDA/EMA inspections, and remediation.



[Leader Name]

Partner · Regulatory Affairs

Led cross-functional IND/NDA submission strategies and agency interactions.



[Leader Name]

Head of Clinical & Safety Practice

Former PV director overseeing global safety registries and sponsor QA governance.



[Leader Name]

Principal · Operations & Systems

Specialist in manufacturing tech transfer, validation, and digital QMS platforms.

HOW WE ENGAGE

Turning high-stakes complexity into lasting progress

01

Assessment & Diagnosis

We rapidly uncover friction, audit vulnerability, and process bottlenecks across systems, data flows, and team interfaces without disrupting ongoing trials or batch releases.

02

Program Design & Implementation

We engineer practical roadmaps, revised SOPs, and governance models calibrated to current stage, resource realities, and impending regulatory milestones.

03

Capability Building & Sustained Value

We mentor internal functional owners, establish clear operational metrics, and institutionalize behaviors that remain inspection-ready long after our team exits.

SECTOR FOCUS

INDUSTRY WE SERVE

- Pharmaceutical companies
- Biotechnology and emerging life sciences
- Medical device and diagnostics organizations
- Contract research and manufacturing partners



THE QUALISS ADVANTAGE

Why life-science leaders partner with us

Pharma context paired with practical delivery

Solutions shaped around each client's operating reality

Senior-level collaboration across disciplines

Clear communication from strategy through execution

OUR METHODOLOGY

A structured, collaborative path to results

Five phases de-risk delivery and build lasting internal ownership.

01 **Listen & Define**

Uncover underlying drivers, strategic intent, and regulatory stakes.

03 **Design Roadmap**

Co-create prioritized, pragmatic implementation milestones.

05 **Measure & Sustain**

Track performance metrics and secure enduring audit readiness.

02 **Assess & Prioritize**

Examine current workflows, systems, and evidence gaps.

04 **Embed Change**

Work shoulder-to-shoulder with internal teams to operationalize tools.

JOIN OUR TEAM

Solve meaningful challenges in life sciences

Experienced, curious professionals: help improve how life-science organizations work.

Open Positions

[Add open roles: Senior Regulatory Strategist, QMS Quality Lead, Clinical Compliance Consultant]

Our Culture

Autonomous ownership, high scientific curiosity, collaborative debate, and absolute professional integrity.

How to Apply

[Add application route: Send CV & project summary to careers@qualiss-solutions.example]



START THE CONVERSATION

Let's discuss your next milestone.

Whether facing an audit,
scaling a clinical trial, or
modernizing quality
systems, our team is
ready to help.

WEBSITE [Add website]

EMAIL [Add email]

PHONE [Add phone]

LOCATION [Add location]

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