

QUALITY & REGULATORY ASSESSMENT

*Reduce and Eliminate
Administrative Waste*

*Accelerate Execution,
Protect the Business*

*Build a winning, best-in-class
Quality & Regulatory team*

*Build Benchmark
QR Processes*



AGENDA (2 DAYS ONSITE)

2-DAY AGENDA	DESCRIPTION
DAY 1: Discovery & Process Mapping	• Kickoff & Alignment – Clarify objectives, scope, and success criteria • Org Structure & Role Review – Understand QR team structure and accountability • Strategy Deployment Review – Assess alignment between QR strategy and execution • Process Walks (Key Workstreams) – Map workflows, identify bottlenecks and waste • Compliance & Audit Readiness – Review audit history, metrics, and regulatory risks • Preliminary Insights & Quick Wins – Identify early opportunities for impact • End-of-Day Alignment – Confirm Day 2 focus and data needs
DAY 2: Deep Dive & Action Planning	• CAPA Process Review – Evaluate issue identification, tracking, and resolution • Continuous Improvement Opportunities – Identify waste, inefficiencies, and gaps • Tech & Automation Assessment – Review QR systems, tools, and digital maturity • KPI & Metric Alignment – Validate metrics and linkage to business performance • Action Plan Development – Prioritize initiatives and define next steps • Leadership Debrief – Present findings, recommendations, and roadmap forward



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OPERATIONS
A LEAN FOCUS PRACTICE AREA

QUALITY & REGULATORY ASSESSMENT

Is Your Quality & Regulatory Function Driving Results—or Just Checking Boxes?

A **Quality & Regulatory (QR) Assessment** provides a comprehensive and objective evaluation of your Quality and Regulatory functions and their ability to support business performance, ensure compliance, and drive operational efficiency. Through in-person interviews, process walks, and cross-functional reviews, we assess your current-state capabilities using standardized Lean methodologies and benchmarks from best-in-class organizations. The assessment identifies inefficiencies, risks, and improvement opportunities—culminating in a clear, actionable roadmap to streamline execution, reduce administrative burden, and elevate your QR processes to a strategic enabler of growth.

RAPID QUALITY & REGULATORY ASSESSMENT DELIVERABLES

QR Assessment™ Deliverables

- **Comprehensive Current-State Assessment** of your Quality & Regulatory processes, systems, structure, and performance
- **Identification of Gaps, Waste, and Risks** across key workflows, compliance activities, and cross-functional interfaces
- **Benchmark Comparison** to best-in-class practices in quality, compliance, and operational efficiency
- **Prioritized List of Improvement Opportunities** tied to potential impact, including quick wins and strategic fixes
- **Actionable Roadmap & Recommendations** outlining next steps, supporting tools, and areas for targeted Kaizen events



REQUEST A CONSULT:
INFO@LEANFOCUS.COM

How do I get started?

Schedule a Quality & Regulatory Assessment

Take the first step toward transforming your Quality and Regulatory function. Contact us today to schedule a consultation and discover how a **QR Assessment™** can streamline compliance, eliminate waste, and elevate performance across your organization.



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