



Quality Systems, Supplier Quality & Regulatory Excellence

Professional Services & Corporate Brochure

TOLO Consulting LLC



QUALITY SYSTEMS

Stronger Systems.
Sustainable Compliance.



SUPPLIER QUALITY

Better Suppliers.
Better Performance.



REGULATORY EXCELLENCE

Reduced Risk.
Inspection Ready.



OPERATIONAL EXCELLENCE

Efficient Processes.
Measurable Results.



CONTINUOUS IMPROVEMENT

Data-Driven Decisions.
Long-Term Value.



CONSULTING LLC

MEET YOUR CONSULTANT

Anthony Oler

Quality Systems, Supplier Quality & Regulatory Excellence

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STRONGER COMPLIANCE

Build and maintain robust quality systems that meet regulatory requirements.



SUPPLIER QUALITY EXCELLENCE

Improve supplier performance, reduce risk, and strengthen supply chain quality.



REGULATORY READINESS

Prepare for FDA inspections and audits with confidence and audit-ready systems.



OPERATIONAL EXCELLENCE

Improve processes, reduce defects, and drive measurable business results.



CONTINUOUS IMPROVEMENT

Use data-driven insights to drive sustainable quality and long-term success.



QUALITY. COMPLIANCE. PERFORMANCE. RESULTS.

Helping organizations achieve excellence through quality systems, supplier performance, and regulatory compliance.



EXECUTIVE SUMMARY



TOLO Consulting LLC provides expert Quality Systems consulting services to medical device, biotechnology, pharmaceutical, and manufacturing organizations. We help clients strengthen quality management systems, improve supplier performance, ensure regulatory compliance, and achieve operational excellence.



TOLO Consulting combines deep quality and regulatory expertise with practical, hands-on solutions that deliver measurable results. We partner with organizations to remediate quality systems, enhance supplier quality, prepare for inspections, and drive continuous improvement across the enterprise.



Our experience spans FDA remediation, ISO 13485 compliance, supplier quality engineering, CAPA leadership, risk management, design controls, validation, internal auditing, and operational excellence initiatives.



Whether your goal is to strengthen quality systems, reduce regulatory risk, improve supplier performance, or achieve inspection readiness, **TOLO Consulting** delivers senior-level expertise and proven results.



QUALITY. COMPLIANCE. SUPPLIER EXCELLENCE. RESULTS.

Helping organizations build stronger quality systems, improve supplier performance, and achieve regulatory excellence.

WHAT CLIENTS GAIN



Stronger Compliance

Build and maintain quality systems that meet regulatory requirements.



Reduced Regulatory Risk

Proactive risk management and inspection readiness reduce the likelihood of compliance issues.



Improved Quality Performance

Improve processes, reduce defects, and drive measurable quality results.



Supplier Quality Excellence

Strengthen supplier performance, reduce risk, and build stronger supplier relationships.



Operational Efficiency

Optimize processes and reduce waste to improve productivity and cost effectiveness.



Better Data & Visibility

Leverage quality metrics and dashboards to drive data-informed decisions.



Continuous Improvement

Implement CAPA, corrective actions, and process improvements that drive sustainable results.



Inspection Readiness

Be prepared for FDA inspections, audits, and global regulatory assessments.



Senior-Level Expertise

Work directly with an experienced consultant who delivers hands-on leadership and results.

WHY TOLO CONSULTING



Why Clients Choose TOLO Consulting

- Clients partner with TOLO Consulting because quality, compliance, and supplier performance are mission-critical to their success.
- We bring more than 15 years of hands-on experience leading quality systems, supplier quality engineering, and regulatory initiatives in medical device, biotechnology, pharmaceutical, and manufacturing organizations.
- Every engagement is personally led by a senior consultant, providing clients with direct access to executive-level expertise and practical solutions that deliver measurable results.



Our Approach

TOLO Consulting aligns quality strategy, compliance requirements, and operational excellence to help clients:

- ✓ Strengthen quality systems
- ✓ Improve supplier performance
- ✓ Ensure regulatory compliance
- ✓ Reduce quality risk
- ✓ Prepare for inspections
- ✓ Improve operational efficiency
- ✓ Drive continuous improvement
- ✓ Enhance product quality
- ✓ Optimize processes
- ✓ Achieve measurable results

Unlike firms that begin with software or tools, TOLO begins with your business objectives—ensuring every solution supports long-term quality, compliance, and operational success.



QUALITY. COMPLIANCE. PERFORMANCE. RESULTS.
Delivering practical solutions that drive quality excellence, reduce risk, and create measurable business impact.



TOLO BY THE NUMBERS



15+

YEARS CONSULTING

Providing senior-level quality and supplier quality leadership and consulting since 2008.



10+

QUALITY & REGULATORY ENGAGEMENTS ANNUALLY

Supporting organizations across medical device, biotech, pharmaceutical, and manufacturing.



\$30M+

CLIENT IMPACT DELIVERED

Driving cost savings, risk reduction, and operational improvements for clients.



GLOBAL EXPERIENCE

Supporting clients in North America, Europe, and Asia across multiple therapeutic areas and geographies.



FORTUNE 500 & MID-SIZE CLIENTS

Trusted advisor to leading organizations and high-growth companies.



FDA • ISO 13485 MDSAP EXPERTISE

Deep expertise in FDA inspections, ISO 13485, MDSAP, and global regulatory requirements.



QUALITY SYSTEMS & SUPPLIER QUALITY

QMS development, supplier quality engineering, audits, CAPA, and compliance readiness.



DESIGN CONTROL & NEW PRODUCT DEVELOPMENT

Experience with design controls, risk management (ISO 14971), and new product introduction (NPI).



QUALITY REMEDIATION & CHANGE MANAGEMENT

Lead remediation projects, process improvements, SOP/work instruction updates, and change control.



SIX SIGMA

Applying structured problem-solving methods to support quality and process improvement.



INDUSTRY EXPERTISE

Extensive experience in medical device, biotechnology, pharmaceutical, and manufacturing industries.



SENIOR-LEVEL ENGAGEMENT

Every engagement is led by a senior consultant—no junior hand-offs.

REPRESENTATIVE EXPERTISE

Anthony Oler • Deep Expertise. Practical Solutions. Measurable Results.



1. SUPPLIER QUALITY ENGINEERING

Leading supplier qualification, supplier development, Approved Supplier List management, Supplier Quality Agreements, supplier performance monitoring, and supplier lifecycle quality activities.



2. QUALITY MANAGEMENT SYSTEMS

Strengthening enterprise Quality Management Systems through remediation, process improvement, procedural development, harmonization, and sustainable compliance initiatives.



3. FDA & ISO 13485 COMPLIANCE

Supporting FDA remediation, ISO 13485 compliance, MDSAP readiness, quality system assessments, regulatory inspections, and audit preparation activities.



4. SUPPLIER AUDITING & DEVELOPMENT

Conducting supplier audits, gap assessments, supplier risk evaluations, supplier qualification activities, and continuous supplier performance improvement.



5. CAPA & SCAR MANAGEMENT

Managing CAPA, SCARs, investigations, effectiveness reviews, corrective actions, preventive actions, and quality system improvement initiatives.



6. RISK MANAGEMENT & DESIGN CONTROLS

Supporting Design Controls, Risk Management, PFMEA, Control Plans, Design Transfer, and Design History File quality activities.



7. VALIDATION & CHANGE CONTROL

Leading validation planning, qualification activities, engineering change control, supplier change notifications, and product qualification initiatives.



8. MANUFACTURING QUALITY

Supporting manufacturing quality systems, process controls, inspection planning, CTQ development, contract manufacturing, and operational quality improvements.



9. CONTINUOUS IMPROVEMENT

Applying Lean methodologies, Six Sigma principles, root cause analysis, statistical improvement, and quality metrics to improve performance.



10. NEW PRODUCT DEVELOPMENT QUALITY

Partnering with engineering and suppliers throughout new product development, commercialization, PPAP, qualification planning, and manufacturing readiness.



11. GLOBAL MEDICAL DEVICE QUALITY

Leading cross-functional quality initiatives supporting global suppliers, international manufacturing operations, multi-site remediation programs, and enterprise quality improvements.



12. REGULATED INDUSTRY EXPERTISE

Extensive experience supporting Medical Device, Biotechnology, Pharmaceutical, and Manufacturing organizations operating under FDA regulations and global quality standards.



QUALITY. COMPLIANCE. SUPPLIER EXCELLENCE. RESULTS.

Delivering practical quality solutions and measurable business outcomes.



CORE CONSULTING SERVICES

End-to-end quality consulting services that strengthen compliance, supplier performance, and operational excellence.



SUPPLIER QUALITY ENGINEERING



Supplier Qualification & Approval



Supplier Development



ASL Management



Supplier Quality Agreements



Supplier Performance Management



Supplier Audits & Assessments



QUALITY MANAGEMENT SYSTEMS



QMS Assessments



QMS Remediation



SOP & Work Instruction Development



Quality Plans



Process Harmonization



Quality System Implementation



REGULATORY COMPLIANCE



FDA Remediation



ISO 13485



MDSAP Readiness



Design Controls



Risk Management



Inspection Preparation



MANUFACTURING & PRODUCT QUALITY



Process Validation



Design Transfer



PPAP Support



PFMEA Development



Product Qualification



Change Control



CAPA & CONTINUOUS IMPROVEMENT



CAPA Management



SCARs



Root Cause Analysis



Lean Process Improvement



Six Sigma Methodologies



Quality Metrics & Improvement



QUALITY. COMPLIANCE. OPERATIONAL EXCELLENCE. RESULTS.

Helping organizations strengthen quality systems and achieve sustainable compliance.

REPRESENTATIVE EXPERIENCE

Trusted by Leading Medical Device, Supplier Quality & Quality Systems Organizations



Johnson & Johnson



DePuy Synthes



Boston Scientific



Zimmer Biomet



Cook Medical



Medtronic



QUALITY SYSTEMS & SUPPLIER QUALITY EXPERTISE



Supplier Quality Engineering



Quality Systems



FDA & Regulatory Compliance



Design Controls & Validation



Manufacturing Quality



CAPA & Continuous Improvement



Supplier Audits



Risk Management

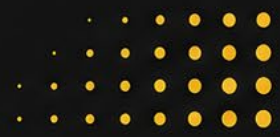


Operational Excellence



Quality Leadership. Trusted Partnerships. Proven Results.

Helping organizations strengthen quality systems, supplier performance, and regulatory readiness.



• REPRESENTATIVE CASE STUDY •

Supplier Quality Remediation

A real-world example of how TOLO Consulting delivers measurable results by strengthening supplier performance, reducing risk, and improving quality systems.



CLIENT CHALLENGE

A global medical-device organization faced aging supplier change notifications, incomplete supplier documentation, and inconsistent quality agreements that created compliance and operational risk.



TOLO SUPPORT

Anthony led supplier-documentation remediation, supplier risk assessments, quality-agreement updates, change-control activities, and cross-functional coordination with internal teams and suppliers.



REPRESENTATIVE OUTCOME



25 aging supplier change notifications closed within **6** months

Strengthened supplier-quality controls and improved the sustainability of the supplier-management process.



QUALITY. COMPLIANCE. OPERATIONAL EXCELLENCE. RESULTS.

Helping organizations strengthen quality systems and achieve sustainable compliance.



Representative engagement presented without identifying confidential client information.

INDUSTRY EXPERTISE

Deep industry knowledge. Proven results. Measurable impact.



MEDICAL DEVICES

Supporting quality systems, supplier quality, compliance, and product lifecycle excellence in highly regulated environments.

TYPICAL ENGAGEMENTS

- Supplier Quality Engineering
- FDA & ISO 13485 Compliance
- Design Controls & Validation
- CAPA & Quality Systems
- Supplier Audits & Remediation



PHARMACEUTICALS

Strengthening quality systems, supplier performance, and operational readiness across regulated manufacturing and product lifecycle activities.

TYPICAL ENGAGEMENTS

- Supplier Quality & Qualification
- Quality Systems & Compliance
- CAPA & Investigations
- Inspection Readiness
- Process & Operational Improvement



BIOTECHNOLOGY

Enabling commercialization and operational excellence through strong quality systems, risk management, and supplier oversight.

TYPICAL ENGAGEMENTS

- Quality Systems Implementation
- Supplier Development
- Validation Support
- Risk Management
- Cross-Functional Quality Leadership



MANUFACTURING

Improving product quality, supplier performance, and operational efficiency across manufacturing and supply chain operations.

TYPICAL ENGAGEMENTS

- Manufacturing Quality Engineering
- Process Validation
- Supplier Performance Improvement
- Change Control
- Continuous Improvement



HEALTHCARE

Supporting compliant operations, quality processes, and measurable improvements through practical quality and regulatory solutions.

TYPICAL ENGAGEMENTS

- Quality Process Improvement
- Audit Readiness
- Documentation & Compliance
- Operational Metrics & Reporting
- Cross-Functional Collaboration



R&D / RESEARCH

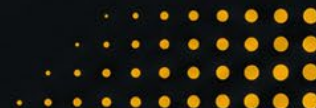
Accelerating innovation with quality oversight, design controls, and product development support from concept through transfer.

TYPICAL ENGAGEMENTS

- Design Controls
- Risk Management
- New Product Quality
- Design Transfer
- Validation Planning



Across industries, TOLO Consulting delivers the quality systems expertise and leadership organizations need to strengthen compliance, improve supplier performance, and achieve **measurable results**.



REPRESENTATIVE ENGAGEMENTS

Proven Leadership. Measurable Impact. Lasting Results.

1  FDA & QUALITY SYSTEMS REMEDIATION	CHALLENGE  Quality system gaps, inspection risk, and outdated procedures threatened compliance readiness.	TOLO DELIVERED ✓ QMS remediation support ✓ Gap assessments ✓ SOP / procedure updates ✓ Inspection readiness ✓ Change control support	BUSINESS OUTCOMES  • Stronger compliance • Sustainable QMS improvements • Better inspection readiness • Reduced regulatory risk
2  SUPPLIER QUALITY EXCELLENCE	CHALLENGE  Inconsistent supplier performance, limited controls, and elevated supplier quality risk.	TOLO DELIVERED ✓ Supplier qualification ✓ Supplier development ✓ Supplier Quality Agreements ✓ Supplier audits & assessments ✓ SCAR / CAPA support	BUSINESS OUTCOMES  • Improved supplier performance • Stronger supplier controls • Reduced supplier risk • Better product quality
3  REGULATORY COMPLIANCE & AUDIT READINESS	CHALLENGE  FDA / ISO gaps, audit readiness concerns, and CAPA / validation deficiencies.	TOLO DELIVERED ✓ FDA remediation support ✓ ISO 13485 compliance support ✓ Design Controls & Risk Management ✓ CAPA support ✓ Validation activities	BUSINESS OUTCOMES  • Reduced compliance risk • Stronger audit readiness • Improved documentation • Successful inspection support
4  MANUFACTURING & PRODUCT QUALITY	CHALLENGE  Process variation, product quality issues, and design transfer / change control challenges.	TOLO DELIVERED ✓ Process validation ✓ Design Transfer support ✓ Product qualification ✓ Change control support ✓ Supplier quality collaboration	BUSINESS OUTCOMES  • Improved product quality • Stronger manufacturing controls • Smoother product launches • Lifecycle quality support
5  OPERATIONAL QUALITY IMPROVEMENT	CHALLENGE  Recurring issues, inconsistent processes, and ineffective continuous improvement.	TOLO DELIVERED ✓ Root Cause Analysis ✓ CAPA effectiveness ✓ Process standardization ✓ Continuous improvement ✓ Cross-functional leadership	BUSINESS OUTCOMES  • Improved efficiency • Sustainable improvements • Stronger quality systems • Reduced rework / risk



TOLO Consulting partners with organizations to strengthen quality systems, **reduce regulatory risk, and deliver sustainable operational excellence.**



BUSINESS CAPABILITIES



QUALITY MANAGEMENT SYSTEMS

QMS design, assessment, remediation & improvement.



SUPPLIER QUALITY ENGINEERING

Supplier qualification, SQAs, ASL management & performance



REGULATORY COMPLIANCE

FDA, ISO 13485, MDSAP, design controls & risk management.



MANUFACTURING QUALITY

Process validation, PPAP, PFMEA, control plans & quality engineering.



CAPA & CONTINUOUS IMPROVEMENT

CAPA, SCAR, RCA, investigations, Lean & Six Sigma



DESIGN CONTROLS & VALIDATION

Design transfer, DHF, validation planning, verification & product qualification

QUALITY ECOSYSTEM

QUALITY PLATFORMS



ETQ



TrackWise



Agile PLM



Windchill

ENTERPRISE SYSTEMS



SAP



Oracle ERP



AS400 / Series

ENGINEERING & COLLABORATION



Microsoft 365



SharePoint



Microsoft Project



Smartsheet



Jira



Microsoft Excel



Microsoft Teams

QUALITY ANALYTICS



Minitab



Quality Exchange

BUSINESS OUTCOMES



STRONGER COMPLIANCE

Sustainable quality systems & regulatory adherence.



FDA INSPECTION READINESS

Reduced risk & confidence in regulatory audits.



IMPROVED SUPPLIER PERFORMANCE

Stronger supplier relationships & reliable supply chain.



REDUCED QUALITY RISK

Fewer issues, complaints & field actions.



OPERATIONAL EXCELLENCE

Efficient processes, standardization & consistency.



CONTINUOUS IMPROVEMENT

Data-driven decisions & long-term business value.



STRATEGY. GOVERNANCE. TECHNOLOGY. RESULTS.

Driving measurable outcomes through quality, compliance, and operational excellence.

QUALITY CONSULTING ROLES & ENGAGEMENT MODELS

Senior expertise. Flexible engagement. Practical quality solutions.



SENIOR EXPERTISE.
DIRECT ENGAGEMENT.
MEASURABLE IMPACT.



SUPPLIER QUALITY ENGINEER

BEST FOR

- Supplier qualification
- Supplier performance
- SQAs & ASL management
- Supplier risk assessments



SENIOR SUPPLIER QUALITY ENGINEER

BEST FOR

- Supplier quality programs
- Supplier audits
- SCAR & CAPA leadership
- Supplier development



QUALITY SYSTEMS CONSULTANT

BEST FOR

- QMS assessments
- QMS remediation
- SOP & WI development
- Quality plan creation



REGULATORY & COMPLIANCE CONSULTANT

BEST FOR

- FDA Quality System remediation
- ISO 13485 & MDSAP
- Design Controls & risk management
- Inspection readiness



LEAD AUDITOR

BEST FOR

- Internal audits
- Supplier audits
- Gap assessments
- Audit-readiness support



CAPA & QUALITY REMEDIATION LEAD

BEST FOR

- CAPA management
- SCAR management
- Root Cause Analysis
- Sustainable remediation



MANUFACTURING & PRODUCT QUALITY CONSULTANT

BEST FOR

- Process validation
- Design Transfer
- PPAP & PFMEA
- Product qualification



QUALITY PROGRAM LEAD / ADVISOR

BEST FOR

- Quality strategy
- Cross-functional leadership
- Enterprise remediation programs
- Executive quality advisory



Every engagement is personally led by Anthony Oler,
Senior Quality Systems Consultant and Certified ISO 13485 Lead Auditor.

Direct access. Senior expertise. Measurable results.



CONTACT

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Quality Systems • Supplier Quality • Regulatory Excellence
Palm Beach, Florida



Quality Management Systems



Supplier Quality Engineering



Manufacturing Quality



Regulatory Compliance



FDA • ISO 13485 • MDSAP

“ *Helping organizations build stronger quality systems through practical compliance and operational excellence.* ”



QUALITY
SYSTEMS



SUPPLIER
QUALITY



REGULATORY
COMPLIANCE



MANUFACTURING
QUALITY



OPERATIONAL
EXCELLENCE

CLOSING

TOLO Consulting LLC partners with medical device, biotechnology, pharmaceutical, and manufacturing organizations to strengthen Quality Management Systems, improve supplier performance, reduce regulatory risk, and deliver sustainable operational excellence. TOLO Consulting combines executive quality leadership with hands-on implementation to help organizations build practical, compliant, and scalable quality systems that support long-term business success.

Whether your organization is strengthening supplier quality, remediating Quality Management Systems, preparing for FDA inspections, improving manufacturing quality, or implementing continuous improvement initiatives, TOLO Consulting is ready to help you achieve measurable quality and compliance outcomes.

“ *Helping organizations build stronger quality systems through practical compliance and operational excellence.* ”