Quality System Audit Checklist

WHAT THIS TOOL IS

The Quality System Audit Checklist is a comprehensive assessment framework designed to evaluate a vendor's quality management capabilities, processes, and controls. This structured audit tool guides quality professionals, procurement teams, and compliance specialists through a systematic evaluation of supplier quality systems based on internationally recognized standards like ISO 9001 and industry best practices.

Important Note: This checklist provides general quality system evaluation criteria applicable across most manufacturing and service industries. However, specific quality requirements vary significantly by industry (automotive, aerospace, medical devices, food, etc.), regulatory environment, and product complexity. Customize the checklist to include industry-specific standards (such as AS9100, ISO 13485, or FDA regulations) and add criteria relevant to your specific quality requirements.

WHY QUALITY SYSTEM AUDITS ARE ESSENTIAL

1 Prevents Quality Failures:

Robust quality systems are the primary defense against defects, recalls, and quality incidents that can damage your reputation and create liability exposure. Systematic audits identify weaknesses before they impact your products or services.

2 Ensures Regulatory Compliance:

Many industries require suppliers to meet specific quality standards and certifications. Quality audits verify that vendors can maintain compliance and support your own regulatory obligations.

3 Reduces Total Cost of Ownership:

Suppliers with strong quality systems deliver fewer defects, require less inspection and rework, and generate fewer customer complaints - significantly reducing your total procurement costs.

4 Supports Continuous Improvement:

Quality audits establish baseline performance and identify opportunities for suppliers to improve their processes, benefiting both parties through enhanced quality and efficiency.

5 Enables Risk Management:

Understanding a supplier's quality capabilities helps you assess risks, determine appropriate inspection levels, and make informed decisions about supplier relationships and contract terms.

HOW TO USE THIS ASSESSMENT

Pre-Audit Preparation:

- Review the supplier's quality documentation and define specific audit objectives based on your requirements. Schedule adequate time (typically 1-3 days depending on complexity) and ensure access to key personnel and facilities.

During the Audit:

- Follow the systematic approach outlined in this checklist, but remain flexible to investigate areas of concern in greater depth. Focus on actual practices, not just documented procedures.

Key Audit Principles:

- Observe actual work practices rather than relying solely on documentation
- Interview multiple levels of personnel to verify understanding and implementation
- Sample records and data to validate system effectiveness
- Focus on systematic issues rather than isolated incidents
- Verify corrective actions from previous audits or customer complaints

Vendor Name: _____ **Date:** _____

Auditor: _____ **Location:** _____

Products/Services: _____

_____

PRE-AUDIT PREPARATION

Why This Matters: Proper preparation ensures audit efficiency and helps identify areas requiring special attention.

Documentation Review

- ☐ Quality manual and procedures received and reviewed
- ☐ Organizational chart and key personnel identified
- ☐ Product/service specifications and requirements clarified
- ☐ Previous audit reports or certifications reviewed
- ☐ Audit scope and objectives defined

SECTION 1: QUALITY MANAGEMENT SYSTEM

Why This Matters: A strong quality management system provides the foundation for consistent performance and continuous improvement.

ISO 9001 / Quality Standards

☐ **Current certification status:** ISO 9001: _____ Other: _____

☐ Certificate is current and scope covers your requirements

☐ Internal audit program is active and effective

☐ Management review meetings conducted regularly

☐ Quality policy is documented and communicated

☐ Quality objectives are measurable and monitored

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

Quality Manual & Procedures

☐ Quality manual covers all applicable processes

☐ Procedures are current, controlled, and accessible

☐ Work instructions are clear and available at workstations

☐ Document control system prevents use of obsolete documents

☐ Records retention system meets requirements

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

SECTION 2: MANUFACTURING/SERVICE PROCESS CONTROLS

Why This Matters: Effective process controls ensure consistent output quality and enable rapid identification of problems.

Process Documentation

☐ Process flow charts or maps are current
☐ Critical control points are identified
☐ Process parameters and tolerances are specified
☐ Operator training and certification records maintained
☐ Equipment maintenance schedules followed
Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A
Notes: _____

Inspection & Testing

☐ Incoming material inspection procedures
☐ In-process inspection at critical points
☐ Final inspection before shipment
☐ Test equipment calibrated and certified
☐ Non-conforming material clearly identified and segregated
Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A
Notes: _____

Equipment & Facilities

☐ Equipment appropriate for production requirements
☐ Preventive maintenance program in place
☐ Calibration program covers all measuring equipment
☐ Facilities clean, organized, and well-maintained
☐ Environmental controls are adequate (temperature, humidity, etc.)
Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A
Notes: _____

SECTION 3: CORRECTIVE & PREVENTIVE ACTIONS

Why This Matters: The ability to identify, analyze, and correct problems is critical for maintaining and improving quality performance.

Problem Identification

☐ System to capture and track non-conformances
☐ Customer complaints logged and investigated
☐ Internal defect/error tracking system
☐ Supplier quality issues monitored
☐ Employee suggestions and feedback encouraged

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

Root Cause Analysis

☐ Systematic approach to identify root causes
☐ Tools used (5 Why, fishbone, etc.) appropriate
☐ Analysis depth adequate for problem complexity
☐ Multiple potential causes considered
☐ Subject matter experts involved when needed

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

Implementation & Effectiveness

☐ Corrective actions address root causes
☐ Implementation timeline reasonable and tracked
☐ Effectiveness verification conducted
☐ Preventive measures implemented where applicable
☐ Lessons learned shared across organization

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

SECTION 4: QUALITY METRICS & CONTINUOUS IMPROVEMENT

Why This Matters: Data-driven quality management enables proactive improvement and demonstrates commitment to excellence.

Data Collection & Analysis

☐ Key quality metrics defined and tracked

☐ Data collection methods reliable and consistent

☐ Trends analyzed and reported regularly

☐ Benchmarking against industry standards

☐ Customer satisfaction measured and monitored

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Key Metrics Tracked: _____

Improvement Initiatives

☐ Continuous improvement program active

☐ Employee involvement in improvement efforts

☐ Process improvements documented and measured

☐ Best practices shared throughout organization

☐ Innovation encouraged and supported

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Recent Improvements: _____

SECTION 5: SUPPLIER QUALITY MANAGEMENT

Why This Matters: Your supplier's ability to manage their own supply chain directly impacts the quality of materials and components in your products.

Supplier Evaluation

☐ Supplier qualification process documented

☐ Regular supplier performance reviews conducted

☐ Supplier corrective action system in place

☐ Supplier development programs available

☐ Critical supplier contingency plans exist

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

SECTION 6: TRAINING & COMPETENCY

Why This Matters: Well-trained personnel are essential for maintaining quality standards and implementing improvements effectively.

Personnel Qualifications

☐ Job descriptions include quality requirements

☐ Training needs assessment conducted

☐ Initial and ongoing training programs documented

☐ Competency verification and certification

☐ Training records maintained and current

Rating: ☐ Excellent ☐ Good ☐ Adequate ☐ Poor ☐ N/A

Notes: _____

OVERALL ASSESSMENT SUMMARY

Area	Rating	Critical Issues
Quality Management System		
Process Controls		
Corrective/Preventive Actions		
Metrics & Improvement		
Supplier Management		
Training & Competency		

Critical Non-Conformances (Must be corrected before approval)

1. _____

2. _____

3. _____

Major Findings (Should be addressed)

1. _____

2. _____

3. _____

Recommendations for Improvement

1. _____

2. _____

3. _____

FINAL RECOMMENDATION

☐ **Approve** - Quality system meets requirements

☐ **Conditional Approval** - Address critical issues within _____ days

☐ **Re-audit Required** - Significant system deficiencies identified

☐ **Reject** - Quality system inadequate for requirements

Follow-up Actions Required:

_____

_____

_____

_____

Next Review Date: _____

Auditor Signature: _____ **Date:** _____

BEST PRACTICES FOR QUALITY SYSTEM AUDITS

Audit Preparation Tips

- **Research the supplier's industry** and applicable quality standards before the audit
- **Review customer complaints or quality issues** from similar suppliers
- **Coordinate with procurement and engineering** to understand specific quality requirements
- **Plan for adequate time** - rushing through audits often misses critical issues

During the Audit

- **Start with a management interview** to understand their quality philosophy and priorities
- **Follow the process flow** rather than just checking off boxes
- **Ask "show me" questions** to see actual implementation, not just procedures
- **Sample records from different time periods** to verify consistency
- **Interview operators and inspectors** to understand practical implementation

Rating Guidelines

- **Excellent:** Exceeds standard expectations, demonstrates best practices
- **Good:** Meets all requirements with strong implementation
- **Adequate:** Meets minimum requirements but has room for improvement
- **Poor:** Does not meet requirements, significant deficiencies present
- **N/A:** Not applicable to this supplier or product/service

Industry-Specific Considerations

- **Automotive:** Include IATF 16949 requirements, PPAP, and measurement system analysis
- **Aerospace:** Add AS9100 criteria, configuration management, and special processes
- **Medical Devices:** Include ISO 13485, design controls, and FDA requirements
- **Food & Beverage:** Add HACCP, SQF/BRC standards, and allergen controls