ISO 9001:2015 Supplier Audit Checklist

Evaluate the quality of a current or prospective supplier/vendor's processes.

By:

Date:

Time:

1. Ensures the audit is conducted systematically;	Yes	No	N/A	Comments
2. Promotes audit planning;	Yes	No	N/A	Comments
3. Ensures a consistent audit approach;	Yes	No	N/A	Comments
4. Actively supports your organization's audit process (ISO 9001:2015, Clause 9.2.1);	Yes	No	N/A	Comments

5. Provides a repository for notes collected during the audit;	Yes	No	N/A	Comments
6. Ensures uniformity in the performance of different auditors;	Yes	No	N/A	Comments
7. Provides reference to objective evidence.	Yes	No	N/A	Comments

Audit Scoring Criteria

8. COMPLIANT: Definition/Impact: Compliant means adherence with the requirements of the standard and the QMS. The process is implemented and documented and records exist to verify this.	Yes	No	N/A	Comments
9. COMPLIANT: Action/Mitigation: Continue to monitor trends/indicators.	Yes	No	N/A	Comments
10. OFI: Definition/Impact: A low risk issue that offers an opportunity to improve current practice. Processes may cumbersome or overly complex but meet their targets and objectives. Unresolved OFIs may degrade over time to become non-compliant.	Yes	No	N/A	Comments

11. OFI: Action/Mitigation: Review and implement actions to improve the process(s). Monitor trends/indicators to determine if improvement was achieved.	Yes	No	N/A	Comments
12. MINOR N/C: Definition/Impact: A medium risk, minor non-conformance resulting in deviation from process practice not likely to result in the failure of the management system or process that will not result in the delivery of non-conforming products nor reduce the effectiveness of the QMS.	Yes	No	N/A	Comments
13. MINOR N/C: Action/Mitigation: Investigate root cause(s) and implement corrective action by next reporting period or next scheduled audit.	Yes	No	N/A	Comments
14. COMPLIANT: Definition/Impact: A high risk, major non-conformance which directly impacts upon customer requirements, likely to result in the customer receiving non-conforming products or services, or which may reduce the effectiveness of the QMS.	Yes	No	N/A	Comments
15. COMPLIANT: Action/Mitigation: Implement immediate containment action, investigate root cause(s) and apply corrective action. Re-audit in 4 weeks to verify correction.	Yes	No	N/A	Comments

Process Activity Map: EQUIPMENT & FACILITIES

16. What equipment and resources are required?				
17. Is equipment suitable and properly maintained?	Yes	No	N/A	Comments
18. Is the work environment maintained?	Yes	No	N/A	Comments
19. Is there evidence of appropriate maintenance of all equipment used by this process?	Yes	No	N/A	Comments

Process Activity Map: PERSONNEL

20. Review employee skill lists for the process.	Yes	No	N/A	Comments

21. Are there lists of skills for each position?	Yes	No	N/A	Comments
22. Do they show enough detail?	Yes	No	N/A	Comments
23. This is often a finding, where lists are generic with inadequate detail.	Yes	No	N/A	Comments
24. Training is a key process of any system.	Yes	No	N/A	Comments
25. Are there particular skills you want to evaluate?	Yes	No	N/A	Comments

Process Activity Map: CONTROL PROCESSES

26. How is the process defined and who is responsible?

27. How are customer requirements defined?
28. What specifications apply defined?
29. What objectives and targets apply process?
30. What controls/check points are there?
31. What acceptance criteria exist?

Process Activity Map: PROCESS INPUTS

32. What triggers the process?				
33. What inputs are required?				
34. Where do the inputs come from?				
35. Are they received in a timely manner?	Yes	No	N/A	Comments
36. Are they fit for purpose?	Yes	No	N/A	Comments

Process Activity Map: PROCESS NAME/DESCRIPTION

37. What steps are involved in the process?				
38. What happens at each step in the process?				
39. What documents and records are generated?				
40. Is the process implemented in accordance with procedures, instructions or plans?	Yes	No	N/A	Comments
41. Are controls applied as described?	Yes	No	N/A	Comments

Process Activity Map: PROCESS OUTPUTS

42. What is the product produced by this process?				
43. Are product measures in place to ensure that product meets requirements?	Yes	No	N/A	Comments
44. How are processes measured?				
45. Are product and process measures achieved?	Yes	No	N/A	Comments
46. What feedback is received from customers?				

Process Activity Map: INSTRUCTIONS & PROCEDURES

47. Review the documents that describe and control the process.	Yes	No	N/A	Comments
48. Review all the important steps and activities of the process being audited.	Yes	No	N/A	Comments
49. This info must be documented within the QMS.	Yes	No	N/A	Comments
50. Evaluate how effectively the process flows through the steps.	Yes	No	N/A	Comments
51. Do you see roadblocks or issues?	Yes	No	N/A	Comments

Process Activity Map: SUPPORT PROCESSES

52. As you audit, you will see how it connects and interacts with other processes.	Yes	No	N/A	Comments
53. Interactions with other processes are always important.	Yes	No	N/A	Comments
54. As you audit the, you will see how it connects and interacts with other processes.	Yes	No	N/A	Comments
55. Audit the relevant links to related processes and support processes.	Yes	No	N/A	Comments

Process Activity Map: KEY PERFORMANCE INDICATORS

56. Review metrics and performance with Managers, Supervisors and operators.	Yes	No	N/A	Comments

57. They should know how things are running, objectives, customer issues, problem areas.	Yes	No	N/A	Comments
58. If they do not, the requirements were not met.	Yes	No	N/A	Comments
59. Is there evidence that quality objectives and targets affected by this process are being achieved?	Yes	No	N/A	Comments

Quality Management

60. Audit Question: Is the quality system documented, controlled and maintained to clearly describe current practice?	Yes	No	N/A	Comments
61. Audit Evidence: Quality manual and all procedures show revision control (sign-offs & dates), history of changes	Yes	No	N/A	Comments
62. Audit Question: Do quality reports, trend charts and data analysis identify areas of opportunity and are used by management on a routine basis?	Yes	No	N/A	Comments

63. Audit Evidence: Product quality yield data, problems and corresponding improvement actions, status of preventive/ corrective/audit results	Yes	No	N/A	Comments
64. Audit Question: Are quality-performance targets clearly defined, included in the business plan and monitored for improvements?	Yes	No	N/A	Comments
65. Audit Evidence: Strategic and tactical objectives, goals, action plans, etc.	Yes	No	N/A	Comments
66. Audit Question: Does executive management participate in periodic quality system reviews that address quality related feedback from customers and internal quality metrics?	Yes	No	N/A	Comments
67. Audit Evidence: Analysis of field failures, inspection yields, resource needs, internal audit results, corrective action status, etc.	Yes	No	N/A	Comments

Continuous Improvement

68. Audit Question: Are preventive actions taken based on the analysis of significant business trends, design reviews, customer satisfaction surveys or other meaningful inputs?	Yes	No	N/A	Comments

69. Audit Evidence: Management review meetings, goal setting, performance measurement, internal audits, action plans, customer surveys	Yes	No	N/A	Comments
70. Audit Question: Is there a formal approach used to actively pursue cost containment and other continual improvement activities throughout the organization?	Yes	No	N/A	Comments
71. Audit Evidence: Employee involvement/recognition program, Lean, Six Sigma, kaizen, SPC, 5-S, cost reduction programme	Yes	No	N/A	Comments
72. Audit Question: Is a corrective action system in place that provides root cause analysis and takes timely and effective action to prevent recurrence?	Yes	No	N/A	Comments
73. Audit Evidence: Corrective actions, trend charts, meeting minutes, non-conformance frequency & cost analysis	Yes	No	N/A	Comments
74. Audit Question: Does the corrective action system cover customer, internal and supplier issues?	Yes	No	N/A	Comments
75. Audit Evidence: Management review meetings and corrective actions	Yes	No	N/A	Comments

Training & Awareness

76. Audit Question: Is the skill and education level required for each job documented and appropriate training provided?	Yes	No	N/A	Comments
77. Audit Evidence: Look for use of training aids and work instructions at work stations	Yes	No	N/A	Comments
78. Audit Question: Is employee qualification/certification maintained where the quality outcome of the process cannot be verified and is strongly dependent upon operator skill?	Yes	No	N/A	Comments
79. Audit Evidence: Qualification records, certification history	Yes	No	N/A	Comments
80. Audit Question: Are suitable methods used to verify training effectiveness?	Yes	No	N/A	Comments
81. Audit Evidence: Records of testing, production quality records, audit records, interview workers to validate training records	Yes	No	N/A	Comments

82. Audit Question: Are suitable records of maintained?	Yes	No	N/A	Comments
83. Audit Evidence: Job descriptions, job skills assessment, training records, training manuals	Yes	No	N/A	Comments

Design & Development Support

84. Audit Question: Are customer needs and requirements incorporated into product designs and/or manufacturing processes?	Yes	No	N/A	Comments
85. Audit Evidence: Market studies, customer/end-user surveys, technical design reviews	Yes	No	N/A	Comments
86. Audit Question: Are Critical-to-Quality (CTQ) characteristics are identified, understood and records retained?	Yes	No	N/A	Comments
87. Audit Evidence: Process capability studies, process plan, manufacturing verification tests	Yes	No	N/A	Comments

88. Audit Question: Are product specifications and drawings generated, controlled and maintained for new or changed product designs?	Yes	No	N/A	Comments
89. Audit Evidence: Product characteristics, application requirements and other information for safe and proper use and disposal	Yes	No	N/A	Comments
90. Audit Question: Is design validation is an integral part of the design process and occurs prior to production release?	Yes	No	N/A	Comments
91. Audit Evidence: Design results, manufacturability, productivity and cost studies, confirmation that product fulfils its specified requirements or intended use or applications	Yes	No	N/A	Comments
92. Audit Question: Are human and technical resources are adequate to meet the requirements for design collaboration, tooling design and electronic drawing and data exchange?	Yes	No	N/A	Comments
93. Audit Evidence: Qualification of technical staff. Equipment/software capabilities, CAD	Yes	No	N/A	Comments

Quality Planning

94. Audit Question: Are production samples inspected and provided to customers upon request?	Yes	No	N/A	Comments
95. Audit Evidence: Completed PPAP or similar forms, inspection reports, availability of qualified resources	Yes	No	N/A	Comments
96. Audit Question: Are customer production requirements and quality specifications are reviewed to ensure they can be met on a consistent basis?	Yes	No	N/A	Comments
97. Audit Evidence: Procedures, design/process review, capacity plans, resource plans, product test, storage, packaging and shipment requirements	Yes	No	N/A	Comments
98. Audit Question: Are reliability test plans developed and routinely followed?	Yes	No	N/A	Comments
99. Audit Evidence: Reliability test plans, test reports	Yes	No	N/A	Comments

100. Audit Question: Is testing is used to verify the design specifications, drive design improvements and provide an on-going check of materials and workmanship?	Yes	No	N/A	Comments
101. Audit Evidence: Improvement/corrective actions taken, design changes implemented	Yes	No	N/A	Comments
102. Audit Question: Is product reliability test data is available upon request and historical test performance data shows a highly stable process and product design?	Yes	No	N/A	Comments
103. Audit Evidence: Reliability test summary reports/charts	Yes	No	N/A	Comments

Customer Documentation

104. Audit Question: Are new and revised customer specifications reviewed and implemented in a timely manner?	Yes	No	N/A	Comments
105. Audit Evidence: Technical review of methods to be used, capability studies on similar parts, documented review procedure	Yes	No	N/A	Comments

106. Audit Question: Are current process control documents in place and used for production start-up and continuing production?	Yes	No	N/A	Comments
107. Audit Evidence: Specifications, engineering drawings, change notices, work instructions and specifications as applicable	Yes	No	N/A	Comments
108. Audit Question: Does customer notification/approval occur for changes to control plans, manufacturing site, product transfers, raw material or product obsolescence?	Yes	No	N/A	Comments
109. Audit Evidence: Customer notification procedure on major changes	Yes	No	N/A	Comments
110. Audit Question: Is there a record control system is in place for the identification, storage, protection?	Yes	No	N/A	Comments
111. Audit Evidence: Document control procedure	Yes	No	N/A	Comments
112. Audit Question: Are quality records maintained?	Yes	No	N/A	Comments

113. Audit Evidence: List of records to be kept with retention periods specified	Yes	No	N/A	Comments

Procurement

114. Audit Question: Is there a formal process used for the selection, qualification and re-qualification of suppliers?	Yes	No	N/A	Comments
115. Audit Evidence: Supplier quality audits and corrective actions, engineering testing, approval records, production trials	Yes	No	N/A	Comments
116. Audit Question: Are purchases from unapproved suppliers prevented by a properly controlled and available approved supplier list?	Yes	No	N/A	Comments
117. Audit Evidence: Approved supplier list, procedures, production material receipt records	Yes	No	N/A	Comments
118. Audit Question: Are preventive actions taken to continuously improve performance of the supplier base?	Yes	No	N/A	Comments

119. Audit Evidence: Supplier quality performance analysis, performance trends, supplier audit reports	Yes	No	N/A	Comments
120. Audit Question: Does the supplier assurance system ensure that all purchased product or material conforms to defined specifications and applicable regulatory or customer requirements?	Yes	No	N/A	Comments
121. Audit Evidence: Receiving inspection, supplier audits, source inspection, qualification testing, Certificate of Compliance, component marking, labelling, etc.	Yes	No	N/A	Comments
122. Audit Question: Does a system exist for the identification, verification and protection of customer supplied product that includes notifying the customer if product is damaged or lost?	Yes	No	N/A	Comments
123. Audit Evidence: Procedures, segregation during storage, limited and controlled access to stored inventories	Yes	No	N/A	Comments

Incoming Material

124. Audit Question: Is receiving inspection performed per documented procedures and detailed work instructions?	Yes	No	N/A	Comments

125. Audit Evidence: Procedures, inspection instructions resources (manpower and equipment) allocated for incoming inspection	Yes	No	N/A	Comments
126. Audit Question: Is inspected material adequately identified as to acceptance or rejection and traceable to receiving inspection report?	Yes	No	N/A	Comments
127. Audit Evidence: Quality control label, marking or use of designated hold area as indicated in the procedure	Yes	No	N/A	Comments
128. Audit Question: Do supplier corrective action requests requiring root cause investigation show responses are analyzed?	Yes	No	N/A	Comments
129. Audit Evidence: Availability of written procedure, standardized corrective action form, analysis of corrective action cycle time and closure measurements	Yes	No	N/A	Comments

Manufacturing Quality

130. Audit Question: Is there is a formal method used to qualify new or rebuilt production equipment prior to production use?	Yes	No	N/A	Comments

131. Audit Evidence: Qualification plan that includes established goals for process yields. Records of process capability, review and approval	Yes	No	N/A	Comments
132. Audit Question: Are control plans used to plan and deploy inspection and test functions throughout the production process?	Yes	No	N/A	Comments
133. Audit Evidence: Process flow chart, statistical tools, key inspection points, inspection frequency, inspection/test method, gaging used, acceptable yield rates	Yes	No	N/A	Comments
134. Audit Question: Are appropriate work instructions are available where needed that accurately describe all work methods including inspections and tests to be done during production?	Yes	No	N/A	Comments
135. Audit Evidence: Sample size, frequency, method, document control dates/revision level	Yes	No	N/A	Comments
136. Audit Question: Are appropriate inspections, tests and process adjustments made per applicable work instructions to verify conformance at key points throughout the process and prior to shipment?	Yes	No	N/A	Comments
137. Audit Evidence: Records of inspections performed at incoming, first piece, in-process and/or final inspection or test	Yes	No	N/A	Comments

138. Audit Question: Is the inspection and process status of the product identified and maintained throughout the production process?	Yes	No	N/A	Comments
139. Audit Evidence: Batch records, travellers, tags, labels, product markings or use of designated and identified areas	Yes	No	N/A	Comments
140. Audit Question: Are customers notified of low yield production lots or issues that affect product reliability?	Yes	No	N/A	Comments
141. Audit Evidence: Corrective actions, records of customer notifications, reliability test data	Yes	No	N/A	Comments

Non-conforming Outputs

142. Audit Question: Are nonconforming materials, parts and assemblies are segregated (where practical) and identified to prevent unapproved use?	Yes	No	N/A	Comments
143. Audit Evidence: Tags, marking, controlled staging areas	Yes	No	N/A	Comments

144. Audit Question: Is reworked material, parts and assemblies are re-inspected or re-tested to confirm compliance to requirements?	Yes	No	N/A	Comments
145. Audit Evidence: Inspection record, tag and stamp	Yes	No	N/A	Comments
146. Audit Question: Is the use of nonconforming material is documented under a formal waiver or concession system?	Yes	No	N/A	Comments
147. Audit Evidence: Written procedure, waiver or concession records	Yes	No	N/A	Comments
148. Audit Question: Is product traceability maintained to facilitate problem evaluation and corrective action?	Yes	No	N/A	Comments
149. Audit Evidence: Serial number records, lot number, date of manufacture, labelling and marking of containers or product	Yes	No	N/A	Comments
150. Audit Question: Is there a positive recall system to notify customers of nonconforming product that has already been shipped?	Yes	No	N/A	Comments

151. Audit Evidence: Documented procedure and review of system	Yes	No	N/A	Comments

Monitoring & Measurement

152. Audit Question: Are gauge repeatability and reproducibility studies conducted to verify suitability of measuring devices for their use in checking product quality or control of processes?	Yes	No	N/A	Comments
153. Audit Evidence: GR & R studies, reports	Yes	No	N/A	Comments
154. Audit Question: Are measuring devices and gauges and test equipment are routinely calibrated and controlled per documented procedures?	Yes	No	N/A	Comments
155. Audit Evidence: Calibration stickers and records, positive identification or segregation of out-of-calibration devices, and inventory, location & status records	Yes	No	N/A	Comments
156. Audit Question: Are gauges and test equipment calibrated against standards traceable to a recognized regulatory body or agency?	Yes	No	N/A	Comments

157. Audit Evidence: Calibration procedures, and calibration stickers and other records	Yes	No	N/A	Comments
158. Audit Question: Are assessments made to check the validity of previous measurements done on products where out-of-calibration measuring devices were used?	Yes	No	N/A	Comments
159. Audit Evidence: Assessment records and corrective actions	Yes	No	N/A	Comments
160. Audit Question: Are appropriate controls are in place to verify the suitability and accuracy of computer software prior to initial use in checking product quality or control of processes?	Yes	No	N/A	Comments
161. Audit Evidence: Verification methods and records, revision levels, distribution/use control	Yes	No	N/A	Comments

Maintenance

162. Audit Question: Are tools stored in an appropriate, clearly defined area, with systematic tracking that provides traceability, particularly of customer-owned tools and equipment?	Yes	No	N/A	Comments

163. Audit Evidence: GR & R studies, reportsAudit Evidence: Review of storage area, labelling, tooling records	Yes	No	N/A	Comments
164. Audit Question: Does a formal preventive maintenance system (PM) exist for production equipment, tools and fixtures?	Yes	No	N/A	Comments
165. Audit Evidence: Review of system, PM plans, PM schedule and compliance results	Yes	No	N/A	Comments
166. Audit Question: Is the preventive maintenance schedule is followed since product cannot be made with tools that are outside of maintenance period?	Yes	No	N/A	Comments
167. Audit Evidence: No equipment, tools, or fixtures are in use that are outside TPM schedule, or have unclear status	Yes	No	N/A	Comments

Process Control

168. Audit Question: Are key part characteristics and process parameters are reviewed and statistically based controls and/or problem solving tools are used to control variation?	Yes	No	N/A	Comments

169. Audit Evidence: Histograms, run charts, SPC charts, pareto analysis, cause and effect diagrams, mistake proofing, reaction plan & process corrections.	Yes	No	N/A	Comments
170. Audit Question: Are written improvement plans are implemented to reduce sources of variation?	Yes	No	N/A	Comments
171. Audit Evidence: Documented reaction plan and process corrections. SPC trend charts showing current status vs. goals, improvement plans	Yes	No	N/A	Comments
172. Audit Question: Is process capability is measured and actions are taken to maintain established minimum Cpk/Ppk targets?	Yes	No	N/A	Comments
173. Audit Evidence: Documented process capability studies and results (actual vs target Cpk/Ppk)	Yes	No	N/A	Comments
174. Audit Question: Are out of control conditions are noted on charts and documented corrective action is taken to bring the process back into control?	Yes	No	N/A	Comments
175. Audit Evidence: Control charts	Yes	No	N/A	Comments

Storage & Packing

176. Audit Question: Are areas around the facility clean and orderly and are tools and equipment properly stored and readily available for use and is lighting and air quality are adequate?	Yes	No	N/A	Comments
177. Audit Evidence: Observe production, office & product storage areas. (Sort, Set-in-order, Shine, Standardize, Sustain + Safety)	Yes	No	N/A	Comments
178. Audit Question: Is proper equipment and methods used to prevent product damage or loss in all phases of the material handling process?	Yes	No	N/A	Comments
179. Audit Evidence: Observe handling and transit of raw material, work-in-process, and finished goods.	Yes	No	N/A	Comments
180. Audit Question: Are documented procedures followed to ensure proper control and preservation of handling, storage (FIFO), packaging, and delivery of product?	Yes	No	N/A	Comments
181. Audit Evidence: FIFO practices are defined, packaging specifications, test results, handling and storage procedures.	Yes	No	N/A	Comments

182. Audit Question: Is the suitability of product packaging reviewed and concerns communicated to the customer prior to initial production shipment?	Yes	No	N/A	Comments
183. Audit Evidence: Technical review, packaging/shipping tests, packaging work instructions, carton strength tests	Yes	No	N/A	Comments
184. Audit Question: Is stored product/material periodically inspected, and where applicable, actions are taken to prevent deterioration per documented procedures?	Yes	No	N/A	Comments
185. Audit Evidence: Lists of shelf-life sensitive materials. Look for poor storage conditions and damage. Handling procedures	Yes	No	N/A	Comments
186. Audit Question: Have contingency plans been developed that describe actions to be taken in the event of a major interruption of the manufacturing process?	Yes	No	N/A	Comments
187. Audit Evidence: Process covering utility interruptions, labour shortages, key equipment failures, major production issues	Yes	No	N/A	Comments

Findings Summary

188. Non-conformance
189. Corrective Action
190. Opportunities for Improvement

191. Observations, Comments & Notes