**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 |
| 1. Promotes audit planning; | Yes | No | N/A | Comments |
| 1. Ensures a consistent audit approach; | Yes | No | N/A | Comments |
| 1. Actively supports your organization’s audit process (ISO 9001:2015, Clause 9.2.1); | Yes | No | N/A | Comments |
| 1. Provides a repository for notes collected during the audit; | Yes | No | N/A | Comments |
| 1. Ensures uniformity in the performance of different auditors; | Yes | No | N/A | Comments |
| 1. Provides reference to objective evidence. | Yes | No | N/A | Comments |

## Audit Scoring Criteria

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. COMPLIANT: Action/Mitigation: Continue to monitor trends/indicators. | Yes | No | N/A | Comments |
| 1. 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 |
| 1. 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 |
| 1. 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 |
| 1. 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 |
| 1. 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 |
| 1. 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. What equipment and resources are required? | | | | |
| 1. Is equipment suitable and properly maintained? | Yes | No | N/A | Comments |
| 1. Is the work environment maintained? | Yes | No | N/A | Comments |
| 1. Is there evidence of appropriate maintenance of all equipment used by this process? | Yes | No | N/A | Comments |

## Process Activity Map: PERSONNEL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Review employee skill lists for the process. | Yes | No | N/A | Comments |
| 1. Are there lists of skills for each position? | Yes | No | N/A | Comments |
| 1. Do they show enough detail? | Yes | No | N/A | Comments |
| 1. This is often a finding, where lists are generic with inadequate detail. | Yes | No | N/A | Comments |
| 1. Training is a key process of any system. | Yes | No | N/A | Comments |
| 1. Are there particular skills you want to evaluate? | Yes | No | N/A | Comments |

## Process Activity Map: CONTROL PROCESSES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. How is the process defined and who is responsible? | | | | |
| 1. How are customer requirements defined? | | | | |
| 1. What specifications apply defined? | | | | |
| 1. What objectives and targets apply process? | | | | |
| 1. What controls/check points are there? | | | | |
| 1. What acceptance criteria exist? | | | | |

## Process Activity Map: PROCESS INPUTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. What triggers the process? | | | | |
| 1. What inputs are required? | | | | |
| 1. Where do the inputs come from? | | | | |
| 1. Are they received in a timely manner? | Yes | No | N/A | Comments |
| 1. Are they fit for purpose? | Yes | No | N/A | Comments |

## Process Activity Map: PROCESS NAME/DESCRIPTION

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. What steps are involved in the process? | | | | |
| 1. What happens at each step in the process? | | | | |
| 1. What documents and records are generated? | | | | |
| 1. Is the process implemented in accordance with procedures, instructions or plans? | Yes | No | N/A | Comments |
| 1. Are controls applied as described? | Yes | No | N/A | Comments |

## Process Activity Map: PROCESS OUTPUTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. What is the product produced by this process? | | | | |
| 1. Are product measures in place to ensure that product meets requirements? | Yes | No | N/A | Comments |
| 1. How are processes measured? | | | | |
| 1. Are product and process measures achieved? | Yes | No | N/A | Comments |
| 1. What feedback is received from customers? | | | | |

## Process Activity Map: INSTRUCTIONS & PROCEDURES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Review the documents that describe and control the process. | Yes | No | N/A | Comments |
| 1. Review all the important steps and activities of the process being audited. | Yes | No | N/A | Comments |
| 1. This info must be documented within the QMS. | Yes | No | N/A | Comments |
| 1. Evaluate how effectively the process flows through the steps. | Yes | No | N/A | Comments |
| 1. Do you see roadblocks or issues? | Yes | No | N/A | Comments |

## Process Activity Map: SUPPORT PROCESSES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. As you audit, you will see how it connects and interacts with other processes. | Yes | No | N/A | Comments |
| 1. Interactions with other processes are always important. | Yes | No | N/A | Comments |
| 1. As you audit the, you will see how it connects and interacts with other processes. | Yes | No | N/A | Comments |
| 1. Audit the relevant links to related processes and support processes. | Yes | No | N/A | Comments |

## Process Activity Map: KEY PERFORMANCE INDICATORS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Review metrics and performance with Managers, Supervisors and operators. | Yes | No | N/A | Comments |
| 1. They should know how things are running, objectives, customer issues, problem areas. | Yes | No | N/A | Comments |
| 1. If they do not, the requirements were not met. | Yes | No | N/A | Comments |
| 1. Is there evidence that quality objectives and targets affected by this process are being achieved? | Yes | No | N/A | Comments |

## Quality Management

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Is the quality system documented, controlled and maintained to clearly describe current practice? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Quality manual and all procedures show revision control (sign-offs &amp; dates), history of changes | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Product quality yield data, problems and corresponding improvement actions, status of preventive/ corrective/audit results | Yes | No | N/A | Comments |
| 1. Audit Question: Are quality-performance targets clearly defined, included in the business plan and monitored for improvements? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Strategic and tactical objectives, goals, action plans, etc. | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Analysis of field failures, inspection yields, resource needs, internal audit results, corrective action status, etc. | Yes | No | N/A | Comments |

## Continuous Improvement

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: Management review meetings, goal setting, performance measurement, internal audits, action plans, customer surveys | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Employee involvement/recognition program, Lean, Six Sigma, kaizen, SPC, 5-S, cost reduction programme | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Corrective actions, trend charts, meeting minutes, non-conformance frequency & cost analysis | Yes | No | N/A | Comments |
| 1. Audit Question: Does the corrective action system cover customer, internal and supplier issues? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Management review meetings and corrective actions | Yes | No | N/A | Comments |

## Training & Awareness

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Is the skill and education level required for each job documented and appropriate training provided? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Look for use of training aids and work instructions at work stations | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Qualification records, certification history | Yes | No | N/A | Comments |
| 1. Audit Question: Are suitable methods used to verify training effectiveness? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Records of testing, production quality records, audit records, interview workers to validate training records | Yes | No | N/A | Comments |
| 1. Audit Question: Are suitable records of maintained? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Job descriptions, job skills assessment, training records, training manuals | Yes | No | N/A | Comments |

## Design & Development Support

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Are customer needs and requirements incorporated into product designs and/or manufacturing processes? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Market studies, customer/end-user surveys, technical design reviews | Yes | No | N/A | Comments |
| 1. Audit Question: Are Critical-to-Quality (CTQ) characteristics are identified, understood and records retained? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Process capability studies, process plan, manufacturing verification tests | Yes | No | N/A | Comments |
| 1. Audit Question: Are product specifications and drawings generated, controlled and maintained for new or changed product designs? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Product characteristics, application requirements and other information for safe and proper use and disposal | Yes | No | N/A | Comments |
| 1. Audit Question: Is design validation is an integral part of the design process and occurs prior to production release? | Yes | No | N/A | Comments |
| 1. 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 |
| 1. 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 |
| 1. Audit Evidence: Qualification of technical staff. Equipment/software capabilities, CAD | Yes | No | N/A | Comments |

## Quality Planning

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Are production samples inspected and provided to customers upon request? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Completed PPAP or similar forms, inspection reports, availability of qualified resources | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Procedures, design/process review, capacity plans, resource plans, product test, storage, packaging and shipment requirements | Yes | No | N/A | Comments |
| 1. Audit Question: Are reliability test plans developed and routinely followed? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Reliability test plans, test reports | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Improvement/corrective actions taken, design changes implemented | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Reliability test summary reports/charts | Yes | No | N/A | Comments |

## Customer Documentation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Are new and revised customer specifications reviewed and implemented in a timely manner? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Technical review of methods to be used, capability studies on similar parts, documented review procedure | Yes | No | N/A | Comments |
| 1. Audit Question: Are current process control documents in place and used for production start-up and continuing production? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Specifications, engineering drawings, change notices, work instructions and specifications as applicable | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Customer notification procedure on major changes | Yes | No | N/A | Comments |
| 1. Audit Question: Is there a record control system is in place for the identification, storage, protection? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Document control procedure | Yes | No | N/A | Comments |
| 1. Audit Question: Are quality records maintained? | Yes | No | N/A | Comments |
| 1. Audit Evidence: List of records to be kept with retention periods specified | Yes | No | N/A | Comments |

## Procurement

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Is there a formal process used for the selection, qualification and re-qualification of suppliers? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Supplier quality audits and corrective actions, engineering testing, approval records, production trials | Yes | No | N/A | Comments |
| 1. Audit Question: Are purchases from unapproved suppliers prevented by a properly controlled and available approved supplier list? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Approved supplier list, procedures, production material receipt records | Yes | No | N/A | Comments |
| 1. Audit Question: Are preventive actions taken to continuously improve performance of the supplier base? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Supplier quality performance analysis, performance trends, supplier audit reports | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Receiving inspection, supplier audits, source inspection, qualification testing, Certificate of Compliance, component marking, labelling, etc. | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Procedures, segregation during storage, limited and controlled access to stored inventories | Yes | No | N/A | Comments |

## Incoming Material

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Is receiving inspection performed per documented procedures and detailed work instructions? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Procedures, inspection instructions resources (manpower and equipment) allocated for incoming inspection | Yes | No | N/A | Comments |
| 1. Audit Question: Is inspected material adequately identified as to acceptance or rejection and traceable to receiving inspection report? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Quality control label, marking or use of designated hold area as indicated in the procedure | Yes | No | N/A | Comments |
| 1. Audit Question: Do supplier corrective action requests requiring root cause investigation show responses are analyzed? | Yes | No | N/A | Comments |
| 1. 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: Qualification plan that includes established goals for process yields. Records of process capability, review and approval | Yes | No | N/A | Comments |
| 1. Audit Question: Are control plans used to plan and deploy inspection and test functions throughout the production process? | Yes | No | N/A | Comments |
| 1. 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 |
| 1. 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 |
| 1. Audit Evidence: Sample size, frequency, method, document control dates/revision level | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Records of inspections performed at incoming, first piece, in-process and/or final inspection or test | Yes | No | N/A | Comments |
| 1. Audit Question: Is the inspection and process status of the product identified and maintained throughout the production process? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Batch records, travellers, tags, labels, product markings or use of designated and identified areas | Yes | No | N/A | Comments |
| 1. Audit Question: Are customers notified of low yield production lots or issues that affect product reliability? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Corrective actions, records of customer notifications, reliability test data | Yes | No | N/A | Comments |

## Non-conforming Outputs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Audit Question: Are nonconforming materials, parts and assemblies are segregated (where practical) and identified to prevent unapproved use? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Tags, marking, controlled staging areas | Yes | No | N/A | Comments |
| 1. Audit Question: Is reworked material, parts and assemblies are re-inspected or re-tested to confirm compliance to requirements? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Inspection record, tag and stamp | Yes | No | N/A | Comments |
| 1. Audit Question: Is the use of nonconforming material is documented under a formal waiver or concession system? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Written procedure, waiver or concession records | Yes | No | N/A | Comments |
| 1. Audit Question: Is product traceability maintained to facilitate problem evaluation and corrective action? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Serial number records, lot number, date of manufacture, labelling and marking of containers or product | Yes | No | N/A | Comments |
| 1. Audit Question: Is there a positive recall system to notify customers of nonconforming product that has already been shipped? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Documented procedure and review of system | Yes | No | N/A | Comments |

## Monitoring & Measurement

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: GR & R studies, reports | Yes | No | N/A | Comments |
| 1. Audit Question: Are measuring devices and gauges and test equipment are routinely calibrated and controlled per documented procedures? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Calibration stickers and records, positive identification or segregation of out-of-calibration devices, and inventory, location &amp; status records | Yes | No | N/A | Comments |
| 1. Audit Question: Are gauges and test equipment calibrated against standards traceable to a recognized regulatory body or agency? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Calibration procedures, and calibration stickers and other records | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Assessment records and corrective actions | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Verification methods and records, revision levels, distribution/use control | Yes | No | N/A | Comments |

## Maintenance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: GR & R studies, reportsAudit Evidence: Review of storage area, labelling, tooling records | Yes | No | N/A | Comments |
| 1. Audit Question: Does a formal preventive maintenance system (PM) exist for production equipment, tools and fixtures? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Review of system, PM plans, PM schedule and compliance results | Yes | No | N/A | Comments |
| 1. 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 |
| 1. 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: Histograms, run charts, SPC charts, pareto analysis, cause and effect diagrams, mistake proofing, reaction plan &amp; process corrections. | Yes | No | N/A | Comments |
| 1. Audit Question: Are written improvement plans are implemented to reduce sources of variation? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Documented reaction plan and process corrections. SPC trend charts showing current status vs. goals, improvement plans | Yes | No | N/A | Comments |
| 1. Audit Question: Is process capability is measured and actions are taken to maintain established minimum Cpk/Ppk targets? | Yes | No | N/A | Comments |
| 1. Audit Evidence: Documented process capability studies and results (actual vs target Cpk/Ppk) | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Control charts | Yes | No | N/A | Comments |

## Storage & Packing

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. 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 |
| 1. Audit Evidence: Observe production, office & product storage areas. (Sort, Set-in-order, Shine, Standardize, Sustain + Safety) | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Observe handling and transit of raw material, work-in-process, and finished goods. | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: FIFO practices are defined, packaging specifications, test results, handling and storage procedures. | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Technical review, packaging/shipping tests, packaging work instructions, carton strength tests | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Lists of shelf-life sensitive materials. Look for poor storage conditions and damage. Handling procedures | Yes | No | N/A | Comments |
| 1. 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 |
| 1. Audit Evidence: Process covering utility interruptions, labour shortages, key equipment failures, major production issues | Yes | No | N/A | Comments |

## Findings Summary

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Non-conformance | | | | |
| 1. Corrective Action | | | | |
| 1. Opportunities for Improvement | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Observations, Comments & Notes | | | | |