

# STEP-BY-STEP GUIDE TO REMOTE AUDITS

**Honeywell**

 Sparta  
Systems

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# INTRODUCTION

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The coronavirus disease 2019 (COVID-19) pandemic has caused multiple challenges across the manufacturing industries. It has also shown the necessity for resilience. These days digital transformation is often the driving force behind an organization's ability to be resilient. Not much longer than a year ago business was operating as usual. The pandemic changed the way businesses operate, forcing a digital transformation. Some were in a better position than others to adapt.

The continuous travel and company restrictions that are still in place mean in-person audits are no longer feasible. To maintain supplier assurance levels, industries are making the jump to remote audits. With added information and communication technologies (ICT), remote audits enable quality and compliance teams to play an active role with ongoing supplier activities without disrupting critical operational areas. Embracing this alternative auditing approach will help maintain a robust supply chain.

The benefits of remote audits are apparent: lower cost, no travel restrictions, no logistical constraints, better use of resources and the ability to continuously monitor suppliers. This eBook will review the tools to perform a successful remote audit.

Note: In this eBook, the term "supplier" also refers to "partner," "vendor," and "external provider."

## REGULATIONS AND DEFINITIONS

ISO 19011:2018(E): GUIDELINES FOR AUDITING MANAGEMENT SYSTEMS DEFINE AN AUDIT AS A SYSTEMATIC, INDEPENDENT AND DOCUMENTED PROCESS FOR OBTAINING OBJECTIVE EVIDENCE AND EVALUATING IT OBJECTIVELY TO DETERMINE THE EXTENT TO WHICH THE AUDIT CRITERIA ARE FULFILLED.

# THE PURPOSE OF SUPPLIER AUDITS

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Supplier audits provide insight and verify that they are operating at the highest level of quality.

The purpose of a supplier audit is to confirm:



**CONTINUED (OR EVALUATE A NEW SUPPLIER'S) ABILITY TO MEET PRODUCT REQUIREMENTS**



**CONTINUED (OR EVALUATE A NEW SUPPLIER'S) ABILITY TO MEET PRODUCTION DEMANDS**



**MAINTENANCE OF AN EFFECTIVE QUALITY MANAGEMENT SYSTEM**



**THE ABILITY TO BUILD AND MAINTAIN A POSITIVE RELATIONSHIP WITH THE SUPPLIER**

## PRINCIPLES OF AN AUDIT

### INTEGRITY

Honesty, ethical, responsible, unbiased

.....

### FAIR

Findings should reflect truthful and accurate activities

.....

### PROFESSIONAL

Dilligence and judgement in auditing

.....

### CONFIDENTIAL

Security of information

.....

### INDEPENDENT

Free from bias and conflict of interest

.....

### EVIDENCE-BASED APPROACH

Audit is verifiable

.....

### RISK-BASED APPROACH

Considers risk and opportunities

# SIX STEPS TO PERFORMING A SUCCESSFUL REMOTE AUDIT

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The key to performing a successful remote audit is divided into six areas: plan, schedule, perform, report, actions, and close-out.



# 1 PLAN

Thoughtfully planning remote audits helps minimize backtracking and provides for a smooth process. Ensure that your policies and procedures accurately reflect the expectations and requirements of suppliers. Current regulations do not provide guidelines on remote audits. Therefore, companies should evaluate each supplier using a risk-based approach and on whether the outcomes are achievable through a remote audit.

Before moving forward with scheduling a remote audit, review the list of essential items for each supplier:

- The quality agreement does not call for specific security and data protection issues
  - Document was produced and signed by both parties to prohibit any recording of screen-shares
- Has a stable connection with good online connection quality
- Any apparent IT concerns, firewalls, security or limitations?
- Can allow access to relevant documented information, including software, databases and records
  - Tip: Watch out for an inefficient manual process or inaccessible documentation
- Has access to other team members in the supplier's organization by video
- Is the organization operating regularly due to contingency situations? If not, the processes/activities being performed are representative and allow the fulfillment of the audit objectives ("ISO 9001 Auditing Practices Group Guidance on: Remote Audits")

**DOCUMENT IF EACH SUPPLIER CAN MEET THE GOALS BY WHETHER THEY:**

**CAN BE ATTAINED WITH THE REMOTE AUDIT**



**PROCEED TO REMOTE AUDIT**

**CAN BE ACHIEVED PARTIALLY**



**A REMOTE AUDIT MAY BE DONE PARTIALLY**

**CANNOT BE ACHIEVED**



**AN IN-PERSON OR ONSITE AUDIT MUST BE PERFORMED**

# 2 SCHEDULE

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## INITIAL STAKEHOLDER REVIEW

After the initial planning, provide a review of the supplier's profile for critical stakeholders with the following deliverables:

- Company (Country of Origin) and point of contact
- How the audit will be performed
- Type of audit (new supplier, routine, risk assessment, etc.)
  - Plan and scope of the audit
- Supplier risk-level category (high, medium, low)
  - Deviations, nonconformances, post-market reviews, complaints performance (on-time delivery and on-quality delivery)
  - Criteria of risk should be defined such as: possibility of failure to meet requirements, consequences resulting in failures and how much risk is accepted
- Product/service/items(es) being audited
- Number of days for the audit
- Number of auditors required



# 2 SCHEDULE

## SUPPLIER NOTIFICATION FOR A REMOTE AUDIT

The remote audit should be organized in the format of an onsite audit. A new or current supplier audit is used to verify the continued ability to meet product requirements, production demands, and an effective quality management system. Ensure both parties are competent in the process and have the online connection capability.

### Provide the supplier with a detailed remote audit notification which contains at a minimum:

- Purpose of the audit
- Scope of the audit
  - Physical locations
  - Departments and areas
  - Product, process, or systems
  - Excluded areas of the audit
  - Timeline for audit and activities
  - Applicable standards, contracts, regulations, codes, and other legal guides
  - Relevant systems and policies and procedures
- Remote Audit
  - Discussion on a secure connection
  - Viewing documents
  - Tours
- Dates, schedule, and auditors
  - Remote tour, determine areas which are necessary to review
  - Documentation request
  - Department manager interviews
- Pre-audit documentation request
  - Examples: Quality policy, index or complete quality manual, organizational charts, list of products and current specifications/IFUs and facility map
- Audit day documentation request
  - Complaint, nonconformance and corrective action and preventive action (CAPA) logs
  - The sequence of processes relevant (flowcharts)
    - How is the process managed?
  - Index of policies and procedures relevant
  - Internal and external audit schedule
  - Last two management review results
  - How is customer satisfaction achieved?
  - Validations pertinent to the product
  - Training
  - Calibrations



# 3 PERFORM

## **OPENING MEETING** (same format as onsite audit)

Remote interaction can be a phone call or videoconference Web meeting.

- Introduction
- Attendance sheet
- Audit plan and activities

### **Explain risk and process approach on the areas to be audited**

- Review objectives, scope, schedule and criteria
  - Standards and regulations
  - Procedures and policies are applicable to work
  - Procedures are up to date
  - Employees are trained
  - Records are maintained
  - Historical information
  - Sampling plans and strategies
  - Verification through observations, discussions and review of documents
- Health and safety questions
- Confirm daily and final close-out meeting(s)

# 3 PERFORM

## CONDUCTING AUDIT AND DOCUMENT OBSERVATIONS

During a remote audit, documents can be reviewed via video conference with screen share, real-time video images, asynchronous document and data review.

Gather information to support the audit activities which can include interviews, observations and review of documented information. Audit observations evidence should be evaluated against the audit criteria to determine the audit finding/ observation. Observations should be documented using risk-based thinking. During the audit confirm inputs match the outputs, training, equipment is maintained, flowcharts match the process, housekeeping and basic GMPs.

Does the supplier identify and control hazards and risk?

# 3 PERFORM

## CLOSING MEETING

According to ISO 19011:2018 guidelines for auditing management systems, the audit team should meet before the closing meeting to:

- Review the audit findings and any other appropriate information collected during the audit against the audit objectives
- Agree on the audit conclusions, considering the uncertainty inherent in the audit process
- Prepare recommendations, if specified by the audit plan
- Discuss audit follow-up, as applicable
- The closing meeting is the same for onsite or remote. The purpose is to present a draft or preliminary audit report to ensure the audit results are clearly understood by top management.
- Document attendance
- Review scope, standards and regulations
- Methodology of reporting
- How to address audit observations
- Recommendations or opportunities for improvement
- Best practices
- Observations
  - Definition of nonconformance and CAPAs
- Confidentiality
- Next steps



# 4 REPORT

The purpose of the audit report is to communicate the investigation results which will guide management on the decisions and activities needed. The report should be a complete and accurate record of the audit. If there are no observations, an audit report is still required. Ensure the audit report is written using common terms or define unfamiliar terms, try to avoid acronyms, and avoid using fluff.

The report should include:

- Objectives and scope
- Audit team
- Dates and locations
- Audit criteria
- Audit findings/nonconformities and evidence of the nonconformity
  - Minor noncompliance or Major noncompliance
- Requirements
- Risk classification
- Provisions for recording corrective action and follow-up activities
- Opportunities for improvements or feedback on the suppliers' best practices
- Statement on the degree to which the audit criteria were fulfilled
- Statement of the confidential nature of the contents

The audit report should be dated, reviewed and accepted then distributed to the relevant parties.

## EXAMPLE OF RISK CLASSIFICATION



# 4 REPORT

**TABLE 1 - IMPACT ASSESSMENT**

Risk Impact #	Description
1	Improperly completed forms/records
2	Failure to meet requirements that do not impact product/service received
3	Failure that could lead to an issue with the product/service received failure could cause significant business risk
4	Failure could lead to significant or total malfunction of the product/service received
5	Noncompliance that is a hazard or may lead to hazardous conditions

**TABLE 2 - FREQUENCY OF OCCURRENCE**

Occurrences	Description
1	Fewer than 10% of lots or parts with issues
2	Between 10% and 20% of lots or parts with issues
3	Between 21% and 32% of lots or parts with issues
4	Between 33% and 50% of lots or parts with issues
5	Greater than 50% of lots or parts with issues

NC #	Regulation / Standard	Nonconformance Description and Process	Supplier Policy #	Risk Impact	Frequency of Occurrence
1	21 CFR 820.160 Distribution Records	Records do not identify the date shipped	Policy #10	3	5

# 5 ACTIONS

Once the audit findings are complete ensure accuracy, sufficiency and appropriateness of the corrective action and documentation received meets and supports the audit findings.

**ACCURACY**

**SUFFICIENCY**

**APPROPRIATENESS**



# 6 CLOSE-OUT

**“The audit is completed when all the planned audit activities have been carried out, or otherwise agreed with the audit client”**

(ISO 19011, clause 6.6). Clause 6.7 of ISO 19011 continues by stating that verification of follow-up actions may be part of a subsequent audit.



# TECHNOLOGY SIMPLIFIES SUPPLIER AUDITS

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With the increased reliance on global suppliers, companies are looking to increase collaboration and transparency across the value chain. Now it is critical to maintain and streamline the supplier process using a single repository of suppliers.

Utilizing a supplier module allows for quick onboarding eliminating multiple paper surveys. The supplier management module collects, tracks, and manages required supplier documents providing real-time status on the dashboard. Risk-based supplier audits can be scheduled, allowing suppliers to update certificates, specifications or instructions for use (IFUs), and other documents in one location, enabling users to communicate bill of material (BOM) needs.

Once the appropriate criteria are evaluated, auditors can generate a formatted report that includes the written audit observations of good practices and risks and problems identified. This report forms the basis of the discussion about the audit results and findings. An audit management system provides reporting capabilities that also generate trends and metrics against data gathered across reports. For example, using a system that can track multiple auditing groups, risk and prioritization can be rolled up and used to determine the prioritization of resources across groups, not just on a siloed basis within each group.

Suppose a quality incident is related to a supplier. In that case, the supplier portal allows real-time communication between the company and the supplier to resolve the issue and quarantine any suspected material or finished goods, providing more significant supply chain reliability.

The ability to quickly add, monitor, and remove suppliers will significantly impact the company's ability to reduce the cost of inadequate quality.



Real-time data visibility and drill-down functionality are proactive qualities. The performance of suppliers integrate with other modules allows manufacturers to identify trends, make decisions without relying on inconsonant data, determine the probability of issues, identify opportunities and drive operational productivity.



# KEEP SUPPLIER QUALITY TOP OF MIND WITH REMOTE AUDITS

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Resiliency has proven to be a key criterion in the supply chain. Those with an electronic system in place were further along in their digital transformation journey; however, organizations can still catch up. The steps provided in this eBook will assist organizations in effectively performing remote supplier audits. Conducting audits is a necessary step to reduce costs, provide safe products and reduce the chance of supplier chain disruptions. To achieve supply chain sustainability stakeholders should take a risk-based approach. This, coupled with a remote supplier audit process, will minimize supplier and, ultimately, patient risk.

**Get started today by following the steps provided.**  
For more guidance on remote audits, **contact us.**



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