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Objectives

- Understand Requirements for Audits
- Identify the Principles of Auditing
- Explore Communication Styles
- Determine Technology Requirements
- Understand the Linkages to Risk
- Identify Remote Auditing Challenges and Opportunities
- Discuss Remote Audit Program Management
- Learn How to Plan and Perform Remote Audits
- Select Audit Documents and Records
- Identify Processes and Their Requirements
- Understand the Process Approach

What is an Audit?

“Audits are fact-finding missions, audits are not fault-finding safaris”

What do Audits Measure?

- Compliance to standards, regulations, guidances, requirements, and specifications
- Performance of processes and systems
- Adequacy and effectiveness of the quality system
- Conformance with contractual obligations

“We audit the product, process or system, not the people”
Types of Audits

- System
- Process
- Product

Requirements for Audits

- Establish, implement, and maintain procedures for quality audits
- Define the audit criteria, scope, interval and methods
- Determine the necessary competence and ensure competence based on education, training, or experience.
- Ensure objectivity and impartiality of the audit process
- Conduct audits considering the status and importance of the processes as well as the results of previous audits
- Ensure audit results are reviewed by management having responsibility for the matters audited
- Ensure corrective action(s) are initiated and if required re-audit the deficient matters

ISO 19011:2018 Guidelines for Auditing Management Systems

1 Scope
2 Normative References
3 Terms and Definitions
4 Principles of Auditing
5 Managing an Audit Program
6 Conducting an Audit
7 Competence and Evaluation of Auditors
Annex A Additional guidance for auditors planning and conducting audits
The Three Participants in an Audit

Client

I hope they pass the audit this time!

Auditor

I do not want to hear it!

Auditee

I am not talking!

Principles of Auditing

- Integrity
- Fair presentation
- Due professional care
- Confidentiality
- Independence
- Evidence-based approach
- Risk-based approach

Communications
Communications

Synchronous vs Asynchronous Communications

Cross-Cultural Communication Styles

Low context implies that a lot of information is exchanged explicitly through the message itself and rarely is anything implicit or hidden.

High context implies that a lot of unspoken information is implicitly transferred during communication.
Audit Program Risks

- Criticality of the process
- Changes in the process
- Quality Performance
- Past audit performance
- Maturity of the system
- Experience of the staff
- Regulatory requirements
- Certification requirements

On-Site Versus Remote Audits

<table>
<thead>
<tr>
<th>Advantages of On-site Audits</th>
<th>Advantages of Remote Audits</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Enhanced ability to visualize the facility, equipment, and processes</td>
<td>- No travel costs</td>
</tr>
<tr>
<td>- Records are easier to produce</td>
<td>- No lost time due to travel</td>
</tr>
<tr>
<td>- Easier to adapt to what is observed</td>
<td>- More flexible scheduling considerations</td>
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<tr>
<td>- Increased ability to read body language</td>
<td>- Minimize the risk of contamination by the auditor</td>
</tr>
<tr>
<td>- Better suited for product audits</td>
<td>- No auditor training</td>
</tr>
<tr>
<td>- No rush to catch a flight</td>
<td>- The auditor can work in pajamas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disadvantages of On-site Audits</th>
<th>Disadvantages of Remote Audits</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Travel costs</td>
<td>- More preparation required</td>
</tr>
<tr>
<td>- Lost time due to travel</td>
<td>- Limited ability to visualize the facility, equipment, and processes</td>
</tr>
<tr>
<td>- Rush to catch a flight</td>
<td>- Difficult to see if things are clean</td>
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<tr>
<td>- Flight delays/cancellations</td>
<td>- The auditee may use technology to slow the pace of the audit</td>
</tr>
<tr>
<td>- Flight delays/cancellations</td>
<td>- Decreased capability to read body language</td>
</tr>
<tr>
<td>- Time zone issues</td>
<td>- Time zone issues</td>
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</tbody>
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The Remote Audit Process

- Determine the Need
- Scheduling the Audit
- Plan the Audit
- Perform the Audit
- Complete and Distribute the Audit Report
- Carry Out Follow-up Activities
- Close the Audit
Determining the Need

- Regulatory
- Certification
- Accreditation
- Internal Policies
- Internal Procedures
- Customer Requirements

Scheduling the Audit

Audit Planning

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Surveillance Audit Planning

- Batch Records
- Quality Control
- Management Review
- Previous Audit CAPAs
- Supplier Management
- Personnel Qualifications
- Organization roles and Responsibilities
- Changes Implemented Since the Previous Audit
- Infrastructure, Work Environment, and Equipment
- ISO Certification, Regulatory Inspections, and Internal Audits

Performing the Audit

Completing and Distributing the Audit Report
Carrying Out Follow-up Activities

Closing Out the Audit

QMS Processes

- Customer Oriented Processes (COPs)
- Support Oriented Processes (SOPs)
- Assessment Support Oriented Processes (AOPs)
- Management Oriented Processes (MOPs)
Process Approach Audits

Identify the Key QMS Process

What are the process input(s)?

What are the process output(s)?

With what physical resources?

With what human resources?

How is the process done?

What are the process measurables?

What are the process risks and opportunities?

Were the previous audit or quality issues resolved?