



SUPPLIER AND INTERNAL AUDITS

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SUPPLIER AUDITS

Supplier Audits

- Continuing Assessment Audit
- Qualification Audit

- Pre-audit Planning
- On-site
- Post Audit work

Pre-Audit Planning

Qualification

- Contact supplier – use the phone!
- Get basic info on their QMS
- Request a copy of Quality Manual and a sample of procedures
- Explain reason for audit, scope, criteria
- Set audit date – target 4 to 6 weeks out
- Plan for one more t-con prior to visit
- Send audit notification letter with agenda
- Send copy of audit checklist (optional)



Pre-Audit Planning

Continuing Assessment

- Contact supplier – use the phone!
- Explain reason for audit, scope, criteria
- Any changes in management or ownership?
- Set audit date – target 4 to 6 weeks out
(plan visit to coincide with production)
- Plan for one more t-con prior to visit
- Send audit notification letter with agenda
- Send copy of audit checklist (optional)



Pre-Audit Planning

- Review supplier Quality Manual / Procedures (Qualification)
- Review supplier Quality data: Nonconformance's, On-time delivery (CA)
- Discuss audit status with Client
- Final T-con with supplier: Discuss any questions with QMS, Quality data, Confirm audit date and time



On Site *Opening meeting*

- Arrive on time!
- Opening meeting / sign-in sheet
- Introductions – restate reason for audit
- Allow time for supplier to present company history
- Plan to have lunch brought in



On Site *Plant tour*

- RECEIVING DOCK
- How are parts received – dispositioned?
- Is there a marked Quarantine / NC area?

NOTE:

- Avoid competitor material
- Follow all safety rules
- NOTE: Maintain control – watch for extraneous information

QUOTE:

- “You can observe a lot by just watching.” *Yogi Berra*



On Site

Plant tour

- PRODUCTION AREA
- Work in process: Check work instructions, electronic, paper? Check revisions
- Ask production employee to explain what they're doing
- Ask employees if they know what the Quality Policy is
- Status of product should be clear throughout process – ID/Lot, next steps, approvals
- Any parts or materials not marked?
- Check calibration tags

NOTE:

- Ask escort for permission before speaking with employees
- Don't badger employees - bring up any issues with your escort

QUOTE:

- “A bad system will beat a good person every time.” *W. Edwards Deming*

On Site *Plant tour*

- WAREHOUSE / FINISHED GOODS
- Check product approval status
- Storage area organization

NOTE:

- At all times: Note Findings / Observations at the time of discovery
- Finding: Specific evidence of a shortcoming to a specific requirement
- Observation: Recommendation for improvement

QUOTE:

- “Quality is pride of workmanship” *W. Edwards Deming*



On Site *QMS Evaluation*



- CONFERENCE ROOM
- Choose Part # - Obtain recent completed batch record – CA
- Obtain recent completed batch record of similar project – Qualification
- Use selected record as a base for QMS evaluation: Training, Supplier qualification, raw material approvals, followed supplier procedures for approval...
- Repeat

NOTE:

- Take “Field trips” back to Production areas as needed to check compliance
- Defensive attitude: Don’t escalate, redirect to audit scope and criteria

QUOTE:

- “Eighty percent of success is showing up.” *Woody Allen*

On Site *QMS Evaluation*

- CONFERENCE ROOM: Check QMS against Supplier Procedures and ISO

EXAMPLES:

- Management review: Last 2 or 3 records, track outputs from one to the next
- CAPA: Should have a Log, including sources. Check oldest open CAPA
- Training: Training matrix
- Internal Audits: Schedule, Independent auditors

NOTE:

- Keep up on your checklist / audit notes with evidence: Rev #s, Records, Dates
- Avoid personnel records beyond training or resume

On Site *Closing meeting*



- CONFERENCE ROOM
- Plan for 30 minutes of Auditor time prior to meeting
- No surprises
- Discuss positive traits first
- List Findings, Observations
- Provide estimate for date they will receive report and expectations for addressing the Findings

NOTE:

- Positive observations: avoid *“The facility was clean and well organized”*

QUOTE:

- *“The advice I would give to someone is to not take anyone's advice.” Eddie Murphy*



Back at the office

Audit Report



- Goal is to complete audit report as soon as possible
- Tell the story of the audit. List primary contacts, basic info about the company and what they provide, (or will provide), positive aspects
- Write Findings that you can defend. Problem statement should list requirement and exactly how the supplier failed to meet it
- Observations should be written as recommendations

QUOTE:

- “It ain’t over till it’s over.” *Yogi Berra*

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INTERNAL AUDITS

Internal Audit *Challenges*

- PRO: Familiarity with systems and processes
- CON: May be seen as something just to get done
- Management Commitment to Quality is a must

NOTE:

- Recruit a variety of Internal Auditors
- Largely the same steps as a supplier audit

QUOTE:

- “It is most important that top management be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below.” *Joseph M. Juran*



Q & A

