AUDIT TIPS

DCVMN – Hyderabad, India

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10 TIPS IN PREPARING AND CONDUCTING AUDITS

1. Be prepared
2. Training
3. What to expect – How mature is the QMS?
4. Manage the inspection
5. Control time
6. Good responses
7. Detect dishonesty. Data integrity
8. Communicate constantly
9. Have the right people participate
10. Be aware of surprise changes
1. BE PREPARED

• Plan ahead of time

• Know who you are auditing. Identify areas of interest

• Identify team leader, roles of other auditors

• Focus on facilities, product quality and Quality System (compliance with SOPs, and with product manufacturing procedures, specifications of materials and finished product)
2. TRAINING

- Provide training and an effective qualification of auditors

- Perform mock inspection situations while training junior auditors.

- Job profile and selection process
3. WHAT TO EXPECT? HOW TO MEASURE THE QMS?

• All companies have problems and changes, .. You need to understand HOW they manage (learn + prevent) them in a documented manner.

• In what evolution state is the QRM?

• Is the company Reactive or Proactive?

• Has Quality Metrics been developed?

• Are the responsibilities of the QMS evenly distributed among the heads of department?

• Is there a top-down QMS philosophy, commitment, planning and accountability?
4. MANAGE THE INSPECTION

• Keep control of audit process in two ways: time and people (auditors and auditees behavior)

• Pay attention to initial meeting to see roles in the company: who is running the show? Be aware of signs of lack of independence of QA

• Identify who are the company / sector person who will accompany the auditors during the facility tours. Ideally, they should be both knowledgeable and experienced
4. MANAGE THE INSPECTION

• Start creating the right atmosphere of the audit process- empathy. Manage and be aware of stress of situation that may rapidly change.

• Start reviewing summary reports, then to the details. Write down the documents requested.

• Look for indexes for fast retrieval of documents. Shows control on the process and facilitates your revision process.
4. MANAGE THE INSPECTION

• Guide the auditee not add anything that is not relevant or have been asked for. Pay attention when information is volunteered.

• Neutralize confrontations with auditees. Clarify in an assertive way, but do not look for acceptance from the auditee.

• Avoid arguing between auditors in front of auditee.

• Avoid company members to argue among themselves.

• Always auditors accompanied. Never alone.
5. CONTROL TIME

• Be sure to complete the agenda, and to have time to review the necessary documentation

• Time management

• Be aware of personnel trying to divert

• Keep track of the time for bringing the documentation (should not exceed, ideally, 0.5 hour). Check for post-it notes, blank spaces, contradictory statements, and lack or poor review
6. GOOD RESPONSES

• Ensure you are provided accurate information. Make sure the auditee has not misunderstood the question or the documents requested.

• Guessing answers does not help the audit. Have the auditee know that it is ok to give the answer later after checking.

• You do not want a fast answer, you want a correct one. Of course, fast and correct, ideal.
7. DETECT DESHONESTY. DATA INTEGRITY

• If the trust is lost because you detect lies, or concealed information, audit is possibly over

• Data Integrity breech

• Try to understand if the problem is at the operator/analyst level, at the supervisory/manager level, or from upper management
8. COMMUNICATE CONSTANTLY

• Ensure that there is a complete understanding of questions asked or requests made.

• Give frequent debriefing sessions.

• Clear up as many issues as possible before the wrap-up and exit meetings.
9. HAVE THE RIGHT PEOPLE PARTICIPATE

• Because an inspection can focus heavily on technical information and data regarding the development, transfer, analytical of a product, it is important to have technical experts trained to participate

• Ideal auditees: good communication skills and expertise (Subject Matter Experts, expected)
10. BE AWARE OF CONTEXT & SURPRISE CHANGES

• An audit or inspection is not the time to initially describe and discuss changes made to a product, process or facility. Such unexpected changes are perhaps the single most critical item that can negatively impact an inspection.

• Deviations found by the inspector: acknowledge any attempt to manage the deviation during the audit. This is a good sign.
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