



# 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 breach
- 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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