



AUDITING SKILLS

DCVMN – Hyderabad, India

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GMP KNOWLEDGE AND COACHED COMUNICATION TECHNIQUES

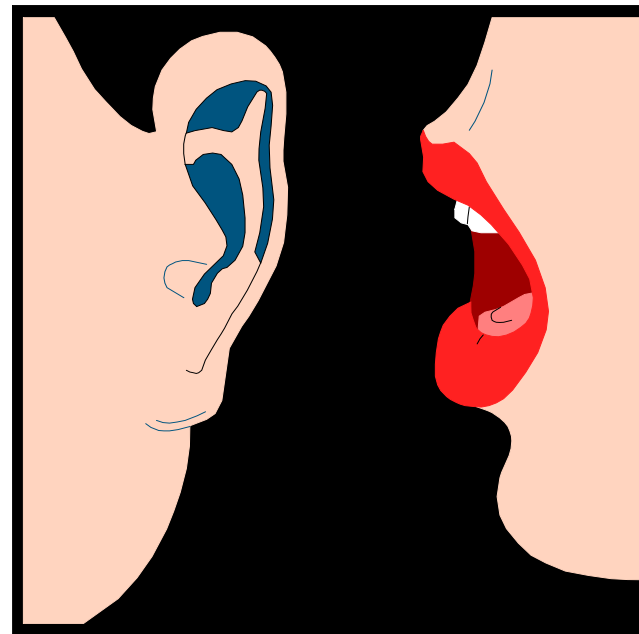


- Read the interview with L. Hartmann & P. Zimmermann, and summarize key concerns / recommendations around the following 8 questions:
 1. What is more important in conducting audits - knowledge in GMP details or communication skills? Why?
 2. Which job training elements are required for a good auditor?
 3. What are the most common mistakes of auditees?
 4. What is your advice to guarantee a successful audit?
 5. What are the most relevant reasons leading into conflicts in an audit?
 6. What can we learn from daily life to improve audits?
 7. What is the most relevant skill to conduct an audit?
 8. How can we detect early warnings of escalating conflicts during audits?

INTERVIEW HANDLING

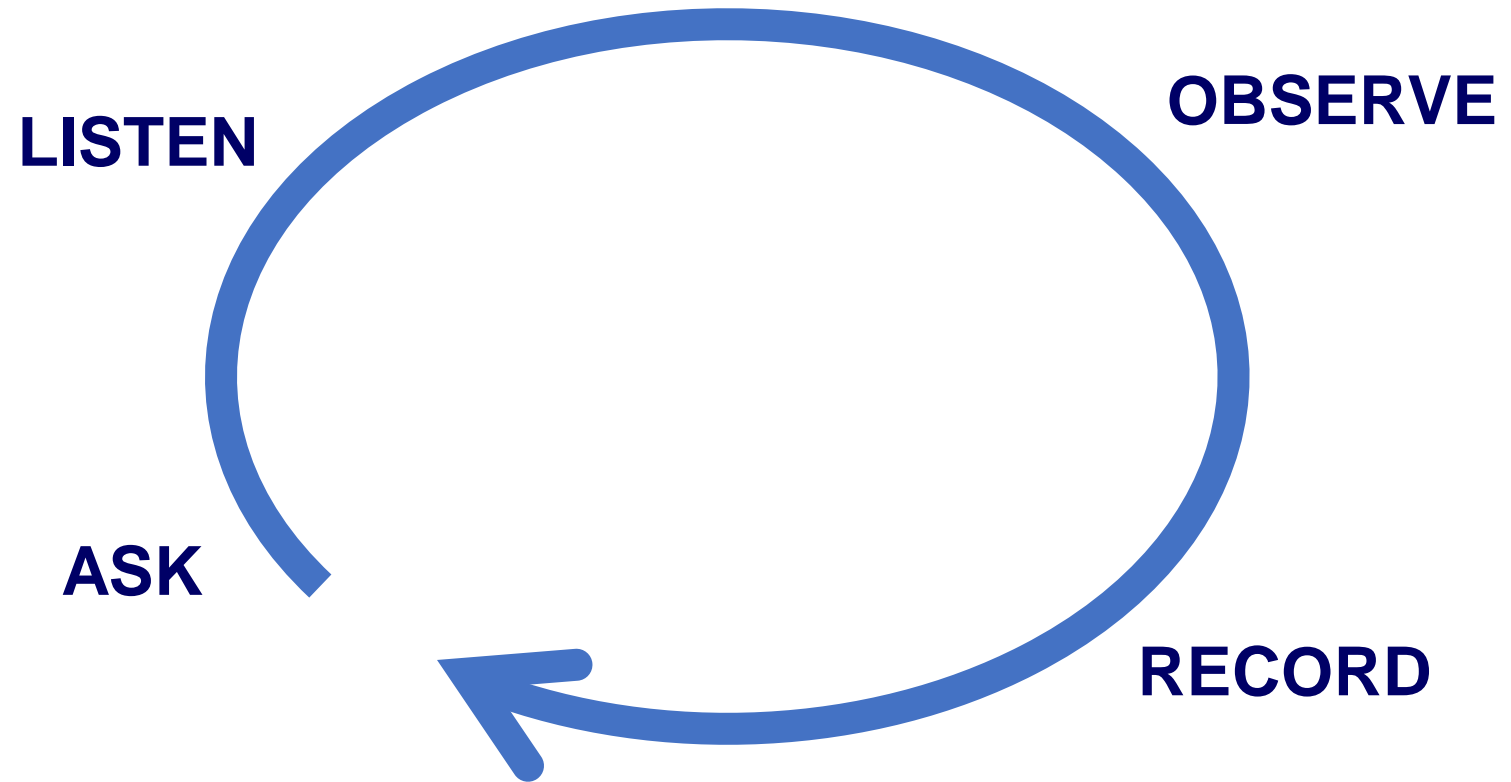


The value of listening



Auditors: Remember to invest most of your time listening

INTERVIEW PROCESS



OPEN QUESTIONS



Seek specific information.

- Give me an example of
- How does this work...?
- Any other comment ?

ADVANTAGES:

- Clarifies.
- Verifies the meaning of words and statements
- Avoids misunderstandings.

CLOSED QUESTIONS



Short answers.

- Were you involved in this process ?

ADVANTAGES

- Allows the auditor to verify the information and avoid misinterpretations and misunderstandings.
- Good for timid and communicative auditees

BIASED QUESTIONS



Biased Questions influence the auditee.

- I suppose you already know this violates basic GMP norms?
- Shouldn't this be in under quarantine?

DISADVANTAGES

- These questions suggest the answer.
- The information gathered is strongly distorted or influenced

AGGRESSIVE QUESTIONS



- Were you the incapable person that did this ?
- Couldn't you have placed this in the right place?

DISADVANTAGES:

- Places the auditee on the defensive, stressed, out of control. Interferes with audit process.
- Information gathered may not be reliable.

MULTIPLE QUESTIONS



- When did you start in the company, how were you trained for the task you are performing, and do you believe you are following the right procedure? -

DISADVANTAGES

- They bring confusion to the auditee -
- Induces the auditee to deviate from important points



IDENTIFY THE QUESTION AS: OPEN, CLOSED, BIASED OR AGGRESSIVE



QUESTION	TYPE ?
- Of course, for you it is obvious this is the wrong seal, correct?	
- Would you please tell me more about the adding of Thiomersal to inactivate ?	
- After having been working all this time, why didn't you read the cleaning procedure ?	
- Did you record all the fermentation process?	
- What do you mean with inactivating the bulk ?	

HANDLING OF INTERVIEWS



Recommended:

Start with open questions (inviting the auditee to speak freely and give more information) ■

¿How ...?

¿In which manner?

¿With which criteria ...?

Then, use closed questions to confirm data ■



Use questions with alternatives only if time is running out ■

EXERCISE: COMUNICATION SKILLS



“feel the power of communication”

Watch the video and summarize / highlight the key concerns, techniques and recommendations to consider during the performance of the audit.

AUDITORS, BE PREPARED!!!!!!!



Auditees may be:

- Timid
- Aggressive
- Distracted
- Very busy
- Evasive
- Stressed
- May have pre-prepared samples of documentation
- Influenced by local culture
- Limited answers-

- Trying to hide by being instructed to do so or by their own decision.-

TIPS FOR THE AUDITOR

Auditing Techniques



Do

- Stop talking
- Calm the Auditee
- Focus on listening
- Remove distractions
- Empathize
- Patience
- Hold your temper
- Question
- Be humble
- LISTEN

Don't

- Judge
- Embellish
- Inattentive
- Speak unclearly
- Talk excessively
- Phrase yes/no questions
- Display an attitude
- Argue
- Criticize
- Answer your question

“to improve or beautify by adding detail or ornament; adorn”

Empathize: “identify with, understand, relate to, feel for, sympathize with, have a rapport”

Be understanding to get the necessary information & evidence

TIPS FOR THE AUDITEE



- Do not volunteer information or data you were not asked for, but NEVER lie
- Be honest, open and cooperative
- Ask the auditor if you're not sure
- Never leave the auditor alone, unless for their own closed door meetings.
- Never argue in front of the auditor, or with the auditor. -
- Be ASCERTIVE, not confrontational.-
- Company's audit team leader coordinates the selection and participation of - auditees and SME.



CONCLUSIONS

Nobody likes to be audited.....

It is a means to have continuous improvement

