

PROPER BEHAVIOR of AUDITOR and AUDITEE.

Auditor: Select a topic and elaborate a **minor** finding including applicable evidence. Auditee: responds properly, shows appropriate evidence. Auditor: acknowledges compliance level.

ARGUING BETWEEN AUDITEES. Auditor: Select a topic; elaborate a **major** or **critical** finding including applicable evidence. Auditee: QA and Production argue between themselves with contradictory statements and they give details which were not asked by the auditor which represent new GMP violations. Auditor: manages the situation; communicates the potential deviations. Auditee: get very nervous and reveals lack of upper management support including lack of personnel.

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BIASSED. Auditor: Select a topic; elaborate a finding including applicable evidence. Auditee: elaborate proper response/attitude. Auditor: reacts in a biased manner (e.g. “this is a non-conformity because I experienced a similar problem where I used to work, and I have read and heard about this before”). Auditee: prepare a proper response/attitude. Auditor: Insists in biased position.

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DELEGATING QA FUNCTIONS. Auditor: Select a topic; prepare a finding including applicable evidence. Auditee: QA representative shall simulate lack of knowledge and involvement in the study (e.g. “this excellent protocol was entirely executed and supervised by production as they are the ones that know the process; I just sign off”). Auditor: asks for applicable records. Auditee: production personnel shows unacceptable records (e.g., duplicated forms, lack of sign offs, adulteration). QA tries to minimize findings. Auditor: communicates seriousness of the problem.

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CONFRONTING / AGGRESSIVE. Auditor: Select a topic: prepare a finding including applicable evidence. Auditee: simulate confronting physical and body language response (e.g. “I do not agree with your observation which is completely wrong and is showing your lack of knowledge”). 1. Auditor: Use de-escalation techniques; “you are entitled not to agree, but the observation is based on this objective evidence XXX shows non-compliance of point XXX of guidance XXX”.

2. Auditor: simulate Response II: “I am the auditor, and what I say is the truth and I do not need to give you any explanation”. Auditee: escalates reaction. Auditor leaves without collecting evidence.

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CONSULTING. Auditor: select a topic; elaborate a finding including applicable evidence. Auditee: prepare answer acknowledging the finding. Auditor: give consultancy on GMP fundamentals and exactly how to do things (e.g. “you need to hire 2 more people in this area who should report to you only, create a new position, replace your existing disinfectants with this new very good and inexpensive one...”). Auditee: acknowledges but tries to show current disinfectants are adequate. Auditor: keeps on giving recommendations without auditing.

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LACK OF DATA INTEGRITY. Auditor: select a topic: elaborate a finding including applicable specific evidence specific (e.g., no double verification on calculations of release testing, backdating, inaccurate data, test-to-pass, wrong cross outs, false entry, etc.). Auditee's answer: production manager minimizes finding showing lack of knowledge. QA remains silent showing surprise and lack of oversight. Auditor: conclude/assess compliance level.

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LACK OF GMP knowledge. Auditor: select a topic; elaborate finding including applicable evidence. Auditee shows evidence of compliance but shows he does not understand main aspects of the topic, was not involved in the study, and does not believe in the GMP the associated requirement (e.g. "Qualification studies were done by vendor, but are of no real use and are just a bureaucratic exercise to please regulators"). Auditor: shows evidence that what is currently done by production is not what it was validated.

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JUMPING EARLY INTO CONCLUSIONS. Auditor: select a topic; elaborate a finding including applicable evidence. Auditee: starts to explain a proper response, but auditor interrupts and jumps early into conclusions and disqualifies auditee (e.g. “this is a disaster, you are doing everything wrong!, this for sure will be a non-conformity, you will see; I am going to talk to your boss about this; who trained you? Did you have any experience before coming here?”). Also, gets very close to auditee and finger-points. Auditee’s response: nervous, out of control, silent, depressed. QA manager intervenes and de-escalates the situation.

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LACK OF OBJECTIVE EVIDENCE. Auditor: in the closing meeting communicate to Auditee a finding with incorrect or no objective evidence (e.g. “temperature in one of the freezers is not recorded correctly, difficult to read, incomplete; I saw it myself”). Auditee: politely, disagrees and shows evidence of compliance.

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AUDITEE FILLS THE SILENT MOMENTS WITH UNWANTED INFORMATION, revealing non-compliances (nervous or self-confident-show off).

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AUDITEE IGNORES AUDITOR. Claims he has no time to waste in this activity. Keeps on with his activity while interacting with the auditor. Answers phone.

Auditor: tries to manage the situation explaining the auditee the purpose of the audit, etc.

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CLOSED QUESTIONS / MULTIPLE QUESTIONS