

Do's and Don'ts

During an FDA Inspection



- Be honest in answering questions.
- Only answer questions asked by the Inspector directly.
- If the question is vague, make sure to ask the Inspector to clarify.
- Let the Subject Matter Experts discuss questions in their expertise.
- Be cool and calm.
- Be polite and show confidence by being an active participant.
- Be aware of your strengths and play to them.
- Be aware of weaknesses or soft spots to limit the damage.
- It's OK to acknowledge you aren't perfect but make sure to emphasize the positives that you are doing well in.



- Do not lie or speculate to the Inspector.
- Do not become angry or pressured into answering questions.
- Do not sign affidavits.
- Do not argue with team members.
- Do not volunteer to change or approve documentation during the inspection. Get management input first.
- Do not speak outside your area of expertise or without reviewing the document.
- Don't discuss topics that may be in poor taste (politics, religion, sports).
- Do not review unofficial records.
- Do not offer the Inspector access to the Company network or computer systems.
- Do not refuse to answer a lawful question. Instead, let the Inspector know you need to speak with management first.



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