

Effectively Responding to Questions During a Regulatory Inspection

Calibration & Validation Group
5 October 2006

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Goal

- Provide information so that you can better answer questions during an inspection with confidence.

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Topics

- Why are they inspecting **us**?
- Basic questions that need to be answered
- Types of questions that might be asked
- Frequently seen problems
- If you discover you have a problem...
- Eight suggestions to improve your probability of inspection success

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Why are they inspecting us?

Or, the reasons for an inspection

- Determine compliance with regulations and requirements
- Determine compliance with registration, license, or authorization
- “For cause”
- “Evidence gathering activity” – (FDA in U.S.)
- Observe trends in industry
- Learn/become familiar with new technologies
- Identify and evaluate the risks that consumers of your products may be exposed to

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The quick and simple rules for an inspection

- Say what you do
- Do what you say
- Be able to prove it

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A more complete list of “rules”

- Say (in writing) **what** you are doing.
- Know **why** you are doing it.
- Be sure that what you say and do is consistent and in keeping with good practice and applicable requirements.
- Have evidence to show what you did.
- Be sure your actions, processes, outputs, and decisions show that you are in a state of control.
- Know the risks and control the important ones.

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Goals: Yours and theirs

- Get the questions answered.
- Leave.

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Factors affecting how we make decisions about risk

- Risk perceptions, including how well we understand the risk: ***the less well understood the situation, the less risk we will accept***
- Heuristics (rules of thumb): ***availability of information and anchoring***
- The amount of trust we have in the source of the information: ***the more we trust the source, the more risk we are willing to accept***

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Types of questions

- **Direct**
 - *How do you calibrate your analytical balances?*
- **Leading** (points to the answer desired)
 - *You frequently have problems with this assay, don't you?*
- **Open-ended**
 - *Tell me about the last lab investigation you had.*
- **Hypothetical**
 - *What would you do if you had a result that was outside of the specification?*

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Frequently seen problems

- Not saying enough
- Not knowing when to stop talking
- Lack of confidence
- Knowing everything
- Rambling
- Not providing information, documents, records in a timely way
- Not providing the needed level of detail
- Improperly “fixing” a just-discovered problem

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If you discover a problem...

- Don't make an immediate, rushed, quick-fix
- Begin an investigation – follow your procedure
- Address the issue head-on
- If the problem is germane to the inspection, discuss it with the official, but understand what the risks may be
- Your actions, decisions, process, should be aimed at showing that your quality system works

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Suggestions to make the inspection a success

- Prepare!
 - * Consider what will be examined, your inspection procedure, who may be interviewed
- Make sure your decisions/actions can pass the “blush test”
- Be confident!
- Give respect, expect respect
- Provide the minimum amount/depth of information that will satisfactorily answer the inspector's questions
- Don't be afraid to say you don't know
- Always, always, always tell the truth**
- Know when to stop talking

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