

# WHAT NOT TO SAY DURING AN INSPECTION IN FIVE EASY PARTS



We understand nerves run high during an inspection but do yourself a favor and avoid some things commonly said to inspectors. This round-up includes comments our experts have seen or heard during their years of experience working in the pharma industry.

## WHAT NOT TO SAY TO AN INSPECTOR

- “How are things at the FDA nowadays?”
- “How long have you been working as an inspector?”
- “I disagree.”
- “Maybe it is a mistake...”
- “What’s your opinion?”
- “You should have seen it before the improvements!”
- “It depends.”
- “Our previous inspector told us to do it.”

## WHAT NOT TO SAY ABOUT YOUR PROCESSES

- “Our company policy does not allow inspectors to see our supplier audit reports.”
- “We usually do it that way.”
- “We don’t normally operate like this.”
- “We have a workaround because it doesn’t work as written.”
- “But we’ve always done it that way.”

## WHAT NOT TO SAY ABOUT YOUR MANAGEMENT

- “We disciplined the employee who committed this mistake and next time he’ll be fired.”
- “Corporate is responsible for that.”
- “We don’t have the key for that.”
- “You’re not allowed to see that – we can’t let you in there.”

## WHAT NOT TO SAY ABOUT YOUR PEOPLE

- “We have had a lot of turnover lately.”
- “We just started a second shift and I don’t think they are well trained yet.”
- “Our training system needs an overhaul.”

## WHAT NOT TO SAY ABOUT YOUR FACILITIES

- “The cases of wine belong to the managing director.”
- “The lunch boxes and ice creams in the pharmaceutical fridges belong to staff.”
- “We don’t really know who has the keys to our buildings.”

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Have your own inspector stories to share? Send them to [healthsciences@nsf.org](mailto:healthsciences@nsf.org).

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