



# SOME TIPS FOR AUDITORS

## KNOW WHAT YOU DON'T KNOW

No one can be an expert in everything. Realise your limitations and don't take on an audit unless you are completely confident that you understand the science, the technology and the key quality critical factors that will enable you to perform a first class audit.

## DO YOUR HOMEWORK

There is an old saying "Proper Preparation Prevents Poor Performance".

Before every audit, make sure you learn as much as possible about the department/company, its products and its processes. Sources such as YouTube can be invaluable to give you a "glimpse" of a process you may never have seen before. Similarly, talk to people in your own organisation about the quality of the product/component/ service you receive from the supplier. Have there been any problems with quality, useability, delivery, performance etc? Talk to your purchasing department. Are you tied to this vendor or do you have other approved suppliers?

## BE SMART, BE ON TIME, BE PROFESSIONAL

Remember that you are an ambassador for your company or department. Create the right impression.

## AGREE THE STANDARDS

Ensure that the auditee knows the standards to which the audit will be conducted (e.g. EU GMP, 21 CFR Part 211 etc.) and agrees that this is an appropriate standard for the audit.

## HAVE A PLAN, BUT BE FLEXIBLE

Have a plan to cover what you want to see and when you want to see it. That helps the auditee as well as you. However, be responsive to the needs of the auditee and local company procedures and be prepared to change that plan when necessary.

## LEARN TO LISTEN

Remember that you have two ears and only one mouth. Try to use them in roughly that proportion! Good listeners make good auditors.

## NEVER LEAVE AN AREA WITHOUT TELLING THE PEOPLE WHAT YOU THINK

This is just common courtesy. Before leaving any area, department or group of auditees, ensure that you have:

- > Thanked everyone for their cooperation
- > Given them your general impression
- > Communicated any areas of concern and given them the opportunity to respond and, if necessary, correct any misunderstandings



## ACCENTUATE THE POSITIVE

Auditing is not just about finding non-compliances. Don't be afraid to compliment auditees on things they do well, and always start your report with the good aspects. This will make the auditee more responsive to the items of concern that you intend to cover.

## LOOK FOR WAYS TO REDUCE COSTS

For example if a supplier, as part of its QC procedures, is taking a larger sample of material and testing it by a method which is more accurate than that which you use for assessment on receipt, then don't be afraid to recommend that your company drops or severely reduces in-house testing as it is not contributing to quality assurance. Always look for ways to make the audit more than pay for itself.

## SMILE, SMILE, SMILE

It's the easiest way to gain trust and cooperation!



For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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