

# PPD audits

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# DURING THE AUDIT WITH THE AUDITOR OVER YOUR SHOULDER

- We have tense, fear, stress etc.
- The atmosphere changes when you actually know that the monitors are here, not to help, but to record everything you are doing.
- Some would be coming with a “fault finding approach” or intimidating approach.
- Some would sometimes misinterpret what lab personnel would be saying hence a false report.
  - e.g. when the accent of the auditor is not so clear to the tech.

# PREPARATION FOR THE AUDIT

- Preparations happen throughout the whole year.
- The monitors look for the very same little things
  - e.g. daily maintenance logs, temperature monitoring sheets, Q.C documentations, etc.
- Make sure all the documents are filed properly and kept safely. (Test results, EQA, QC, etc.)

# FOR THE TECHS

- All the Techs are properly trained and their competency documentations are up to date.
- Techs are registered with the governing body or regulatory body for that country, with valid licences.
- Each Tech should have their CVs in their personal files and they are updated yearly.
- Make sure they know exactly where they will find the documents for their work
  - e.g. SOPs and make sure each department has its own SOP copy at that department, and make sure that these documents are always up-to-date.
- Make sure Techs follow the SSPs for the study, and they apply the GCP and GCLP at all times.

# FOR EVERYONE

- Follow the safety procedures at all times.
- Make sure the reagent bottles and other media have their open date, preparation date, expiry date lot numbers, and initials of the Tech who prepared/opened them are written on them.
- NEVER use expired reagents unless if they are for training purposes, and they should be clearly labelled "FOR TRAINING PURPOSES ONLY".
- Document/Record all incidents, and their corrective actions, (steps taken) i.e. Q.C failures, Instrument failure, safety accidents.
- Make sure the evacuation plan is visible to the lab staff in case of fire or accidents.
- Make sure the first aid kits are readily available and ready to use.
- Make sure the lab staff are well trained on safety issues (how, what, and when, to do) and who to contact.

REMEMBER

IF YOU HAVE DOCUMENTED NOTHING,  
THEN YOU HAVE DONE NOTHING