

# FDA Audits

What we know, what we don't.

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# FDA Audits

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- The FDA may audit clinical research sites that participated in studies for products going to market.
- Every site should operate with the expectation that they will be audited.

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- Timing-the audit may be soon after the end of the study (2013) or later.
  - Organization of records is essential
  - If key staff leave, make sure new staff know where records are kept

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- It is unlikely that FDA will send a lab specific auditor like PPD
- Known to review temperature charts, chain of custody, shipping documents
- Ensure that personnel records are up complete
- Make sure that SOP's are archived properly
- May or may not look at things like Chemistry QC records

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- Information in Charts must match information in lab such as dates, visit codes, collection times...
- Lab reports must have required information such as name of lab, units, date of collection etc...

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- Treat them the same as a PPD auditor
  - Find a quiet place for them to look at records
  - Do not volunteer documents or information-let them ask for what they want
  - Provide documents as quickly as possible-must be provided by the end of the visit

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- Getting ready-what do I do now?
  - Ongoing good GCLP and record keeping is your best bet
  - Trend analysis
  - Sites may start to form FDA audit teams-select a lead staff member in the lab for this team.