PERSONNEL RESPONSIBILITIES

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The GLP Triangle

- Management
  - Study Directors/PIs
  - Quality Assurance

TFM is considered to be the common entity where all GLP functional units intersect

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Management Responsibilities

- Assure a current summary of training and experience and job descriptions are maintained for each individual engaged in or supervising the conduct of a study

"Excuse me...I know the game's almost over, but just for the record, I don't think my buzzer was working properly."

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Management Responsibilities

- Designate a study director before the study is initiated

- Replace study director promptly as necessary
  - Death, ill health
  - Termination
  - Workload
  - GLP Challenged
  - GLP Defiant
  - Not technically qualified

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Management Responsibilities

- Assure test, control and references substances and mixtures tested for
  - **Identity**
  - **Strength**
  - **Purity**
  - **Stability**
  - **Uniformity**
  - **Solubility**

  as applicable

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Management Responsibilities

- Facility is in compliance with GLP
- Approve SOPs
- Authorize significant changes in SOPs

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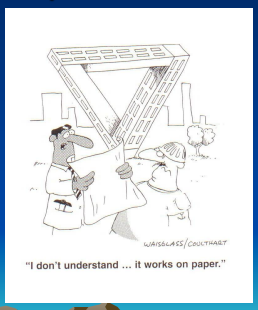
Management Responsibilities

- Assure SOPs are adequate to insure the quality and integrity of data generated in the course of a study



"I don't understand ... it works on paper."

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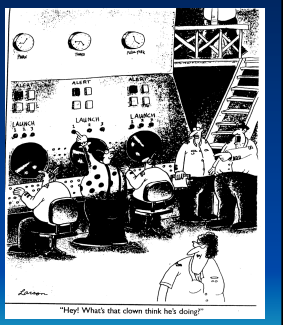
- Assure that personnel clearly understand the functions they are to perform
  - Establishment of technical and GLP training programs



"Hey! What's that clown think he's doing?"

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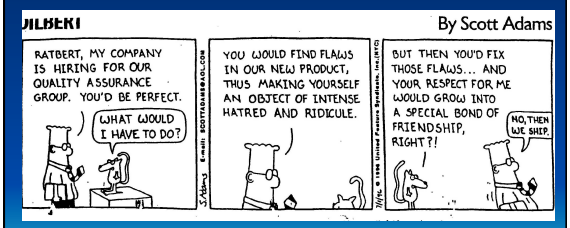
Assure deviations from GLPs reported by QA are communicated to the Study Director and corrective actions are taken and documented



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Study Director Responsibilities

- For each nonclinical laboratory study, a scientist or other professional of appropriate education, experience and training or a combination thereof, shall be identified as the study director. The study director has **overall responsibility** for the technical conduct of the study, as well as for the **interpretation, analysis, documentation and reporting of results,** and represents the **single point of study control.**

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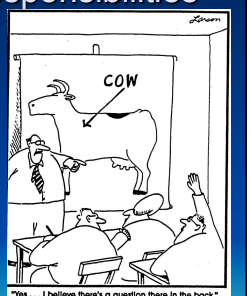
Study Director Responsibilities

- All applicable Good Laboratory Practices are followed
- Assure that the protocol, including any change, is approved as provided by xx.120 and is followed
- Test systems are as per protocol



"Yes . . . I believe there's a question there in the back."

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Study Director Responsibilities

- All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.


"Notice all the computations, theoretical scribblings, and lab equipment, Norm. -- Yes, curiosity killed these cats."

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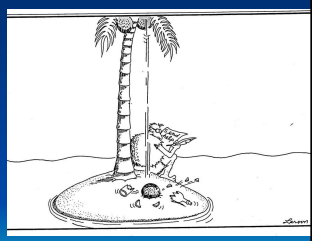
Study Director Responsibilities

- Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented



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Study Director Responsibilities

- Authorize all deviations from SOPs during a study
- Sign and date all changes or revisions to protocols; give reasons for all changes
- All raw data, documentation, protocols, specimens and final reports are transferred to the archives at the close of the study

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Principal Investigator Responsibilities (OECD)

- At test sites where the study director cannot exercise immediate supervision, a principal investigator may be assigned to oversee the critical phase(s) - OECD document
- a.k.a. contributing scientist
- Ensure relevant phase(s) of the study are conducted in accordance with protocol, SOPs and GLPs
- Assist in drafting protocol, if necessary
- Ensure personnel are properly briefed and have access to protocol and SOPs

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Principal Investigator Responsibilities (OECD)
• Ensure experimental data are accurately recorded
• Record promptly and inform study director in a timely manner of SOP and protocol deviations
• Ensure raw data and records are maintained, integrity preserved
• Ensure samples and specimens are protected against deterioration and mix-up, and dispatched in a timely manner
• Sign and date a report of the relevant phase enabling SD to write a final report and sign a true compliance statement
• Submit raw data along with a compliance statement
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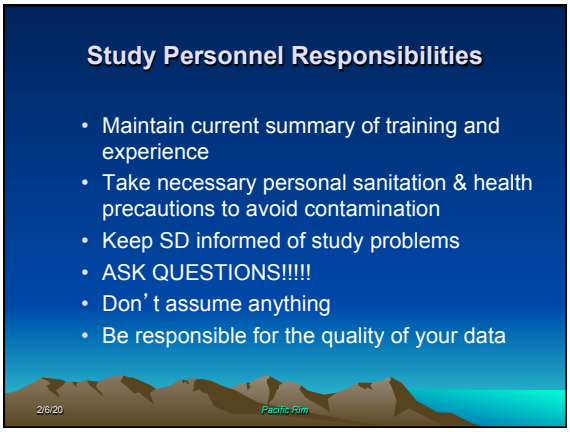
Study Personnel Responsibilities
• Maintain current summary of training and experience
• Take necessary personal sanitation & health precautions to avoid contamination
• Keep SD informed of study problems
• ASK QUESTIONS!!!!!
• Don't assume anything
• Be responsible for the quality of your data
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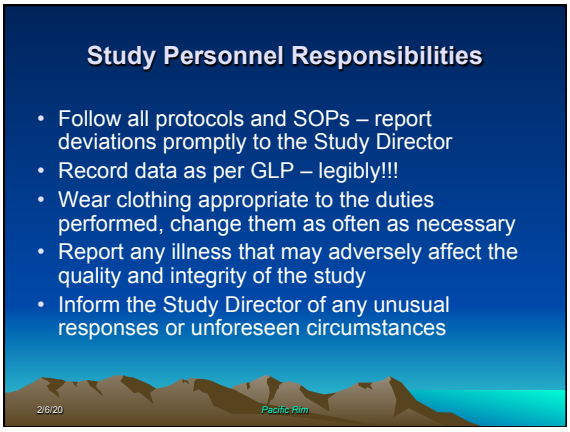
Study Personnel Responsibilities
• Follow all protocols and SOPs – report deviations promptly to the Study Director
• Record data as per GLP – legibly!!!
• Wear clothing appropriate to the duties performed, change them as often as necessary
• Report any illness that may adversely affect the quality and integrity of the study
• Inform the Study Director of any unusual responses or unforeseen circumstances
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Quality Assurance Unit Responsibilities

- A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the GLPs. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

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Quality Assurance Unit Responsibilities

- Maintain a copy of the Master schedule sheet of all studies conducted at the testing facility indexed by test article and containing the test system, nature of the study, study initiation date, current status, identity of the sponsor and name of the study director.
- Maintain copies of all protocols for which the unit is responsible

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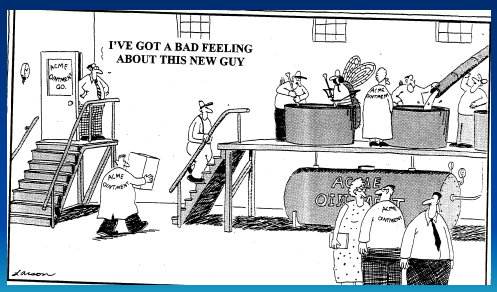
Inspect each study at intervals adequate to ensure the integrity of the study



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Quality Assurance Unit Responsibilities

- **Each study must be *inspected* at least once**
  - Assess training/competency of staff
  - Determine protocol/SOPs are being followed
  - Determine SOP/protocol deviations have not occurred without proper authorization
  - Review raw data to date

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Maintain written and properly signed records of each periodic inspection

- Date of the inspection
- Study inspected
- Phase or segment inspected
- Person performing the inspection
- Findings and problems
- Action recommended and taken to resolve existing problems
- Scheduled date for re-inspection

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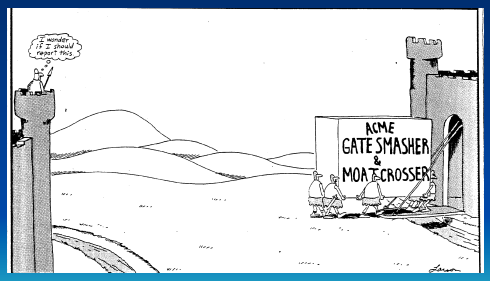
Immediately report any problems likely to affect study integrity to management and the study director



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Periodically submit to management and the Study Director written status reports on each study noting any problems and the corrective action(s) taken

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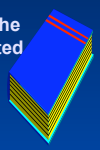
Quality Assurance Unit Responsibilities

- **Review the final study report to assure that such report accurately describes the methods and SOPs, and that the reported results accurately reflect the raw data**
  - Done according to protocol/SOPS
  - All GLP requirements included
  - Circumstances affecting data quality reported
  - Tables/text accurately reflect raw data
  - Agency guidelines followed when applicable



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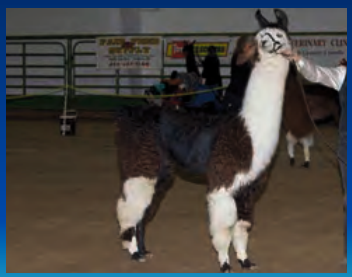
Questions or Comments???



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