

QA SCENARIOS

NAICC 2008

QA Sessions

Routing of QA Reports

- Sponsor companies who want them sent through sponsor QA
 - Field QA extension of sponsor QA
- Sending separate reports to SD, SDM, sponsor QA
- Sending them to SD with request to route to SDM
- Obtaining signatures
- What if field site SOP conflicts with how sponsor told field site QA (in a letter) to route them

Soil Characterization

- What is needed for compliance?
 - Protocols
 - QA reports
 - Data audits
 - Phase reports

Ack what the heck

- How to deal with sponsor or consultant QAs (or even study directors) who demonstrate that they do not know the field and/or GLPs.

Workload

- How do you judge or determine overall workload of a PI or facility
- Not just GLP, all workload
- How do you weigh a soil dissipation trial vs. a simple RAC trial?
- If workload seems too high how does one address this with test site management?