



WHY ARE THERE SO MANY **GLP** INSPECTIONS/VISITS AT A CRO

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LET'S NAME A FEW...

- Sponsor – QA, Study Director and Monitors
- Management Company – QA and Study Director
- Contract Laboratory that provides Study Director services for a Sponsor
 - Essentially, they are operating as a Management Company would
- EPA

WHAT MIGHT THEY FOCUS ON?

Sponsor QA

- The GLP compliance program and relationship with the Study Director and Management Company
- A full GLP facility inspection will occur
 - Call or email to schedule, agree on time and should be told of scope for the inspection
- Receive and respond to a QA report
 - Sponsor's Test Facility Management, Study Directors, Monitors and other personnel may have access to the report

WHAT MIGHT THEY FOCUS ON?

Sponsor Study Director

- Early on; Assess capabilities of the CRO to perform studies per protocol and to assure they meet the needs scientifically
- During study conduct; see study progress, plot evaluations, general study oversight.
 - No report typically, but the Study Director should communicate overview of visit with the sponsor QA and other personnel

Sponsor Monitors

- Same as Sponsor Study Directors but will also need to feel confident in the relationship the CRO has with the Study Director

WHAT MIGHT THEY FOCUS ON?

Management Company QA

- The GLP compliance program
- A full GLP facility inspection will occur
 - Call or email to schedule, agree on time and should be told of scope for the inspection
- Receive and respond to a QA report
 - Management companies Test Facility Management, Study Directors, may have access to the report
 - Sponsors typically do not see the inspection reports.... Or do they?

WHAT MIGHT THEY FOCUS ON?

Management Company Study Director

- Early on; Assess capabilities of the CRO to perform studies per Sponsor' and protocol requirements and to assure they meet the needs scientifically
- During study conduct; see study progress, plot evaluations, general study oversight.
 - No report typically, but the Study Director will more than likely communicate overview of visit with the management company QA and hopefully to the Sponsor Monitor

EPA

- Notification ~2 weeks prior to a physical inspection of the facility and a data audit
 - They will inform CRO of studies pre selected and will look at the data
 - They may pick at least one ongoing study from the Master Schedule to look at current compliance status of the facility

HOW OFTEN?

Everyone is different but the industry standard is...

- QA will inspect every 3 years
- Study Directors and/or Monitors may come every year
- EPA has a data base that helps select the frequency of an inspection, based on various factors

More often if;

- There is a unique study design or unique crop for that area
- Issues have been found with previous visits/inspections
- There has been significant shifts in QA or Management or high turn over exists

EXCESSIVE.....

All the different visits/inspection may seem a bit excessive....but they are actually looking at different things

GLP Compliance vs Capabilities and Study Progress

WHAT CAN YOU DO?

QA inspections from different companies for the same study

- Let them know that Sally QA is coming out next week/month to inspect on behalf of the same study
 - It will still be up to the person requesting the inspection to contact Sally QA and for the two of them to agree on a course of action

WHAT CAN YOU DO?

What about a visit and inspection from Company XYZ on the same day?

- That may be too hectic for you everyone comes together - then again, it may be just right
- Have a conversation with the person arranging the visit/inspection

What about a visit from company XYZ and an inspection from the same company a few days apart?

- You may want to get it all done on the same day - then again this may be just right
- It may not be possible, but it does not hurt to ask...

Be honest, many times accommodations can be made

WHAT CAN YOU DO?

- Have you had a recent EPA facility inspection?
 - Some QA's take that into consideration when selecting which site to inspect
- Does the request to visit/inspect land on one of your busiest times?
 - It is okay to propose alternate dates
 - However it is best to inspect when the facility has active studies going on to see “normal operations”

communicate, communicate and communicate again...

OTHER CONSIDERATIONS?

Who is auditing the auditors?

- How confident is the Sponsor, that the Management Company is assuring compliance at the CRO's?
- Should the Sponsor QA audit the QA at the management company?

For the CRO;

- If a Sponsor visits, are you notifying the Study Director?
- If a Study Director visits, are you notifying the Sponsor?
- If EPA inspects, are you notifying Study Director and Sponsor prior to their inspection?

FINAL THOUGHTS...

- Some Sponsors and Management Companies are starting to coordinate with each other to eliminate the redundancy
- Some are sharing audits or will split the workload across companies

In time the process and redundancies will smooth out

Patience and communication is the key