

Special Issues Faced by a Sponsor QA

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Role of Sponsor QA

- Assess and report (to the Sponsor) on adherence to GLP and study requirements by external partners (CRO)
 - Inspections and audits
 - Report findings
 - Suggestions for improvements
 - Follow-up as needed

Sponsor QA Watch-Outs

- Relationship between Sponsor (QA) and CRO
 - Too much involvement/micro-management
 - Respect confidentiality of other CRO clients
- Relationships within Sponsor organization
 - Agreement on goals/deliverables
 - Consistent message to the CRO
- Inter-personal relationships

Other Considerations

- Pre-test facility inspection and audit
- Location of test facility vs. CRO office
- Familiarity with accepted practices
 - Local
 - Crop specific
- Quantity/Quality of contacts
- Regulatory agency inspection of CRO

Measuring Success

- Productive 2-way communication between all parties
- Complete and compliant study package (and/or other deliverables)
- Findings and issues resolved in a mutually agreeable/timely manner

Questions?

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