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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