Evaluating CRO QAU Qualifications & Effectiveness:

Test Site Management View

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CRO QAU – Test Site Management
View

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- Smith Biological Services
- Payette, Idaho

- 25 years experience, since 1986
  (prior to GLP ruling)
- Contract QA services
Smith Biological Services – Jo Anne, Byron, & QA
Independent Contractor:

- We bid on work and must compete with other contractors for work
- We contract QA services
  - never have had full time QA employee
  - in 25 years - at least 10 QA contractors
  - helped train QA
General Qualifications for QA

- Science!
- Science background – B.S. degree, but not required
- Agricultural background helpful
- Analytical
QA Qualifications - continued

- Good Laboratory Practices
- Knowledgeable of GLPs
- Confident
- Ability to correctly interpret
- Experienced
- Reputable
- References
- Frequent and on-going training
QA Qualifications - continued

- Who would make a good QA?
- Good work ethic
- Interest in the work and assisting
- Open-minded
- Competent
- Honest – capable of admitting mistakes
- Good communication and inter-personal skills
- Responsible – timely submission of work
Contract Research as a Business

- CRO’s ability to obtain research studies
- Competitive
- Sustainable
- Required to provide QA
Contract Research as a Business

- What sponsor looks for from CRO:
  - Knowledgeable of subject and methods
  - Reputation
  - Affordability
  - Quality of work
  - Timeliness
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What CRO looks for from QA:

- Knowledgeable of GLPs and process
- Reputation
- Affordability
- Quality of work
- Timeliness
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- Reputation
  - Most reputable QA(s)
  - selection: scheduling, availability, cost
  - CRO reputation linked with QA performance
  - How can QA gain reputation?
    - High standards
    - GLP comprehension
    - Experience
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- Affordability
- Competitive
- Contract QA distance from CRO
- How can QA be affordable?
  - Sense for standard pay rate
  - Efficient
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- Quality of Work
- Knowledge and comprehension of GLPs
- Interest in work
- Recurrent training
- Performance

How can QA achieve quality in work?

- experience
- begins with interest and ethics
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- Timeliness
- Interest in work
- Workload
- How does QA achieve?
  - Awareness of reporting time requirements
  - Efficient use of time
  - Avoid over scheduling work
Test Site Mgt Expectations of QA

- The test site environment
- Outdoors in agriculture
- Weather
- Off-site test plots
- Chemical handling safety
- Operation of farm equipment
Test Site Mgt Expectations of QA

- Expectations of QA at the test site
- Travel
- On time
- Arrive prepared
- protocol reviewed
- proper materials for audit
- Outdoor apparel
- Weather factor
Test Site Mgt Expectations of QA

- CRO and QAU Relationship
- Common goal
- Professionalism
- Public safety concerns
- Balance of strict and common sense
- Willingness to contribute
- QA as a reflection of CRO
Evaluating CRO QA

- How does the CRO evaluate QA?
  - Feedback
  - Foresight
  - Respectful
  - Value
  - Accomplishment
The Big Picture

- What are we doing and why?
  - Testing products to support safe food, workers, and environment
  - Conducting tests with scientific records sufficient to recreate the study.
Teamwork

- Sponsor, CRO, and QAU all have the same goal with different responsibilities.

- Our most important need from QAU is to help us maintain a high standard of compliance in record keeping and reporting.
Quiz!

- Which is the correct answer?
A. Test plot has adequate identification
B. Applicator has adequate spray apparel
C. Good day for an application
A. Wind is less than 5 mph
B. Reason for needing electronic field notebook
C. Good thing this was only the first calibration
Thank you!

- Jo Anne Smith, Smith Biological Services, Payette, ID
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