



WATCHING THE WATCHERS: FOCUS ON THE QAU

EVALUATING A CRO QAU QUALIFICATIONS & EFFECTIVENESS: SPONSORS VIEW

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Expected Interactions:

- Independent QA's
 - Work specifically for one CRO or
 - Full time consultant
- In-house QA's
 - Part-time seasonal staff or
 - Full time field or lab QA
- Multi-Site CRO – Lead QA
 - Utilizes contract field QA's

Worth Mentioning:

CRO QAU is not contracted by the sponsor, therefore does not work for or report to the sponsor



How do we Evaluate and Qualify?

- Sponsor will assess the compliance level of the CRO with one of the components inspected being the QAU
 - Is the QAU independent, in-house or do they have a lead QA?
 - How many do they have? Is it enough?
 - Are they new to the QA industry?
 - Does QA have their own SOPs or do they use the CRO's?
 - What training has been made available for the QAU?
 - We may audit the auditor.....watch them audit



Continued:

- What does our past years experience tell us about that QA?
 - Are the audits sponsor receive useful?
 - Do they have meaningful findings?
 - Do they think outside the box of study activity?
 - Are the audit reports timely?
 - How's communication?
 - Do they follow the instructions from the sponsor?

Let the data speak for itself...it is an excellent way to tell us how effective they are



Other Considerations:

- Does not need x number of years experience or a degree
- Does QA influence the compliance activities at the CRO?
 - Simply an inspector for study activity
- Who does facility inspections?
 - If not them, do they consider the GLPs as a tool when auditing; look at SOPs, archives, training files etc



Continued:

- We will not disqualify a CRO because of the QAU alone, **HOWEVER...**

The effectiveness of the QAU does factor in when our Study Director's are assessing the CROs



What can Sponsor QA do?

Field QA interactions:

- Provide training
 - CD - Quiz
 - Video conf, Net meeting or MS live meeting
- GLPs
- Auditing techniques
- Expectations
- Study specific do's and don'ts



Continued:

- Have them sign a Quality Assurance responsibilities and expectations statement
 - Not a formal contract or agreement
 - Also signed by PIs and test site manager
- Communication is key
 - During field visits, provide feedback of the results of the sponsor raw data inspections
 - How well does the PI provide feedback to their QA from sponsor audits?



What can Sponsor QA do?

Lab QA's Interactions:

- For specific issues, or one time occurrence, set up a meeting with them, discuss the outcome you need
- Have reoccurring meetings
 - Use an agenda
 - Discuss any QA or study related items
 - Invite as needed study directors, monitors, technicians, management, etc...



Continued:

- Provide Training
 - Expectations
 - Study specific do's and don'ts
 - For labs that provide PI reports, sponsor QA should review the QA statement and compliance statement and provide feedback
- Sponsor visits



Build a Lasting Foundation

- Contact them as often as needed
 - Phone
 - E-mail
 - Letter
 - In person
- Ask them to be available when visiting the CRO
 - Perfect time to review expectations, answer questions or just get to know them



Continued:

- Be a resource, regardless of the question or concern
- Be approachable
- Be available (open door policy)
- Make sure they know how important their work is.....we need each other



Last but not least:

- As sponsor QA we recognize you have to satisfy multiple sponsor expectations
- We are all trying to accomplish the same thing – the QAU family
- As QA professionally we can learn from each other

THANK YOU FOR YOUR TIME
AND ATTENTION TODAY



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