FDAnews Announces Clinical Quality Assurance Workshop

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FALLS CHURCH, Va., Feb. 2, 2013 /PRNewswire-iReach/ -- Clinical Quality Assurance
Roles and Responsibilities for Auditors and Managers
Presented by MSceppa Consulting and FDAnews
Feb. 27-28, 2013 – Raleigh, NC

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Now you can learn how to FDA-proof your CQA audits … eliminate costly mistakes … and avoid FDA warning letters that say: "You failed to obtain and document that valid informed consent was obtained for each of the subjects enrolled in the study as required by stated regulations."

Clinical trial sponsors rely on clinical quality assurance (CQA) auditors to find vulnerabilities before noncompliance can shut down their studies.

But with millions of dollars and decades of research at stake, study staffers aren't always eager to cooperate.

That's why even the most experienced CQA auditors must apply the necessary tools and skills to the CQA function, including how to:

- Understand the basic principles of GCPs and international regulations
- Determine if GCPs are being followed and what needs to be documented
- Balance the relationships — QA, clinical and the CRO — in the ever-changing economy where clinical study outsourcing is common
- Define responsibilities with outsourced clinical trials and the role communication plays in maintaining compliance
- Select sites to be audited — strategies for deciding who to audit
- Audit a CRO or central laboratory — who and how do you audit these specialized providers
- Manage the audits (logistics, time, etc.) — understanding the management of the audit

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