From: Toth-Allen, Jean
Sent: Thursday, October 26, 2006 12:14 PM
To: [purged]
Subject: RE: QA in Clinical Trials

Dear [purged]:

Thank you for your inquiry regarding quality assurance (QA) as applied to clinical trials.

While ICH E6 does not specifically define quality assurance, section 5.1 is entitled "Quality Assurance and Quality Control." That section speaks to writing SOPs regarding the conduct of studies as well as obtaining agreements aimed at ensuring the quality and integrity of data resulting from such studies. It is therefore consistent with a simple definition of QA as "the process of assuring the quality of an organization's outcomes or products" - where the quality and integrity of clinical studies is the desirable outcome here.

Recently a number of presentations, including some by FDA personnel, have stressed the application of "quality systems" to the conduct of a clinical study. ("Quality Systems" is not QA, but can be a useful part of a QA program.) This is particularly true with regard to device studies where application of the principles behind design controls, which are part of FDA's manufacturing regulations for devices (Quality Systems Regulation - 21 CFR Part 820 - subpart C - 820.30), have been used to demonstrate how device sponsors can use already familiar processes to assist them in conducting quality studies. Even more generally, application of quality systems has been touted as a means for building quality into the conduct of a clinical study and thereby lessen or even potentially eliminate the need for traditional monitoring. This, however, would need to be demonstrated before any such approach to the conduct of clinical studies could be considered acceptable never mind eliminate the need for monitoring. Meanwhile, I would indeed consider monitoring and auditing to be aspects of QA for clinical studies as they are presently conducted. Discussion of methods for assuring quality and integrity of clinical studies continues, however, and "building quality in from the start" is but one aspect of such discussions.

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.

Good Clinical Practice Program
OSHC, Office of the Commissioner, US FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [purged]
Sent: Friday, October 20, 2006 2:51 PM
To: OC GCP Questions
Subject: QA in Clinical Trials

The shift to integrate quality assurance more throughout clinical trial lifecycles is a good theory. There is still no general guidance or industry standard that I am aware to clarify what would be required for quality assurance auditing versus clinical monitoring. There is the perception that Quality should not perform ANY monitoring duties or audits that may mimic or be perceived as a monitoring function(s). Monitors frequently refer to their monitor duties as “QA”. Is there any information available other than BIMO that can be used by QA as a reference or guidance, when establishing QA as an independent function in the oversight of clinical trial conduct? ICH E6 provides for independent auditing, but does not give any more information.

[purged]