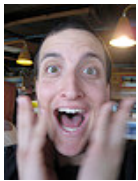


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QUINTILES

Reevaluating Studies: A CRO & A Coincidence?

By Ed Silverman // [August 1st, 2011](#) // 8:30 am[2 Comments](#)

Last week, the FDA announced that any clinical tests conducted between April 2005 and June 2010 by a contract research organization called Cetero Research may have to be reevaluated because two FDA inspections and an outside audit found falsified data and manipulated samples. In explaining its move, the agency maintained there were "significant instances" of misconduct.

The agency says Cetero failed to conduct an adequate internal investigation to determine the extent and impact of the violations, and did not take sufficient steps to assure data integrity during those five years. And so drugmakers must check their databases for trials that were used to support New Drug Applications and Abbreviated New Drug Applications - and may have to repeat or confirm results ([back story](#)).

For its part, Cetero subsequently issued [a statement](#) saying the CRO initiated its own internal investigation of its Houston bioanalytical laboratory in 2009 after discovering six chemists had misreported the date that samples were extracted prior to analysis. They did this to seek overtime pay for hours when they did not actually work. But the CRO insists reports were filed with the FDA and agency feedback was sought, although none was received. Cetero clients were also contacted.

"We leaned in roughly June 2009 and that's the time at which we self reported the findings to the FDA," Cetero ceo Troy McCall tells us. "We requested a meeting at the time that we originally provided them with our preliminary findings and during the course of our 18 month investigation. We were providing them with regular updates...They received all the information we provided to them on an interim basis.

"We took these issues so seriously that we not only terminated the employees who were responsible for these actions, but we also replaced management and ultimately the site leadership," McCall continues. "...That was probably another half dozen or so people." He reiterated that all of the terminated employees were based in the Houston facility.

There is, however, an interesting tidbit concerning some other former and current Cetero employees - several of them have had experience suitable for dealing with the

recent troubles. How so? They also once worked for MDS Pharma Services, another CRO that is now owned by INC Research and, notably, had rather similar problems with the validity and accuracy of test results. In fact, in January 2007, the FDA notified drugmakers to reevaluate pharmacokinetic studies that were conducted for them by MDS from 2000 through 2004 ([read here](#)).

Which former and current Cetero employees worked at MDS? And when? Well, there was [Jerry Merritt](#), who was MDS senior vice president and general manager from 2000 to 2006, when he left to run Cetero, although he was succeeded as ceo early last year by McCall. And [Murray Ducharme](#), the chief scientific officer at Cetero, was previously an MDS vice president from 2000 to 2006, although his Cetera bio neglects to mention this ([look here](#)).

Then there was [John Capicchioni](#), who was the MDS senior vice president of business development from 1994 to 2006, when he joined Cetero as vice president of business development, although his bio also overlooks time spent at MDS ([see this](#)).

There was also Herb Smith, who was MDS senior director of quality assurance from 1999 to 2007, when he became vp of quality assurance at Cetero, although he retired in April. Finally, there is April Johnson, who worked at MDS as a marketing manager from 1999 to 2005 and as a marketing director of early clinical research and bioanalysis from 2005 to 2007, when she joined Cetero as vp, business relationship management ([see this](#)). And, yes, her bio fails to mention MDS.

In other words, several current and former members of the Cetero managerial team arrived from another CRO that experienced similar breakdowns affecting the validity of bioequivalence data, which caused regulators to question the ability to conduct a proper audit ([read a sample letter](#) the FDA sent to drugmakers with pending ANDAs).

The problems at MDS, by the way, factored into growing concern a few years ago about oversight of CROs. The rise in the number of clinical trials prompted a corresponding growth in the number of such companies, along with complaints about quality and competency. In February 2007, for instance, Gilead reported that the FDA had found “certain irregularities” in studies conducted by MDS ([read this](#)).

We asked Cetero for comment about the experience some of their executives brought with them from MDS. Johnson, who also acts as the Cetero spokesperson, declined to comment.

Comments

Observer

August 1st, 2011
9:15 am

This is quite a good piece of reporting, Ed. It's also worth noting that the ceo spoke to you directly as part of his response strategy - a wise move on his part.

The follow-on question is - will he speak to you again after this post?
“Just askin’ “

**original
industry
insider**

August 1st, 2011
10:02 am

This is why any experienced sponsor’s Phase I Director will ALWAYS insist that all plasma samples from pk or other types of BA/BE studies be retained frozen until the NDA/ANDA is approved. We had some data irregularities from several pk studies from a CRO bioanalytical lab a few years back, and traced it to a problem with the method validation. With today’s micromethods there should be sufficient volume for repeat testing.

Because we had insisted on retained samples, we instructed the CRO with the suspect data to ship all of the frozen samples to another lab, and this time we made sure to check the method validation of that second beforehand. Samples were shipped, assays were performed (at the first CRO’s expense), the data passed muster with internal QC and the data were saved. We even brought in an outside pk consultant to review the data. We sent every last scrap of information we had to FDA so that their clinpharm folks could reconstruct exactly what happened, and they gave the ok to the data.

Like Pasteur said, “chance favors the prepared mind”.

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