

REGULATORY UPDATE 10/2010

With all that is going on in the FDA these days, I thought I would try to keep people as updated as I can. There has been a lot of discussion over the contributing scientist reports and peer review. Evidently, FDA has hired a lot of people from industry, who have said their number one problem when they were in industry was Sponsors trying to suppress or alter adverse findings in pre-clinical studies. It appears that FDA's main concern is transparency. Based on discussions at the SQA meeting in San Jose, recently issued 483s, and conversations with some of the laboratories involved, I have compiled the following:

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- Final reports should be written from signed contributor reports – not draft.
- Source reports should be archived upon completion – companies should not wait to archive source reports with the final report.
- Draft reports should not be sent to Sponsors for comment until all contributor reports are signed.
- When draft reports are sent to Sponsors for comment, FDA expects the draft report and all correspondence from the Sponsor to be archived (note, EPA has always required this under section 160.90 “Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, shall also be retained”).
- Pathology Peer review should only be done from signed pathology reports. As per the pathologist exemption, only the slides and signed final report constitute the raw data. Therefore, without a signed report, there is no raw data or report.
- If there is disagreement between the pathologists, the SD should reconcile the discrepancy in their final report.
- FDA will continue to issue 483's as they have been for writing draft reports from draft contributor reports and peer reviewing pathology reports from unsigned drafts. Upon re-inspection, if the practice is still occurring, warning letters will be issued.
- Reports must be written for all studies – even those terminated or if a compound is discontinued. The concern is that many of these compounds resurface at a later date.
- If a test site or testing facility sends data off-site, the expectation by both agencies is that the facility maintains a copy. While this has always been the case in EPA, a current 483 was recently issued to a test site for not keeping a copy of the data.
- FDA investigators are undergoing training on auditing electronic data.

There has also been a lot of discussion regarding archiving responsibilities for studies. I have not seen anything in the GLPs that mentions anyone other than the testing facility being responsible for establishing archives. Obviously, if the Sponsor submits the study in support of registration, then they should be equally responsible for assuring data are archived. In the case of pesticides, FIFRA requires Sponsors to maintain original data for the life of product registration. However, it is unclear what happens when Sponsors go out of business or refuse to pay CROs to archive their data. It would be nice if the regulators can weigh in on this.