Regulatory Update 1/2013

FDA GLPs

I know everyone is interested in the progress on the revised FDA GLPs. I have not heard anything of late so the status appears to be no different than it was in the Fall. Revisions are complete and just going through the various clearances and reviews before being issued as proposed regulations in the Federal Register.

EPA

EPA is continuing with their "desk-top" inspection program. The Inspector General is investigating EPA GLP Compliance branch. The investigation was evidently triggered by a complaint regarding lack of funding for the program. Perhaps this might get the group more funding to hire more inspectors. Although we heard faint rumblings of a "fee for service" or third party program, it appears that such a move would be illegal under FIFRA.

GENERAL

Companies taking risks with compliance on the chance they won't get "caught", should rethink their position. Studies were recently rejected by an OECD member country due to compliance issues found during EPA inspection. They could just as easily be rejected based on 483's issued by FDA. The MOU's for accepting data are dependent on the monitoring authority determining that the laboratory is in compliance with GLPs. If an inspection is conducted (by either EPA or FDA) and the laboratory is found to not be in compliance, then no member countries have to accept those studies. Please note – listing items in the compliance statement **DOES NOT PUT YOU IN COMPLIANCE!!!!!!**
The primary areas I see companies taking compliance risks (and these have both been cited by EPA and FDA) are the following:

Test Article Characterization – this characterization must be GLP according to US GLPs. There is no wiggle room. I have seen CoA's that don't even list a quality standard for the characterization that was done, and others that reference GMPs. GMPs apply to finished drug product only. Dr. McCormack is supposed to be giving an in-depth presentation on this at the SQA meeting in Indianapolis. There have been 483's issued, so to revisit this subject I am attaching a Q&A from FDA. These questions were submitted in 2003, and FDA has not changed their stance.

Electronic Data – sorry, but this is a "no-brainer". Paper chromatograms **ARE NOT RAW DATA** by anybody's definition. FDA has hammered this down our throat forever and EPA has written it up as an inspection finding. I don't know why industry is not paying attention. In addition, backing up files is not archiving. All electronic records must be archived. I think the source of some confusion might be that people are thinking there must be a server in the archives. The data can be on the main server, as long as it is under the control of the archivist and "archived".

USDA

USDA has implemented changes to the Animal Welfare Act that become effective January 30, 2013. My feeling is that this is a result of the numerous natural disasters that have occurred. Briefly, all USDA-licensed and registered facilities must have a written plan by July 29, 2013 that:

- identifies types of emergencies in the local area
- identify common emergencies at their particular facility
- outline specific tasks that the facility staff will undertake in emergency situations
- establish a chain of command, identify materials and resources that are available at the facility or elsewhere
- ensures that all pertinent employees are trained in the plan by September 27, 2013

Additionally, the plan must be reviewed annually and maintain documentation of the review.

I have attached the Federal Register Notice…

I am also attaching my upcoming training schedule – GLPs 101 and GLPs for Study Directors and Monitors will be held March 12-14, while GLPs, Black, White and Grey will be May 8-9. As usual, the classes will be interactive and fun!!!

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