Merry Christmas and Regulatory Update

I would like to wish everyone a Merry Christmas, hope your Holiday season goes well, and provide a brief regulatory update. As you know, Dr. Viswanathan has retired from FDA but is extremely busy consulting. We were fortunate to have him give a presentation at the PRCSQA meeting where he provided some insight on the GLP modernization effort. In addition, the AHSS of SQA had a webinar with Vernon Toelle of FDA and got a little more information. On the EPA side, Francisca Liem was invited to present at PRCSQA, but had to cancel at the last minute and telephoned in instead. The following information is a result of my notes and information provided through various sources.

FDA Modernization

Comments received from last December are being addressed. About 25% of the comments have been addressed and they are working on the others. Vernon Toole indicated that there should be a proposed draft in February 2013. Many (but not all) of the comments from December will be addressed at that time, with all of them addressed when the final rule is published. Possible modifications include:

- Management Responsibilities will be enhanced and management responsibilities better defined. The include clarifications that Managemant is responsible for ensuring a Master Schedule is maintained and QA has access to such; archives are maintained and in compliance with GLPs; resources are available as needed, etc.
- Electronic records will be better defined along with the requirement to archive such.
- The requirement for an "individual archivist" may be relaxed to allow for a paper archivist and electronic archivist.
- Empty containers will not be required to be retained but the SD must verify and document their disposal.
- Test and control articles characterization under GMP may be accepted when "appropriate" depending on the stage of GMP being cited.
- Other areas of reform include Pathology Reports, Peer Review Process, Contributing Scientists Reports, and Draft review of reports by Sponsors. However, Dr. Viswanathan stated that these are extremely difficult and complex areas to address.
- Jean Toth-Allen and Vernon Toelle are the co-chairs of the modernization effort.

EPA News

Francisca Liems' travel to meetings (as well as other EPA inspectors) has been sharply curtailed, due to lack of adequate personnel. Evidently, it does not matter whether an organization is willing to pay the expenses to get EPA to a meeting,, the "higher-ups" have indicated that due to personnel shortages travel is restricted. On an even more serious note, with only 4 EPA inspectors left and budget issues facing the US Government, it does not appear that adequate EPA inspections of testing facilities and sites are going to occur. This is critical because the MOU and MADs between all the OECD member countries are linked to having the monitoring authorities inspect at adequate intervals (2-3 years). Right now EPA cannot fulfill that obligation, so the MOUs may be in danger. In addition, the Netherlands rejected a study done at a CRO in the US. The CRO went out of business and no EPA inspection for GLP compliance had been conducted so the study was deemed not in compliance with GLPs. SQA is planning a meeting with EPA to discuss the gravity of the lack of funding and inspectors. Sponsors should make sure all their CROs have had a current inspection by EPA, and though somewhat unfair, should avoid any lab that has not been inspected by EPA until these issues are resolved.

Other News

Although Canada has adopted GLPs for pharmaceutical testing and has had the GLP requirement for pesticide research since 1998, their directives are not necessarily the same as the US. Specifically, the Canadian directive does not include Animal Health studies or Medical Device studies. However, if a study is being conducted in Canada and falls under with the Health Canada or PMRA directive, the facility MUST be inspected by and recognized by the Canadian authorities – you CANNOT simply claim compliance with EPA or FDA GLPs and bypass the Canadian Regulatory process.

The FDA GLP Animal Health inspections for 2011 have resulted in an unusually high number of OAIs. Out of 7 inspections conducted for GLPs, 5 were classified as VAI/OAI with only 2 NAI.

If one reads the recent warning letters being posted by FDA, it is obvious that a large portion of the inspections are being directed at foods or food establishments. This could be why it appears that fewer GLP inspections are being conducted.

Crop Biotechnology Session at SQA

I will be chairing virtually an entire day of sessions dedicated to Crop Biotechnology at the SQA meeting next April. The morning sessions will include presentations on the following:

- International rand USDA Regulatory Requirements
- FDAs role in crop biotechnology and approval
- EPAs role in biotechnology and approvals
- EPA inspections of biotechnology laboratories
- Molecular Characterization of GMOs
- Protein Characterization of GMOs

The afternoon session will include a Panel Discussion and Q&A covering the most confusing aspects of GMOs including (please feel free to send me other issues for discussion):

- What is the test substance for the various types of studies?
- How do you prove homogeneity in a feeding study?
- How do you run one study to satisfy the US and international requirements?
- When can one "fragment" a study in to several "studies" and what is a single "study".
- I am sure there are more, but I really think this could be a good draw if we advertise properly.
- When is a modification or addition of a trait considered a "food or feed additive" which would be subject to FDA GLPs?

HOOD RIVER GLP CLASSES - SPRING 2012

- GLPs 101 - March 27
- GLPs for Study Directors and Monitors – March 28-29
- *Good Laboratory Practices – Black, White and Grey – May 9-10
- * an in-depth look at the GLPs along with industry standards and practical applications

Guess that's it for now – I know I have forgotten something, but hopefully will catch that later. I am seriously thinking about totally discontinuing my paper newsletter, so please forward this update to anyone you know who may want to get put on the electronic mailing list.

Debi Garvin www.pacrimqa.com debi@pacrimqa.com