Society of Quality Assurance Update – meeting notes April 26-30

For those of you who did not attend the recent SQA meeting, or those of you who didn't get to all the sessions, (April 26-30), here are some notes from the meeting. Please note, this is not an all inclusive list but rather a "high-level" overview.

GENERAL - CVM was out in force, sending several representatives, including Elizabeth Luddy, Deputy Director of ONADE, and Fredda C. Shere-Valenti, who participated in pre-conference training, the AHSS evening discussion and the regular meeting. CDRH sent Chrissy Cochran from their BIMO group, who likewise participated in evening sessions as well as the regular meeting. EPA was represented by Francesca Liem. There were additional agency speakers, but noticeably absent (and sorely missed) was Dr. Viswanathan (CDER and bioequivalency). Presentations on OECD, ICH, and China were front and center as more and more studies are sent abroad, and are multi-national.

GLPs – A Federal register notice was supposed to have been issued on April 26 outlining the intent for new rulemaking. The new FDA proposed GLPs are supposed to be out (as far as I can tell) around the end of June. Dr. Jim McCormack gave an FDA update on behalf of SQA based on information acquired through FOI. The most alarming statistic was that only 34 GLP inspections were conducted in 2009.

EPA – Francisca Liem stressed that EPA, just like FDA, is concerned about data falsification. She also stressed that ultimately the Sponsor is responsible for data integrity and compliance on all submitted studies, so they should be qualifying labs, monitoring labs and assuring that compliance statements are true and accurate. Findings were largely the same as they have been historically. She also stressed that if you do a study in the US and meet EPA GLPs, the data will be accepted internationally. There is no need to reference OECD GLPs.

CVM – Dr. Elizabeth Luddy provided some fabulous insight on what issues reviewers have with protocols and reports, in additon to excepts from incomplete letters and non-concurrences. . She highly encouraged all companies to get concurrence with CVM on all protocols and to feel free to call with any questions.

CDRH - Chrissy Cochran was a breath of fresh air!!! Not only did she articulate the changes that are underway at the agency, but she did so in an open and friendly manner. She provided details of the BIMO program and emphasized that the GLP inspection program is in place, with inspection frequency increasing. In 2008 there was 1 BIMO inspection from CDRH, in 2009 they increased to 5 (2 directed, 3 OIA followup), and in 2010, there have been 6 directed GLP inspections to date. She also reiterated FDAs new stance on 483s and responses: Companies have 15 days to respond to a 483 if they want to have their response considered; warning letters must be issued within 120 days; If a warning letter is issued, the agency will reinspect within one year; if significant violations are still found, it won't be good news; if issues have been addressed you will receive a close out letter. …

PART 11 – FDA is launching a new Part 11 initiative, and will be inspecting based on the original rule and 2003 guidance in relation to the applicable predicate rules. It was stressed that there will be no 483's citing Part 11; all citations will cite predicate rule requirements.

BIOANALYSIS - Although there was no official update, Dr. Chris Tudan briefed members of BASS on the meeting in Montreal and efforts towards globalization (he has a 20+ page writeup). Evidently, there is a lot going on in the area of globalization and harmonization of bioanalysis .

ELECTRONIC RECORDS –Throughout the meeting it was stressed that one CANNOT call the paper copy of electronic records the "raw data" as defined by GLP. If data are collected electronically, it must be saved, maintained, and audited electronically. Several presentations showed how easy it is to falsify chromatographic data and have such go undetected unless the electronic files are audited.

OTHER – There is no need to reference OECD GLPs in studies conducted in the US as long as they are conducted in compliance with EPA or FDA GLPs. Through MAD and various MOUs, EPA and FDA GLP studies are accepted internationally. If parts of studies are conducted in other countries, that countries GLPs should be referenced for their portion.