April 2012 Update

I am typing up a very quick update from the recent SQA meeting. I am sure there will be plenty of talk generated as a result of what went on. I am also attaching a couple of documents - One is the MHRA document on GCP; the other is the BARQA Quality System workbook - a great guide for those wanting to take steps towards a Quality System for Research without going full GLP; the third is the revision to PR 86-5; and finally the strategic plan from FVM (the Office of Food and Veterinary Medicine). I do realize that some of you have my attachments stripped, so I am also going to send this to my webmaster to put on my website. It should be under Regulatory Update April 2012.

FDA -

Revision to GLPs is expected in 2013. However, the election could influence the issue date. They are working through the responses they got from the December 2010 notice and have made headway.

FDA appears to have come to some type of decision on Pathology Peer Review and Draft Pathology Reports. Although they acknowledge that the Pathology Report is technically raw data (as per the early preamble), they apparently do not have a problem with Peer Review of a Draft Pathology Report as long as everything is documented and transparent. Ideally they would like to see two reports, but in one of the meetings indicated that both pathologists could sign the pathology report - one as the study pathologist and one as the peer review. They do want to see (in the report) how differences were handled.

Cardio vascular guidance - CDRH is seeing much improved quality with studies being conducted as per the guidance vs. those that are not and older studies. They heavily encourage Sponsors to have a meeting with FDA regarding study design. You have to have a subset of animals to show worse case scenarios. They would also like to see an independent report by the veterinarian.

Bioanalytical - Specific samples should be used for system suitability checks - do not use a calibration standard.

Only 45 GLP inspections were conducted last year. The piggy back inspections for Part 11 compliance are mostly being conducted at GMP facilities under CDERs direction.

EPA

EPA has had a policy change and is now allowing exact copies to be used for long term archiving instead of originals as specified in FIFRA. This could be a

huge savings to industry.

EPA is now requiring facilities to send all documents and support records to them in advance of an announced inspection. They will be conducting the data reviews at their offices and then following up with a much shorter site inspection. The number of inspections were down last year.

PR 86-5 has been revised and incorporates some issues that had come up with OECD (see attached)

This is very brief, but I though folks would appreciate an update.