

Quality Assurance (QA) Focus

(21st in a series of helpful GLP hints)

Update on the Revised GLPs

Ms. Frances Liem of the US EPA announced at the SQA Annual Meeting in Montreal, Canada that the consolidated GLPs are currently on hold. She explained that the US EPA has undergone a change in their priorities and that there will be no further action towards issuing the consolidated regulations.

What is to become of the regulatory relief we were promised? We can only wait and see if the proposed consolidated regulations will be picked up in the future, the comments made at the time of the proposal responded to and the final rule published.

IR-4 QA SOPs revised. The changes proposed by members of the Quality Assurance Committee (QAC) to QA SOP inspection checklists have been incorporated. SOP's 8.0 through 8.13 have been revised and a new SOP, 8.14 has been written. The revised QA SOP's have been reviewed by the QAC, the HQ research staff and the Senior Management Team at HQ, and approved by the Executive Director. All University and USDAARS participating QA's will receive a copy of the QA Unit SOP's which contain revised checklists and some new forms for tracking reports, documenting QA training and procedures used at HQ to finalize final reports.

Update from the Society of Quality Assurance (SQA) Annual Meeting, Montreal, Canada, Oct. 9-13, 2000.

We at IR-4 are ever diligent to better understand what the EPA is focusing on and to prevent problems from occurring, therefore, the following news from Montreal is presented.

At this meeting, Ms. Frances Liem of the US EPA, provided an update of the programs and issues being focused on by her office. Some of the highlights include:

1. The Environmental Laboratory Accreditation Conference has officially closed the possibility that GLP facilities will be subject to accreditation through this program. This

became official when Mr. Mike Stahl of the US EPA's Office of Compliance issued a letter to NELAC indicating that this was his recommendation.

2. The EPA Office of Compliance's GLP monitoring program has two focus areas for year 2001: review of reports submitted for FQPA chemicals, and testing programs for antimicrobials.

3. The US EPA will continue its partnership with the SQA and welcomes input from SQA members on the implementation of the Cross Media Electronic Records and Reporting Regulations (CROMERRR).

4. The confirmation letter for the Memorandum of Understanding (MOU) between the US EPA and Canada for acceptance of GLP data is currently in draft form and is moving forward. After a three phase process the US and Canada will mutually recognize data generated under each others GLP regulations and inspections/certifications of each others programs.

5. The US EPA Office of Compliance conducted 101 laboratory inspections in FY 2000. Three hundred and twenty three studies were reviewed and 47% of the laboratories inspected were receiving their first EPA inspection. By the EPA's own numbers, 52% of the laboratories were in full compliance with the GLPs (no findings presented at the time of inspection). Improvements were attributed to greater compliance to Subdivision B (personnel), and Subdivision G (protocol and study conduct). Most declines in compliance were attributed to Subdivision J and included deficiencies in raw data not being archived at closure of study (on or before the date the final report is signed), archive not minimizing deterioration, and the lack of names of supervisory and study personnel in final reports.

There were 18 studies rejected by the US EPA's Office of Pesticide Programs based on GLP deficiencies. They were comprised of 1 toxicology study (at 1 lab), 6 product chemistry studies (at 2 labs), and 11 antimicrobial studies (at 3 labs).

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The EPA's Office of Pesticide Programs rejected studies based on GLP deficiencies that included: 1) Lack of QA; 2) No QA inspections; 3) Calculation errors; 4) Incorrect analytical method cited; 5) Lack of calibration records; 6) Lack of protocol; 7) Multiple obliterations of data; 8) Missing data; 9) Final report not reflecting raw data; 10) Raw data not archived; 11) Lack of initials of persons entering data; 12) Raw data incorrectly recorded; 13) Use of pencil and correction fluid in data.

Ms. Liem also indicated that there were problems at audits where the sponsor had archived the data on CD and made the CD available to the EPA for purposes of inspection (exact copy of the records as they were scanned onto the CD). The inspector issued a finding when certain records were not made available to the EPA for inspection because the images were not readable from the CD. She cautioned everyone to be sure there is proper verification that information copied is readable and that this verification be documented.

Ms. Liem also shared what she termed puzzling encounters. They included: 1) A final report was revised after QA review without follow up by QA; and 2) A sponsor claimed to

be the performing lab on a study that was originally performed non GLP, but changed their mind after the work was completed and tried to use the data as a GLP study.

During the closing plenary session a question and answer period occurred. When the results of the plenary are available, they will be presented. All those interested in learning more about GLPs and the profession of Quality Assurance are encouraged to attend an annual meeting or a regional chapter meeting in your area. More information is available through the SQA website at www.sqa.org.

Quality Assurance and GLP Training

As a precursor, the SQA's Education Committee will be providing a training program in spring of 2001. The dates are April 23-27, 2001 in Raleigh, NC. This week-long program will consist of three back to back sessions: 1) auditing of clinical studies and facilities; 2) computer issues and electronic records; 3) auditing GLP data (toxicology, metabolism and analytical chemistry). For more information, contact Tammy White at IR-4 HQ or the SQA Headquarters at the web address provided above.

Article by Tammy White
