

IR-4 QUALITY ASSURANCE

QA Focus -(24th in a series of helpful GLP updates and other important information)

Update from the IR-4 Quality Assurance Unit (QAU)

The IR-4 QAU is in the process of concluding our scheduled field inspection program for the 2001 field research season. The QA field in-life inspection plan for 2001 has targeted approximately 107 field trials at 46 test sites. This permitted us to monitor 20% of the IR-4 field trials during their field phase (up from 16% last year).

The IR-4 QAU is also very busy conducting the auditing of final reports identified for submission to the US EPA by the end of October 2001. The IR-4 QAU has audited some 73 final reports, conducted approximately 54 closure audits, completed over 550 field data book audits and conducted some 119 field in-life inspections to date. These in-life field inspections were performed by IR-4 QAU personnel (85) and by on site, facility QA at contract field test site locations (34). We thank the IR-4 QAU program, field study personnel and study monitoring personnel for their assistance and persistence in working so diligently on completion of these GLP required audits and inspections.

In previous articles we have tried to keep everyone informed about current regulatory progress being made towards the development of new regulations at the EPA concerning electronic reporting and record keeping. The EPA published the draft Cross Media and Electronic Record and Reporting Rule (CROMERRR) in the Federal Register on August 31, 2001 (Volume 66, Number 170), Proposed Rules, Pages 46161 - 46195. It is the EPA's intent to develop a rule to establish performance standards to assure accuracy, record integrity, and accessibility of electronic reports and records applying generally to all record keeping requirements contained in Chapter I of Title 40 of the Code of Federal Regulations. The text of the rule can be found at:

<http://www.epa.gov/fedrgstr/EPA-AIR/2001/August/Day-31/a21810.htm>

Comments on this proposed rule will be considered if received before November 29, 2001. These comments should be addressed to the United States Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, (Mail Code 2201A), Attn: Docket Number EC-2000-007, 1200 Pennsylvania Avenue, NW, Washington, DC, 20460. Commenters are also requested to submit an original and 3 copies of their written comments and attachments.

CROMERRR is designed to outline electronic issues and needs for the submission of data and reports via open

systems (the internet) to assure integrity and retention. It is a volunteer program. However, it is the records requirements that may affect those of us involved in GLP studies. If you are hand writing an observation (ie, freezer temperature using a min/max thermometer) this rule doesn't apply. But, if you use data pods or electronic temperature thermocouples, this rule will apply.

“The rule sets forth the criteria under which the Agency considers electronic records to be trustworthy, reliable and generally equivalent to paper records in satisfying regulatory requirements. The intended effect of this proposed rule is to permit use of electronic technologies in a manner that is consistent with EPA's overall mission and that preserves the integrity of the Agency's enforcement activities. The most important section of this document that will apply to GLP studies is Subpart C, sec 3.100 which sets forth requirements that regulated entities must satisfy if they wish to maintain their electronic records in satisfaction of EPA record-keeping requirements. EPA believes that for electronic records to be trustworthy and reliable their corresponding electronic record-retention system must: 1. Generate and maintain accurate and complete copies of records and documents in a form that does not allow alteration of the record without detection; 2. ensure that records are not altered throughout the records retention period; 3. produce accurate and complete copies of an electronic record and render these copies readily available, in both human readable and electronic forms as required by predicate regulations, throughout the entire retention period; 4. ensure that any record bearing an electronic signature contains that name of the signatory, the data and time of signature, and any information that explains the meaning of the affixed to the signature; 5. protect electronic signatures so that any signature that has been affixed to a record cannot be detached, copied or otherwise compromised; 6. use secure, computer-generated, time-stamped audit trails to automatically record the date and time of operator entries and actions that create, modify, or delete electronic records; 7. ensure that records are searchable and retrievable; 8. archive electronic records in an electronic form that preserves the context, metadata, and audit trail; and 9. make computer systems (hardware and software), controls, and attendant documentation readily available for agency inspection.”

If we look under the definitions section, this proposed rule defines an electronic record as any combination of text, graphics, data, audio, pictorial or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.

There has been much discussion on this topic and there will be more in the future. We will keep you informed.

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