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## IR-4 QUALITY ASSURANCE

### Quality Assurance (QA) Focus

(22nd in a series of helpful GLP hints)

#### Update from the IR-4 Quality Assurance Committee

The IR-4 Quality Assurance Committee held its yearly planning meeting in conjunction with the IR-4 Field Training Workshop, San Antonio, Texas with 9 members in attendance. The planning meeting focused on three items: 1) targeting and distribution of QA GLP in-life inspections for the 2001 field research season; 2) final report auditing plan for 2001; and 3) review of QA procedures to improve uniformity and efficiency.

The QA field in-life inspection plan for 2001 will target approximately 107 field trials at 46 test sites. This will permit us to monitor 20% of the IR-4 field trials during their field phase (up from 16% last year). Information was still needed in order to schedule some of the field contract sites in the Western Region and the cooperating Canadian test sites. The target list has been distributed to QA and Field Coordinators. Notification and scheduling of targeted inspections will be performed through Regional (Field and QA) and ARS Coordinators.

The IR-4 QAU has a very challenging goal of auditing some 114 final reports by the end of October 2001. This year marks the first opportunity that the QAU has had to plan its working year with a list of scheduled report submissions. We look forward to working with the IR-4 Study Directors and the EPA Technical Working Group in accomplishing mutual goals and schedules.

We continued our October 2000 discussions and incorporated some new material to execute our plans to improve overall QAU consistency and efficiency. The QAU Consensus Document will begin to identify areas that need

improvement and communicating our conclusions and expectations to the QAU and IR-4 research participants. Distribution of Vol. 00. Issue #1 will occur by March 31, 2001 for final comment by the QAU.

#### Update on GLP and other Regulatory Issues

The Cross Media Electronic Records and Reporting Rule (CROMERRR) was signed by then EPA Administrator, C. Browner in December of 2000. However, because the rule is still under review by the new Administration's Transition Team, it has not yet been published in the Federal Register, which brings in a new twist.

The Federal Register on February 28, 2001 (Volume 66, Number 40), Proposed Rules, Page 12746-12747, [www.wais.access.gpo.gov](http://www.wais.access.gpo.gov) [DOCID:fr28fe01-15] announced 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. This action delays until June 1, 2001 the effective date of certain provisions in the Electronic Signatures in Global and National Commerce Act of 2000 that may affect federal environmental record keeping requirements.

We will keep everyone informed as to the effect and impact such a rule could have on e-records which are generated as part of IR-4 research. These may include electronically acquired data (temperature records, chromatography, etc), data analysis, and reports. We can provide additional background and reference information upon request.

Article by Tammy White