
IR-4 QUALITY ASSURANCE

QA Focus -(25th 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 planning the 2002 QA scheduling meeting. As the field assignments and EPA submission plan are put together, QA will be reviewing the 2002 work plan and scheduling our targeted audits for the upcoming season. The QAU is scheduled to hold this meeting on Feb. 26-28, 2002 in southern Florida. A tour of the Homestead Research Station has been arranged.

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, Page 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 February 27, 2002 (The EPA extended the comment period). IR-4 Headquarters has submitted our comments to the US EPA requesting that the records requirements outlined in the proposed rule be severed. The proposed rule currently is written as a voluntary program. However, the records requirements are set up such that they are **not voluntary** in the originally proposed context. You can "volunteer" to either keep hand entered records or e-records, but if you use an electronic system as defined in the rule, the requirements will be **mandatory**.

Overview of 2001 QAU inspection/auditing program

The IR-4 QAU has been very productive this year. The QAU members conducted approximately 33 facility inspections, 664 field data book audits (685-2000, 497-1999), 120 field in-life inspections, multiple laboratory in-life, data and report audits, and over 97 final report audits (up from 74 the year before). QA statements were signed for approximately 79 final reports, and approximately 18 are with the Study Directors, nearing completion.

Article by Tammy White

IR-4 Field Research Directors' Report

IR-4 Annual Meeting October 17-18, Tulsa, OK

IR-4 Field Research Directors met on 10/17/01 for discussions on several topics, including draft protocols, product shipment procedures, and residue sample shipment issues. There was consensus on the importance of supplying field research directors with timely access to draft protocols, so that critical input can be provided. Southern region field research directors continue to have difficulty receiving test

substances in time for optimal trial commencement. There was also concern about instances in 2001 where Federal Express refused to ship residue samples because of a so-called policy restricting shipment of "perishables". Dr. John Wise of the Northcentral Region and Michigan State University was elected chair of the IR-4 Field Research Directors Committee.

Article by John Wise