

IR-4 QUALITY ASSURANCE

QA Focus -(31st in a series of helpful GLP updates and other important information)

Update from the IR-4 Quality Assurance (QA) Committee

The IR-4 QAU is in the middle of the field research season. We appreciate all the support received from our field researchers in scheduling and conducting in-life inspections. The estimated dates of field activities presented in the protocol cover letters is very important for QA and Lab scheduling purposes. Please remember to get those cover letters in so they can be forwarded to IR-4 HQ for inclusion on our master schedule. These initial dates are very useful, but your active updates on specific trial related activities to your Regional QA are irreplaceable. Keep up the good work.

The Society of Quality Assurance (SQA's) Regulatory Forum held a meeting on April 17, 2003 in Baltimore, Maryland. Ms. Frances Liem of the US EPA's Office of Enforcement and Compliance Assurance attended this meeting and participated in a Question and Answer session which highlighted contemporary GLP themes. The highlights of this discussion will be presented in the next IR-4 newsletter. Themes discussed included:

1. EPA UPDATE

- a. Biotech Facility Inspections
- b. Electronic Data Issues - EPA audit experiences in relation to e-records
- c. Impact of Letter from SQA to John Suarez, EPA (Jan 31, 2003)
 - i. RE: Additional resources - has it made a difference?

2. General Auditing Issues from the EPA inspectors viewpoint
3. International Community Updates
4. Thoughts on FDA's new guidance on Part 11

The IR-4 program has been inspected by the US EPA at three additional test sites during the last three months. The University of Maine's IR-4 Field Research Directors, Dr. D. Yarborough and Dr. F. Drummond, both participated in this inspection held April 1-3, 2003. The North Dakota State Analytical laboratory was inspected on May 12-13, 2003. There was also an inspection at the USDA ARS Tifton field test site. It was originally scheduled for May 20-22, 2003, but was postponed and later rescheduled for June 24-26, 2003. This inspection was completed and the inspection report is pending. The summaries of the University of Maine field test sites and North Dakota State Analytical Lab inspections have been shared with IR-4 participants and the Tifton summary will be shared after it is issued by the Agency.

The SQA's 2003 Annual Meeting will be held Oct. 12-16, 2003 in Arlington, VA. Meeting information, pre-conference training and registration materials are available via the SQA web site at www.SQA.org.

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