

## IR-4 QUALITY ASSURANCE

**QA Focus** -(29th in a series of helpful GLP updates and other important information)

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

In addition to our regular auditing and inspection activities, in October the IR-4 QAU met for two days during the Annual Meeting, then most of us attended the SQA Annual Meeting in New Mexico. On November 19-21, an independent review of the QA program was held at Headquarters, and some of our members participated in an EPA inspection of a cooperating field test site. We've been busy!

The Project Management Committee (PMC) of the IR-4 Project scheduled the review of the IR-4 monitoring program to make an assessment of its strengths, weakness and areas where improvements can be made. The team was led by Dr. Willis Wheeler. Dr. Paul Schwartz of the USDA/ARS, Dr. Ken Kanagalingam (a QA consultant formerly with the US EPA's Laboratory Data Integrity Branch) and Dr. Wynn John of DuPont Crop Protection, Residue Programs Manager, made up the review team. The review was held at IR-4 Headquarters on Oct. 19-21, 2002. HQ QA staff and Study Directors were interviewed directly and Regional QA Coordinators, Test Site QA members, Regional Field and Laboratory Coordinators and a group of Field Research Directors via teleconferences. The results, findings and recommendations of this review will be reported to the PMC. The IR-4 QAU thanks the review team for their assistance in this matter and looks forward to their recommendations on how the IR-4 QA Unit can better function in IR-4's overall GLP compliance program.

### **SQA Pre-Conference Training Session - A Brief Summary**

I had the opportunity to attend "Quality Responsibilities of Management" on 10/15/02. The presenters were primarily from Eli Lilly, Inc., along with Jim McCormack of the FDA. The session included dozens of "real life" situations, and provided time for feedback and questions. We learned that FDA "will be" stressing inspection, by the use of interviews and review of documents, of the Management role during site visits.

The regulatory perspective on "who is Management" presents IR-4 a challenge, given that the structure of our Project Management is committee-based and regionally influenced, yet FDA places "Management" at the testing

facility. This location is defined as the place where test system (crop) meets the test substance, so you can see the complication. Our typical protocol reflects a "multi-site" structure, and since the Study Director is typically remote, this adds even more importance to the Management role. While my trip report contains much more information on this session, here are some of the critical points:

In terms of, "who is Management," the definitive parameters are:

- must have authority to designate/remove a Study Director
- is the entity which oversees QA activities
- has power to control the availability of resources
- assures that test substances/mixtures are tested properly
- assures that personnel know what to do (training, job descriptions, etc.)
- assures that GLP deviations are corrected

As you can see, these responsibilities are both central and regional in nature. It is also important to note that, while duties can be delegated to others, there should be written procedures for delegation of such duties.

The second major area that the FDA speaker repeatedly stressed: all GLP deviations are traceable to Management deviations. FDA will hold Management accountable for GLP compliance; nothing will change [at a facility] unless they are "aware and involved." Since the GLP's were designed as a quality management system, their responsibilities are paramount to maintaining GLP compliance.

The IR-4 program had five US EPA GLP compliance inspection since 2002, including 4 field test sites and one analytical laboratory. The findings at the most recent field test site were minor: 1) not having calibrated a balance on one occasion before its use to weigh test material as specified in the test site SOP; and 2) a failure to calibrate the scale used to weigh samples in the field. It is because of our commitment to maintaining GLP compliance that EPA inspections result in only minor findings like these. The test site involved with this last inspection should be quite proud.

The IR-4 QAU would like to extend a grateful thanks to all the Field Research Directors and their staff for making a great effort to review, address, take corrective action and return completed QA inspection reports so promptly. The entire IR-4 Project is indeed very grateful for your continued support and diligence.

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