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## IR-4 QUALITY ASSURANCE

QA Focus -(26th in a series of helpful GLP updates and other important information)

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

The IR-4 Quality Assurance Committee held its yearly planning meeting in Miami, Florida with 8 members in attendance. The planning meeting focused on three items: 1) Targeting and distribution of QA GLP in-life inspections for the 2002 field research season; 2) Final report auditing plan for 2002; and 3) Review of QA procedures to improve uniformity and efficiency.

The QA field in-life inspection plan for 2002 will target approximately 113 field trials at 48 test sites. This will permit us to monitor 18.6% of the IR-4 field trials during their field phase (down from 20% 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 Quality Assurance Unit (QAU) has a very challenging goal of auditing some 137 final reports by the end of 2002. This year marks the second 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. When calculating workload for year 2002, we used all reports on the submission plan, although some may not be submitted to QA this year. We did this because last year's estimates were made using only those reports to be submitted through Oct., and we found that the Unit actually inspected many more reports than originally estimated.

We conducted a discussion of the documents created to capture the consensus from last year's San Antonio National Training Meeting. Our comments have been submitted as part of our larger trip report. We also discussed several observations and questions from individuals in order to build consensus of the group on core issues.

### Update on GLP and other Regulatory Issues

The Cross Media Electronic Records and Reporting Rule (CROMERRR) is currently in the hands of the EPA. The extended comment period, expired on February 28, 2002. Based on information disclosed at recent public meetings held on the issue, the EPA is considering severing the record-keeping requirements from the current rule. Additional information will be presented as available.

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