
IR-4 QUALITY ASSURANCE

QA Focus -(28th in a series of helpful GLP updates and other important information)

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

The HQ QA SOP 8.5 has been updated to permit a more uniform and efficient mechanism for dispersing field data book audit reports and getting the responses to the audits back to the appropriate parties. The primary change to this QA SOP is a request that the Field Research Director forward their responses and any corrected pages to IR-4 HQ QA and not the Study Director. Once received at HQ QA, the responses will be attached to the original QA audit report from the field data book and sent to the Study Director and Testing Facility Management. We in the IR-4 QA hope this new system will alleviate any previous problems we have had with keeping up-to-date records of response receipt by having those responses logged into the QA routing system upon arrival at HQ.

IR-4 Headquarters and Regional QA personnel held their meeting in conjunction with the IR-4 Annual Meeting on Oct. 8-9, 2002. Meeting agenda items included: 1) QA communications; 2) Field site SOPs and their uniformity; 3) Field data and final report checklists (looking for necessary revisions); 4) Field/Lab data correction procedures; 5) Evaluations of the IR-4 protocol; 6) Review of the past year's inspection/audit results to look for uniformity and areas needing special attention.

Mr. Martin Beran, Mr. Samuel Fernando, Dr. Neal Thompson and Ms. Tammy White participated in a session at the SQA annual meeting in Albuquerque, New Mexico on Oct. 17, chaired by Ms. Kathryn Hackett-Fields and Mr. James McFarland. The session highlighted the IR-4 Project and provided an overview of our unique cooperative projects and the teamwork it takes to keep us running efficiently.

The IR-4 program has now been involved with four EPA inspections in 2002. To date, we have had one significant infraction reported by the EPA as a result of these inspections, but it was not a GLP infraction. The infraction cited was not having data (GLP or otherwise) retained to support information in a final report. In this case, a non-GLP characterized test material was used in an IR-4 study. While the material had been tested prior to its use in the study, the non-GLP data from that analysis was not retained by the cooperating manufacturer. While this was not a GLP infraction, our compliance statement accurately reflected the non-GLP nature of the test material. Subsequently to the finding being issued, IR-4 asked the cooperating manufacturer to analyze the retention sample of the batch used in the study. This analysis confirmed the material concentration and identity. The data from this analysis were forwarded to the US EPA for confirmation of the test material.

The success of the IR-4 QA final report auditing program can be seen in the number of audits performed this year. There have been 74 final report audits conducted this calendar year, which is in line with last year's totals for the same period, however over 83 report completion reviews with QA statements drafted have been performed this year. Only 54 such QA reviews had taken place in the same period last year, a 54% increase. Thanks to all QA Auditors and the Study Directors for their teamwork and effort to help make this process continually more efficient.

The IR-4 QAU has also been very busy conducting the 2002 field season in-life critical phase inspections all the while keeping up with our 2001 field data book audits. Of the 610 trials on the master schedule as active 2001 trials, 468 of them have been audited. Currently there are 77 field data books with QA awaiting audit, and there are 65 field data books with the Regional Coordinators or with the Field Research Directors.

Article by Tammy White