

IR-4 QUALITY ASSURANCE

Quality Assurance (QA) Focus

(20th in a series of helpful GLP hints)

Update on the Revised GLPs

The consolidated GLPs were published as a proposed rule in the Federal Register on 29 December 1999. No further information is available on their status at this time. Several IR-4 QAU members attended the SQA annual meeting 11-13 Oct. 2000. An update will be made available in the next Newsletter from the meeting attendees.

IR-4 QA Standard Operating Procedures (SOPs) are in a review/revision process. Prior changes, proposed by members of the Quality Assurance Committee (QAC) to QA SOP inspection checklists, have been incorporated. SOPs 8.0 through 8.13 have been revised and reviewed by HQ QA and research staff. The SOPs are currently being reviewed by the members of the QAC. When complete and approved by management the revised QA SOPs will be distributed to all IR-4 participating QA members.

A discussion of issues in need of consensus by the IR-4 QAU is currently underway. The IR-4 QAU will be holding discussions on topics ranging from the interpretation of GLP compliance issues to the expectations of data collection meeting instructional requirements. An IR-4 team building program, encompassing QA members, Study Directors, Field Coordinators (ARS and Regional), and Laboratory Coordinators, is scheduled to occur on October 25 and 26. The emphasis of this session is the generation of mutually agreeable expectations of study conduct, review and reporting. The groups also will be working on a program where all would have an opportunity to review the progress and success of each others work product as part of an overall process improvement program.

Capturing and Reporting Data in the Electronic Age: A Workshop at the American Chemical Society 220th National Meeting, Washington, D.C., August 20-24, 2000

Excerpted from a report by Satoru Miyazaki, IR-4 North Central Regional Field Coordinator.

The Workshop consisted of a series of presentations detailing equipment, experiences and regulatory aspects of using electronic equipment for data capture and reporting.

Field Aspects

American Agricultural Services, Inc. demonstrated its electronic Advantage™ Project Management Assistance that includes Field Trial Notebook (eFTN). The Advantage™ system automates the creation of studies, trials, sample numbers and labels, and electronic field trial notebooks. The system automatically creates status reports, protocols, and study reports in the word processor program of choice. Advantage™ systems are (*claimed*¹) fully validated and fully compliant with GALP and EPA GLP regulations. The company claimed up to 80% increases in efficiency once implemented.

ACDS Research, Inc.: Electronic records offer many advantages for study directors and sponsors, but there are problems for field investigators: high costs, electronic data devices are often pushed beyond their limits in the field resulting in loss of data, and methods to detect e-record falsification are needed.

Bayer AG: Bayer uses Astrix Field Notes electronic field notebook for field work and LabNotes to manage lab residue trial samples. Bayer uses Excel and WordPerfect to create study protocols, bid forms, and work agreements. An Excel spreadsheet is used to facilitate management of the field trials. Since Bayer introduced electronic systems in 1997, the number of residue studies conducted each year has increased. In 1995-98 there were 150-170 studies, 300 studies in 1999, and 900 studies in 2000.

Laboratory Aspects

Uniroyal Chemical Company: The Chromeleon™ system from Dionex, collects data and controls a wide variety of

¹ Comments in italics are editorial in nature added by HQ staff.

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chromatographic equipment. The system is capable of chromatographic data manipulation, reporting, and generating a permanent audit trail of the parameters employed in the collection and analysis of data. The audit trail maintains a chronological record with electronic signatures of all people accessing or editing files.

FMC Corporation: The Turbochrom 900 is used in the FMC residue chemistry lab to collect and store raw data from LC or GC instrumentation. When residue studies are submitted to EPA, the Compare Plots section of Turbochrom is applied to demonstrate chromatograms between analytical standards, control and treated samples. Turbochrom is capable of generating summary spreadsheets.

Petition Submissions Aspects

The American Crop Protection Association (ACPA): There is a need to determine economics both for EPA and industry as the technology is still developing. Registrants hesitate over unilateral approach to electronic submissions. ACPA recognizes that electronic data submissions are more efficient than paper and will improve EPA's review quality; however, there are concerns about confidentiality.

OPP, EPA: OPP is working with pesticide registrants to develop a standard process for accepting and reviewing electronic data submissions. Adobe Acrobat 4.0 is the tool for these initial efforts. EPA accepts the data on CD-ROM directly entered as Acrobat PDF files, not scanned and pasted data. Time required for reviews should be reduced by one third to one half.

Rohm & Haas Company: Under the NAFTA Joint Review Registration Program, registration for Zoxium® Fungicide

was filed in the US, Canada, and Mexico. Environmental fate studies were piloted electronically following the draft Canadian Pest Management Regulatory Agency (PMRA) guidelines. Rohm & Haas has received very positive feedback from PMRA.

Quality Assurance (QA) Considerations

Perspective Consulting: Training exists to teach field contractors how to operate data collection programs but there is little training designed for teaching QA how to audit the data that are generated. Standard operating procedures must be refined in areas of raw data definition, assignment of users and access level as well as security, computer maintenance, raw data backup methods and backup frequency.

Office of Environmental Information, US EPA: Electronic reporting of environmental compliance data is being introduced by EPA. EPA's Cross Media Electronic and Record Keeping Rule (CROMERRR) will be published in fall 2000. Electronic reporting for environmental compliance presents unique legal, regulatory and evidentiary challenges. (See Tammy White's article in the Summer *IR-4 Newsletter* for more information on CROMERRR - Ed.)

Laboratory Data Integrity Branch, US EPA: CROMERRR applies to record keeping requirements under 40CFR, but does not apply to anything originally recorded on paper. Fax or e-records converted from paper records are excluded. There will be more GLP requirements for electronic record storage and retrieval under CROMERRR involving signatures and time-stamped audit trails, among other things. CROMERRR's goal is to give registrants the option to use electronic records, but it is not mandatory.

Article by Tammy White
and Sandy Perry