

Memo of Meeting

Date: August 2, 2001

1350 Piccard Drive, Rockville, MD 20850

Representing Scientific Software, Inc., Pleasanton, CA 94588

Dr. Soheil Saadat, Ph.D., President & CEO  
Mr. Michael H. Elliot, Vice President, Sales and Marketing  
Mr. Joe McGough, CyberLAB National Accounts Manager  
Ms. Kathy O'Dea – CyberLAB Product Manager

Representing the Food and Drug Administration:

Mr. Scott J. MacIntire, Division Director, Office of Enforcement, Division of Compliance Information and Quality Assurance  
Mr. Paul J. Motise, Consumer Safety Officer, Office of Enforcement, Division of Compliance Information and Quality Assurance  
Dr. Charles Snipes, Ph.D., Compliance Officer, Center for Drug Evaluation and Research  
Mr. O.J. Cartwright, QA Officer, Center for Veterinary Medicine  
Dr. Joseph Kawalek, Ph.D., Res. Chemist, Center for Veterinary Medicine

The meeting was held at the request of Scientific Software, Inc., to discuss its electronic records software, Cyberlab in the context of 21 CFR part 11. The firm's advertising claims that its software is part 11 functional. At the start of the meeting we explained that FDA doesn't formally evaluate products or services that enable regulated companies to comply with FDA requirements and that our comments should be taken in that context.

The firm's representatives explained Cyberlab as a web based knowledge management system, designed with part 11 in mind, that handles a variety of file formats to track, access and archive electronic records. The system handles both human and machine-readable files under the hierarchical metaphor of location, file cabinet, drawer and folder. Metadata are also retrieved. Almost all of the firm's customers are regulated by FDA.

The system implements electronic audit trails that record the operator identification, the nature of the event (record creation, modification, deletion, printing, and system log on) and corresponding date/time. Audit trail granularity is configurable. Activated audit trails cannot be turned off.

System access control is based upon user identification code and password. Privileges are configurable. Password controls are configurable from within the Windows NT platform.

Electronic signature manifestations show the signer's printed name, date/time of signing and the reason for signing. The firm provides an electronic signature plug-in for Adobe Acrobat Exchange.

We discussed system validation. The firm is amenable to customer audits of its software development activities. It will provide customers with selected design level specifications, with third party escrow possible.

During the meeting the firm's representatives gave us a brief product demonstration.

The meeting lasted about two hours.

P. Motise

cc:  
HFA-224  
FDA attendees  
Part 11 Guidance Dockets  
Doc ID MemoOfMeetingScientificSoftware080201.doc