

Memo of Meeting

Date: December 6, 2001

Representing Werum Software & Systems AG:

Rolf Blumenthal, Director of Department PAS-X Development
Dietmar Mueller, Director Sales & Operations
Rudi Schlierenkamper, Director of Department Pharma int

Representing LGM Corporation

Bruce Fowler, President
(Compliance Consultant to Werum AG.)

Representing FDA:

Charles A. Snipes, Compliance Officer, Center For Drug Evaluation and Research
Charles Ahn, Consumer Safety Officer, Office of Regulatory Affairs
Paul J. Motise, Consumer Safety Officer, Office of Regulatory Affairs

The meeting was held at the request of Mr. Fowler, consultant to Werum, to discuss the firm's electronic records software system in the context of 21 CFR Part 11. At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products or services that enable people to comply with FDA regulations. We advised that the meeting would be an information exchange and that our comments should not be taken as formal FDA positions.

The Werum representatives explained that the company produces an electronic records software system (PAS-X, Process Automation System) for use in the pharmaceutical and biotechnology industries. Customers currently include several large multi-national pharmaceutical companies. The product includes part 11 functionality, and that was the focus of our discussions.

The Werum representatives explained that the product is designed to enable paperless production in manufacturing execution systems. They stated that PAS-X is a client-server application for Unix, Windows NT and Windows 2000 computing platforms. Werum offers the system as a collection of program modules, each for a different aspect of product manufacture and control, that companies can install on a customized basis.

During the meeting we discussed the firm's validation efforts and internal software quality assurance systems. The representatives said they would welcome customer audits of their software development activities. The firm also provides customers with specifications documentation and test protocols. Software change control is implemented via program version control and customers are notified of available updates; program modifications are not automatically downloaded to customers remotely.

The PAS-X system uses electronic signatures based upon identification codes in combination with passwords. End users can build a dictionary of words that the program would not accept as a password. The program also allows system administrators to configure minimum password length (longer than the six character length that is hard coded into the program) and character make up. The representatives briefly reviewed how end users can be assigned various access control restrictions and how part 11 authority checks are implemented.

Regarding electronic copies of electronic records, and archiving of electronic records, the system can generate records from the electronic database, or reports in PDF (text searchable) format, as well as paper printout. We commented that part 11 requires that the electronic copies for FDA be suitable for FDA review and that some FDA personnel may need to process information in the copies in a manner of the kind that can be done in the original – something that certain PDF files may not permit. We gave an example of sorting values in a table in a PDF file. The Werum representatives explained that the electronic data from the original electronic record database would also be retained and could be provided to FDA in a processable form.

During the meeting we reviewed the PAS-X implementation of audit trails. Audit trails display operator names, dates/times of actions that record, modify and delete electronic records, and the electronic record name. Both old (original) and new (changed) values are displayed when someone reads the human readable representation of the electronic record. Original changed values appear legible but with a strike out font. The audit trail also includes the reason why a change was made. Audit trail functionality is hard coded into the software and cannot be deactivated. Information in the audit trail can be processed (e.g., searched and sorted.)

The meeting lasted about two hours.

cc:
FDA Attendees
HFA-224
Part 11 Guidance Dockets

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P. Motise 12/26/01