

Memo of Meeting

Date: April 23, 2001

Location: 1350 Piccard Drive, Rockville, MD 20850

Representing NetRegulus, 11755 East Peakview Avenue, Englewood Colorado, 80111:

Mr. Michael J. Prudhomme, Chief Technology Officer
Mr. Mark Allen, Director, Regulatory Affairs and Quality Assurance

Representing the Food and Drug Administration:

Paul Motise, Consumer Safety Officer, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement
Charles Snipes, Compliance Officer, Division of Scientific Investigations, Center For Drug Evaluation and Research
Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health
Mark Hackman, Consumer Safety Officer, Center for Foods and Applied Nutrition
Vernon Toelle, Consumer Safety Officer, Center for Veterinary Medicine

The meeting was held at the request of NetRegulus, to discuss the firm's software applications--a system that according to the firm's representatives provides functionality in the areas of device tracking, registration, clinical studies, complaint management and corrective actions and prevention. The representatives also explained that the software was designed with 21 CFR Part 11 technical requirements (such as audit trails) in mind. The representatives claim that some of those functions such as audit trails are available independently to help with older, non-compliant systems.

At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products and services that enable people to meet agency regulations. We emphasized that our meeting was for the purpose of information exchange.

By way of background, the NetRegulus representatives explained that their firm is a two year old company and its employees include information technology specialists and people who worked up to 12 years in FDA regulated health care industries, including medical device firms. They emphasized that their software was designed from the ground up to be part 11 compliant and aimed at class III medical devices.

The firm's representatives also explained how their software links to manufacturing systems. The system consists of several software modules in a suite that can either stand alone or integrate with other electronic record systems.

With respect to add-on tools for existing non-compliant systems, the firm's representatives said they have a module that can append to existing relational databases, including Microsoft Access 2000, to generate audit trails. They commented that for larger database requirements they would recommend using a different database engine.

The system platforms they support include Windows 95, 98, NT, ME and 2000. Via web access they also support Linux and Unix. Database support is provided for SQL Server 7 and 2000.

The representatives demonstrated their software, as installed on a laptop computer. We focused on the audit trail feature. The audit trail entries showed the operator, the date and time of an event and the nature of the event, such as record creation or modification. The audit trail cannot be disabled, although the entry for a reason for a change can be turned off.

We discussed system validation. The representatives said they were willing to have their customers or third parties audit their software development activities. They added that they provide baseline validation information and configuration data, and that they assist in site validation.

With respect to electronic copies of electronic records generated by the application, the representatives explained that copies could be made in Excel or SQL server file formats.

The meeting lasted about two hours.

P. Motise
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