

Memo of Meeting

Date: July 19, 2001
1350 Piccard Drive, Rockville, MD 20850

Representing NuGenesis Technologies Corporation:
Ms. Victoria V. Lander, Market Development Manager
Ms. Mary Ellen Goffredo, Vice President, Marketing
Mr. Greg Murphy, Vice President, Enterprise Solutions
Mr. Guy Verrastro, Mid-Atlantic District Manager

Representing the Food and Drug Administration:
Paul Motise, Consumer Safety Officer, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement

The meeting was held at the request of NuGenesis Technologies to discuss the firm's electronic recordkeeping software in the context of 21 CFR Part 11. At the outset we explained that FDA does not formally review, approve or disapprove products and services that enable regulated establishments to comply with FDA requirements. We commented that our remarks should be taken in that context and that our meeting was more of an information exchange.

NuGenesis has been active in educating industry on part 11 and the firm hosts a web site and on-line discussion forum for the regulation. The firm's representatives reported that more than 1400 messages have been posted to the forum and the firm's listing of solution providers includes 121 establishments. NuGenesis has presented two on-line seminars devoted to part 11, with total attendance of 895 people.

The firm's representatives gave us an overview and demonstration of its scientific data management software and noted that it has customers in the pharmaceutical industry. The firm's product captures, catalogs and stores PC based scientific data and was designed with part 11 requirements in mind. The product's main modules are Capture, Catalog, Archive, Find and View. Web access enables remote access to human readable records. The Archive module is based upon the Oracle Database and the product includes a run-time engine; a separate instance of the program can be run if an end user already has Oracle running. A Windows based helper application is provided, as well.

Electronic signatures take the form of a combined identification code and password. Human readable displays of electronic signatures include the signer's printed name, the date and time of signing and what the signature means.

Archived records permit data to be processed. Machine-readable records can thus be preserved in a form that can be restored for analysis.

Audit trail functionality extends to date/time of operator actions that create, modify or delete a record.

During the meeting we discussed software validation and the firm's willingness to have its software development activities audited by customers. It has engaged in 21 such audits.

The meeting lasted about two hours.

cc:

HFA-224

FDA attendees

Part 11 Guidance Dockets

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