

Memo of Meeting

Date: March 15, 2000

Location: 1350 Piccard Drive
Rockville, MD 20850

Representing Andersen Consulting, Inc.
11951 Freedom Dr.
Reston, VA 20190

Ms. Mary Jo Veverka
Ms. Tara G. Doubman
Mr. Daniel Mensch

Representing FDA

Dr. Steven Solomon, Director, Medical Products Quality Assurance, Office of Enforcement, HFC-240

Mr. Paul Motise, Consumer Safety Officer, Medical Products Quality Assurance, Office of Enforcement, HFC-240

Dr. Jim McCormack, BIMO Program Coordinator, Division of Compliance Policy, Office of Enforcement, HFC-230

Dr. Randy Levin, Associate Director for Electronic Review, CDER, HFD-120

Ms. Karen Moksnes, Compliance Officer, Office of Compliance, CDER, HFD-320

Dr. James McCormack, BIMO Program Coordinator, Office of Enforcement, HFC-230

Mr. Jorge F. Christian, Compliance Officer, Division of Compliance, CVM, HFV-232

Mr. Stewart Crumpler, Office of Compliance, CDRH, HFZ-343

The meeting was held at the request of Andersen Consulting to discuss validation of computer systems and related emerging trends and challenges.

At the start of the meeting Dr. Solomon explained the nature, activities and affiliations of the FDA attendees, as the FDA Part 11 Compliance Coordinating Committee; he explained that our comments should not be taken as formal FDA policy statements.

The Andersen Consulting representatives explained that their firm has more than 60,000 personnel worldwide, covering a wide variety of industries, some of which are FDA regulated. The firm's structure accounts for vertical markets coverage as well as activities that extend across different industries. They explained the renewed interest in computer systems validation in the FDA regulated sector, especially in light of 21 CFR Part 11. The firm is assisting its clients in supporting their compliance and upgrading existing systems in light of current FDA expectations.

During the meeting we discussed the following:

Electronic commerce: We discussed in general terms how the growth of electronic commerce has focused attention on the need for, and challenges of, attaining computer system reliability. Many of the issues we are addressing in the part 11 context are the same other industries face in implementing electronic commerce in general. Electronic commerce tools are becoming more available, but add a layer of complexity to software validation.

Off the shelf software and software quality standards: We discussed the problems related to that portion of the software industry that is not regulated and the limited number of industry standards that apply. Some unregulated industry segments do not share FDA's concepts of software validation -- some equate testing alone with validation. We also talked about the absence of oversight bodies to ensure software quality. ISO compliance does not ensure compliance with FDA GxP requirements. The specificity in ISO/IEC 12207, Software Lifecycles, may be an improvement. We discussed the PDA shared reliable vendor audit model, as published in the association's Technical Report Number 32, in the context of software validation -- inferring software structural integrity without source code review.

Risk based level of validation: We discussed the CDRH model of gauging the level of software validation by the level of health risk to the consumer. The Andersen Consulting representatives commented that companies equate "risk" with potential financial, business, and public relations losses.

Software industry associations: We commented that unlike many FDA regulated industries, there did not appear to be comparable trade associations that encourage collaborative development of documents and programs to ensure product quality. The Andersen Consulting representatives noted that

collaboration occurs to some extent in the development of open system standards, but not in the area of quality assurance.

Management involvement and administrative inefficiencies: We discussed the importance of management's commitment to quality systems in the medical device arena and how those concepts could be ported to software validation. The Andersen Consulting representatives commented that their audits showed administrative inefficiencies that reduce the return on investing in validation. Inefficiencies include excessive debates over what needs to be done, who's to do it, levels of approval, and the extent of testing and documentation.

Application Service Providers (ASPs) and Netsource Providers: The emergence of contract facilities that assist and house electronic recordkeeping and enterprise projects is growing quickly. Andersen Consulting has encountered netsource providers that set up clinical trials and capture data electronically on a global basis. We commented that some of those firms may not be subject to direct FDA regulation, while others (e.g., if current regulations classify their actions as a contract research organization) would be directly regulated.

Internet validation: We discussed how one could not be expected to validate the entire Internet, but that proper functioning of the Internet would be vital to data integrity and privacy, especially in the fast growing field of clinical trial electronic data management.

Andersen Consulting/Microsoft joint venture: Andersen Consulting and Microsoft recently consummated a joint venture, an independent entity consisting of technology experts to assist firms in implementing Microsoft software in the business community. [Note: The March 14, 2000 Washington Post reported this event and identified the joint venture as Avanade, to be based in Seattle.]

Action Items:

We agreed to continue the line of communication between the committee and Andersen Consulting. Ms. Veverka will put her colleague, Mr. Seth Levine, the firm's part 11 contact, in touch with Paul Motise, to continue dialog regarding Internet performance issues.

Ms. Veverka will send Dr. McCormack a PDF file for a document on a CDER/Andersen Consulting joint project.

Ms. Veverka or Ms. Doubman will send Mr. Motise the Andersen Consulting white paper on computer systems validation soon after it has been finalized.

The Andersen Consulting representatives thanked us and the meeting, which lasted about two hours, ended.

P. Motise

cc:

FDA meeting attendees and Part 11 Compliance Coordinating Committee members who were not in attendance

HFC-200

HFC-240 (Chrono)

HFA-224

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P.Motise 3/15/00