

Memo of Meeting

Date: February 25, 2000

Subject: 21 CFR Part 11; Electronic Records; Electronic Signatures

Representing the International Society of Pharmaceutical Engineers (ISPE):

Paul D'Eramo, Executive Director, Worldwide Policy & Compliance Management, Quality & Compliance Services, Johnson & Johnson, New Brunswick, NJ

Representing the Good Automated Manufacturing Practice (GAMP) Forum:

Dr. Guy Wingate, Computer Validation Manager, Quality Directorate, Glaxo Wellcome Operations, Barnard Castle UK

Representing the Parenteral Drug Association (PDA):

George J. Grigonis, Jr., Systems Quality Assurance, Merck & CO., Inc., West Point, PA

Representing FDA

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

Tom Chin, Consumer Safety Officer, Division of Compliance Policy, Office of Enforcement, HFC-230

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

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

Christine Nelson, Consumer Safety Officer, Office of Compliance, Center for Devices and Radiological Health, HFZ-330

Jorge F. Christian, Compliance Officer, Office of Compliance, Center for Veterinary Medicine, HFV-232

Khyati Roberts, Lead Policy Analyst, Center for Drug Evaluation and Research, HFD-006

Betty L. Jones, Deputy Director, Office of Compliance, Center for Drug Evaluation and Research, HFD-301

Jennifer Thomas, Associate Director for Policy, OCBQ, Center for Biologics Evaluation and Research, HFM-600

Karen Moksnes, Compliance Officer, Office of Compliance, Center for Drug Evaluation and Research, HFD-320

Randy Levin, Associate Director for Electronic Review, ORM, Center for Drug Evaluation and Research, HFD-120

The meeting was held at Mr. D'Eramo's request, to discuss the respective activities of ISPE/GAMP and PDA, and how those groups might interact with the FDA's part 11 compliance committee.

At the start of the meeting Dr. Solomon set the framework for the session by describing the function of the FDA committee and how we have been and continue to interact with interested parties in the context of our good guidance practices to develop agency guidance documents. He cautioned that the opinions expressed would not necessarily be those of the agency and that formal agency policy is expressed in formal agency documents. He added that the FDA representatives were not in a position to give definitive answers to matters that were still open but that we would listen to the visitors' input.

Dr. Wingate, who heads a GAMP steering committee, explained the overall history of GAMP and its composition and objective of bringing together pharmaceutical producers, suppliers and regulators. GAMP's original focus was on process validation in drug production. The group prepared a draft document on how firms should go about the project of implementing part 11. (Copies of the document were distributed to the FDA committee before the meeting.)

Mr. D'Eramo and Dr. Wingate explained that GAMP is now a committee within ISPE and ISPE will publish the GAMP documents under its own heading. GAMP/ISPE have no firm plans regarding disposition of what is now the draft document. Although memberships are separate, GAMP has a working relationship with PDA.

Mr. D'Eramo explained that ISPE is a non-profit organization having individual, not corporate membership. GAMP has individual membership, as well, but members are sponsored by some 50 to 60 manufacturers.

Mr. Grigonis explained the PDA part 11 task force project, and gave a background briefing on the related but distinct project for supplier qualification and auditing (the basis for PDA's Technical Report 18.) Both projects entail FDA participation to some degree. Currently, the part 11 project has P. Motise as an FDA advisor. Mr. Grigonis explained the overall concept behind the part 11 project: to help industry comply with part 11 and follow practices that would also be compatible with other standards in the context of electronic commerce and other regulatory standards.

Mr. Grigonis elaborated that the part 11 project entails some 60 people, covering a core and extended committees. The group expects to develop electronic recordkeeping models for existing and new systems.

Mr. D'Eramo briefly explained how his firm is going about part 11 implementation. New systems must have part 11 features before they are put in place. Existing systems, he explained, are being brought into compliance or replaced on a priority basis that heeds the integrity risks of electronic records.

During our discussions we commented that FDA's compliance policy on enforcing part 11 puts emphasis on product quality and data integrity problems, as well as FDA's ability to conduct audits. We remarked that a firm's "risk based" approach should consider those factors.

We also noted that FDA has encountered some serious problems with "legacy" systems and that we are prepared to take (and have taken) regulatory actions as circumstances warrant.

We discussed the importance of predicate rule recordkeeping requirements and how agency guidance would reinforce their relationship to part 11.

During the meeting, the representatives asked how their groups could be of assistance to the FDA committee. We commented that they might identify a few firms that would be will to be visited as part of FDA training programs. We also suggested that the groups compile a matrix of electronic recordkeeping practices mapped to a wide number of U.S. and international standards.

The ISPE/GAMP and PDA representatives thanked us and the meeting, which lasted about two hours, ended.

P. Motise

cc:

Meeting Attendees (by e-mail)

HFC-200

HFC-240 (chrono)

HFA-224

P. Motise

2/28/00

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