

Memo of Meeting

Date: May 23, 2001

Location: 2094 Gaither Road, Rockville, MD 20850

Representing PDA/ISPE/GAMP:

William Stoedter, Director, Regulatory Affairs, PDA

Russell Madsen, Sr. VP Science and Technology, PDA

John McKenney, President, SEC Associates, Inc.

Guy Wingate, ISPE/GAMP (International Society of Pharmaceutical Engineers,
Good Automation Manufacturing Practices

George J. Grigonis, Merck & Co., Inc., PDA Task Group – Part 11 (Lead)

Representing the Food and Drug Administration:

John Taylor, Director, Office of Enforcement

Paul Motise, Consumer Safety Officer, Office of Enforcement

Tom Chin, Consumer Safety Officer, Office of Enforcement

Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological
Health

John Murray, Electronics Engineer, Office of Science and Technology, Center for
Devices and Radiological Health

Mark Hackman, Consumer Safety Officer, Center for Foods and Applied Nutrition

Jennifer Thomas Associate Director For Policy, Center For Biologics Evaluation
and Research

The meeting was held at PDA's request to update FDA personnel on the joint efforts of PDA, ISPE and GAMP at publishing documents that would assist persons in meeting electronic recordkeeping requirements issued by FDA and other organizations.

At the start of the meeting Mr. Taylor explained how we were preparing industry guidances on part 11, what the process entailed, and the fact that we were at different stages in the preparation of guidances on validation, a glossary, time stamps, retention, electronic copies and audit trails. He encouraged the PDA/ISPE/GAMP representatives to fully participate in that public process and to send their comments to the dockets we had established. He noted that although we had not yet published draft guidances, we had already established the relevant public dockets to hold references, comments, and memos of meetings.

Mr. Grigonis explained that PDA, in consultation with other groups such as ISPE and GAMP, was preparing a technical report on good electronic records management, to assist FDA regulated firms meet emerging requirements in this

arena. He explained that the project deliverables include models for bringing existing systems into compliance and for ensuring that new systems were compliant, along with an infrastructure to ensure ongoing training in use of the deliverables and keeping the documents current.

During the meeting the industry representatives presented information and followed the attached presentation.



Acrobat Document

The industry representatives reviewed their project accomplishments thus far, including surveys of the regulated industry and suppliers, on-going monitoring of mainstream related events, cooperation with other groups, conferences, and work products. A stakeholder comment period was to begin in mid May. The centerpiece is the Good Electronic Records Management (GERM) document, a good practices reference more than an explicit “how to” text, that would follow a document lifecycle approach. A separate glossary is also under development.

The industry representatives explained the parallel efforts of GAMP/ISPE with respect to a Part 11 guide, aimed mainly at an approach to implementation of the regulation. The GAMP/ISPE document also related to European Union standards applicable to electronic recordkeeping. GAMP expects to publish a first version of a Part 11 guide in the second quarter of 2001.

The industry representatives explained that GAMP and PDA would try to publish their respective documents, and that each document would have the same preface and would cross-reference the other.

The industry representatives reviewed the April 2001 GERM conference, held in Tampa, Florida, to promote the GERM work products and as a follow up to the joint PDA/FDA June 2000 FDA conference. The GERM conference was supplemented with educational workshops. Conference speakers from outside FDA regulated industries provided incentives for part 11 compliance beyond the FDA regulatory arena.

The industry representatives asked how they could interact with FDA, assist in the process of developing FDA guidance, and FDA fairly consider their views. We suggested they send their comments and references to the part 11 dockets, and that we will fairly consider all public comments to the docket. We added that we could not co-author our documents with third parties. We also suggested that the industry representatives continue their outreach to other organizations.

The meeting lasted about two hours.

cc:

FDA meeting attendees

HFC-200

HFA-224

Part 11 Guidance Dockets

P. Motise

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07/30/01