Part 11 News and Views

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Introduction

- New part 11 compliance committee at FDA
- Public conference on part 11
- New questions and answers
- Latest Warning Letter citing part 11 deficiency

New Part 11 Compliance Committee at FDA

- Representation
  - Office of Enforcement
  - Office of Regulatory Affairs
  - Center for Devices & Radiological Health
  - Center for Drug Evaluation and Research
  - Center for Biologics Evaluation and Research
  - Center for Food Safety and Nutrition
  - Center for Veterinary Medicine

New Part 11 Compliance Committee at FDA

- Responsibilities
  - Advise agency on part 11 compliance issues
  - Develop and recommend draft policy and guidance on part 11 for the agency
  - Communicate information about committee work to FDA centers and offices

more...

New Part 11 Compliance Committee at FDA

- Responsibilities
  - Serve as primary agency forum for discussing part 11 issues and making recommendations for uniform implementation of part 11
  - Promote, develop and coordinate part 11 training and educational events for FDA and regulated industries

Public Conference on Part 11

- When: June 19 and 20, 2000
- Where: Wyndham Franklin Plaza Hotel
  17th and Race Streets
  Philadelphia, PA 19103
  Phone: 215-448-2000
- Sponsored by: FDA and Parenteral Drug Association (all industries welcome)

Public Conference on Part 11

- Purpose: to exchange information on
  - Experiences in implementing part 11
  - Available products and services to help implement part 11
- Presenters: industry and vendors
- FDA will consider information presented at event in developing future guidance

Public Conference on Part 11

- You are invited to speak!

Public Conference on Part 11

- Abstracts of proposed presentations are due:
  - March 19, 2000
  - To: Parenteral Drug Association (PDA)
    7500 Old Georgetown Rd., Suite 620
    Bethesda, MD 20814
    or via e-mail to madsen@pda.org
- Watch for Federal Register notice for more information

Audit Trails & Draft Documents

- Problem: industry says compliance with audit trail requirement is too difficult and should apply only to certain types of records
- For example, apply audit trail requirement to test data but not draft procedures or CAD drawings of device designs before they are approved

Audit Trails & Draft Documents

- Problems to address in future guidance:
  - Integrity of e-record
    - Audit trails track changes AND authenticate author(s)
    - In the absence of an audit trail, author repudiation can be a problem

more...

Audit Trails & Draft Documents

- Problems to address in future guidance:
  - Abuse
    - Sanitizing file of adverse information while still a draft (in absence of audit trail)

more...

Audit Trails & Draft Documents

- Problems to address in future guidance:
  - Granularity
    - Larger “draft” document may be made up of several smaller “final” modules
    - Does that mean “final” modules do not need audit trail?
    - Some predicate rules do not allow drafts. Records must be created comtemporaneously with the event being memorialized *more*...

Audit Trails & Draft Documents

- Problems to address in future guidance:
  - Contamination
    - If audit trail can be enabled and disabled selectively or there are separate systems, records needing higher control may be “accidentally on purpose” given lower control

Questions and Answers

Audit Trail Options

- Q: If raw data from an instrument is documented in an e-record that cannot be changed based on procedural and security controls, and the operator, time and date are captured, would this meet audit trail requirements?
- A: Whether or not the data can be changed is irrelevant as long as an audit trail is automatically generated electronically. Perhaps an audit trail for a document that cannot be changed would be easier to implement because it need not track changes?

Back Up Power Supply Issue

- Q: Does part 11 require a back up power supply for automated equipment supply?
- A: No, but part 11 requires “The ability to generate accurate and complete copies of records in both human readable and electronic form…” If a power failure could result in the loss of required records or data, a back-up power supply would be one way of assuring compliance with parts 820 and 11 in the event of a power failure.

E-Sig Data in Document

- Q: Must the name, date and time of an electronic signature be displayed on every page of the signed document?
- A: No. The information must be linked to the document and must be readable in electronic and hard copy but may appear in only one place in the document just as on a conventional paper document

Electronic Data Subject to FDA Access and Inspection

- Q: Does the concept of "meta data" require the manufacturer to provide unlimited access to all electronic data within a computerized system?
- A: No. The manufacturer must provide access to only those records required under predicate rules and their associated audit trails.

Software Programs & Copies

- Q: I maintain my records are in software programs that my local district office does not have, but I can provide electronic copies of the documents in Microsoft Word or Excel along with the audit trail. Is this acceptable to FDA?
- A: Yes.

Retaining Records on Rejects

- Q: Must records be retained from instruments used in manufacturing if the lots or batches were rejected?
- A: Yes. 820.100 (CAPA) requires analysis of data to ID nonconforming product and problems. If data on rejected lots is not retained you will not be able to perform analysis. If records are deleted after analysis, FDA may be unable to determine if you performed an analysis in compliance with 820 requirements.

Data for Investigations and CAPAs

- Q: Must data generated in support of an investigation and a CAPA be controlled as an electronic record subject to part 11?
- A: Yes. Results of investigations must be documented [See 820.100 and 820.198]. If the data is in an electronic record, it is subject to part 11 and must be available for inspection and review by FDA.

Access to E-Records via Internet

- Q: Access to an electronic record system is via e-mail through the Internet, and security controls are in place to restrict external access by unauthorized personnel. Does this constitute a closed system?
- A: No. This is an open system. Internet access generally involves a number of relay station servers, which is why you encrypt your credit card when placing an order via Internet.

Closed Systems with Telephone Access

- Q: When might an e-record system accessible via telephone be considered a closed system?
- A: If there is direct telephone access to a single server with a store-and-forward "relay" type environment, and persons responsible for content of records on the server control access, the system is closed.

Raw Data vs Results

- Q: Must all data maintained, even if the data is manipulated automatically to provide information in “pass or fail” format?
- A: Not for devices. See part 820 preamble pp. 52631 & 52646. Part 820 requires that “results” of acceptance activities be recorded but not necessarily all raw data. “Results” must have audit trails. Be sensitive to need for raw data during failure investigations under CAPA.

Latest Warning Letter

- For your information, during the inspection our Investigator noted there is no assurance that the XXXX could create an audit trail that was computer generated and time stamped to independently record the date and time of operator entries and action, as required by 21 CFR 11.10(e). [10/15/99 - DEN-DO]

Summary

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Mini Case Studies

The End