Commentary

21 CFR Part 11; Electronic Records; Electronic Signatures Electronic Copies of Electronic Records

The guidance provides a starting point for identifying what needs to be done, or should be done, to furnish FDA with electronic copies of electronic records that are subject to Part 11.

by
Leonard A. Grunbaum
President and Chief Operating Officer
META Solutions, Inc.

This article provides the primary positives and negatives of the draft Guidance for Industry: *21 [Code of Federal Regulations] (CFR) Part 11; Electronic Records; Electronic Records: Electronic Copies of Electronic Records* from the author's point of view. Readers experienced in the issues involved in furnishing Food and Drug Administration (FDA) with electronic copies of electronic records that are subject to Part 11 requirements can use this information as an overall frame of reference. Readers inexperienced in these issues will hopefully find a "reader-friendly" introduction to the guidance document specifically, and to the subject matter in general.

Overview

The guidance provides a starting point for identifying what needs to be done, or should be done, to furnish FDA with electronic copies of electronic records that are subject to Part 11. As the document states:

> *"...identifies key principles and practices in generating electronic copies of electronic records so that the electronic copies are accurate, complete and suitable for our inspection, review and copying. [It] also addresses attributes of such electronic copies that make them accurate, complete, and suitable for our inspection, review and copying."*

This is still a draft document and not intended for implementation; FDA is soliciting comments from Industry, and the final guidance may change significantly or otherwise. Nevertheless, those affected by the regulation – individuals who must comply with the regulation and those who must apply it – are now able to assess the agency's "current thinking" on furnishing electronic copies of electronic records to the agency. Even though the "current thinking" is in draft form, affected individuals can begin to determine whether their policies and procedures are in line with the principles, practices, and answers provided in the guidance. Should a company's policies and procedures, or an investigator's "current thinking" or experience, not be in line with the Agency's "current thinking," this is a good time to start aligning them accordingly. Should a company have issues not covered within the

Agency's "current thinking," this is a good time to solicit professional advice, or even advice from the Agency, on how to address relevant issues.

Positives

The following issues represent the primary positive aspects of the guidance. They are not necessarily addressed in priority order:

- As stated on the first page of the guidance: "... is intended to assist persons who are subject to the rule to comply with the regulation [and it] may also assist FDA staff who apply Part 11 to persons who are subject to the regulation." This means that both industry personnel and regulators are starting from the same place in understanding key principles and practices. The result should be that an inspector would more easily understand what a company is doing, and why it is doing it, thereby increasing the value of both the inspection and possible audit findings.
- Section 5.2 states: "It is important that any file conversions you perform when you generate an electronic copy of an electronic record be validated" to ensure that "... information in the original electronic record has not been altered in, or deleted from, the electronic copy." This is an important reminder to ensure that you have thought out the process (and hopefully documented it as you would in any validation effort) prior to generating the copies. There is a negative aspect to this as well, as is described in the following section.

Negatives

The following issues represent the primary negative aspects of the guidance. They are not necessarily addressed in priority order:

- The "definitions and terminology" section includes the following: "Unless otherwise specified below, all terms used in this draft guidance are defined in FDA's draft guidance document, *Guidance For Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms*...." FDA clearly indicates that draft guidance documents are not for implementation, yet they point the reader to a draft document for definitions and terminology. The risk to someone using these definitions is that they will change when the glossary is finalized.
- Section 5.1 indicates: "[t]he file format of the electronic copy of the electronic record might differ from that of the original electronic record, yet still be suitable for our inspection, review, and copying." Further, it states that the Agency "will consider electronic copies of electronic records to be accurate and complete if they convey all the information and revisions in the original electronic records." As examples, the document mentions embedded notes, comments, hidden text contained and metadata (e.g., audit trails). While helpful in concept, the document would be more helpful if it contained at least one concrete example of an original electronic record, and a copy of that record in a different format, with specific illustration of how embedded notes, comments, etc., could be included.
- Regarding Section 5.2, the document does not define "validation" in this context. The referenced glossary contains a definition of "computer system validation," which seems broader in scope than making copies of electronic records. The guidance document should define "validation" as it relates to making copies of electronic records (e.g., to confirm the completeness and accuracy of the electronic copy), or refer to the validation of the system that generates the electronic copy, thereby conforming to the definition in the glossary. Further, the guidance should provide for "validating" the completeness and accuracy of the electronic copy by describing the need for a "validation plan" for doing so, criteria for acceptance, testing, a report of results, etc.
- Section 5.5 provides for "Having an authentication value [to confirm] that the electronic copies we use in assessing your activities will retain their integrity." The document mentions, as an illustration, "digital signature message digest" and "hash value." These items should be defined and examples provided.
- In Section 5.6, the Agency states: "We consider it very important that we be able to process the data in electronic records using our own computer hardware and software." The question for the Agency is, "are your computerized systems validated per the requirements of 21 CFR Part 11?" The guidance should indi-

cate that the Agency's systems, are in fact, validated. If not, Industry can question whether the Agency will be able to process data properly.

Summary

I often hear grumbling that a given guidance document doesn't go far enough or address all applicable issues. Maybe so, but one must appreciate that a given guidance document represents FDA's current thinking on a subject and addresses some frequently asked questions. It is not meant to cover everything about the subject. A guidance document is merely the starting point for adopting policies and procedures. In this case, to effectively make electronic copies of electronic records. As the document states in Section 5.6:

> *"If you are using an alternative approach that you believe satisfies applicable requirements, and you have any questions regarding the agency's ability to inspect, review, and copy such electronic records, we encourage you to contact us [emphasis added]."*

Take them up on it. ❑

About the Author

Leonard A. Grunbaum is the President and Chief Operating Officer of META Solutions, Inc. He is responsible for all operational aspects of the company, and the management of all aspects of the validation consulting services to the pharmaceutical industry. Len has a BA and an MBA from Long Island University. He was a Director of the Electronic Data Processing (EDP) Auditors Association. Len is the author of "Do It Right The First Time: A Handbook for Controlling Technology Through Good Validation Practices," published in the February 2000 issue of the Journal of Validation Technology. *Len can be reached by phone at 732-845-4904, by fax at 732-845-4834, or by e-mail at len_g@metasol.com.*

Article Acronym Listing

CFR:	Code of Federal Regulations
EDP:	Electronic Data Processing
FDA:	Food and Drug Administration