



## **Electronic Signatures and Electronic Records** *Frequently Asked Questions and Answers*

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### **FAQ EXCERPT BEGINS**

#### **When using a hybrid system approach to e-signatures, how do you link the handwritten signature to the e-record?**

Since 21 CFR 11 (Part 11) does not require that electronic records be signed by using only electronic signatures, e-records may be signed with handwritten signatures that are applied to electronic records or with handwritten signatures that are applied to a piece of paper. If the handwritten signature is applied to a piece of paper, it must link to the electronic record. The Food and Drug Administration (FDA) will publish guidance on how to achieve this link in the future, but for now, it is suggested that you include in the paper as much information as possible to accurately identify the unique electronic record.

For example and at the least, include: file name, size in bytes, creation date, and a hash or checksum value. However, the master record is still the electronic record. Thus, signing a printout of an electronic record does not exempt the electronic record from Part 11 compliance.

#### **I keep electronic records, but have signatures on paper (hybrid systems). Is there a deadline for converting to electronic signatures?**

There is no deadline for converting to electronic signatures. As a matter of fact, there is no requirement that you must have an electronic signature system in place. Having handwritten signatures on paper is acceptable if the signature is linked to the electronic record, so signers cannot repudiate their associative responsibility.

#### **When does an audit trail begin?**

Audit trail initiation requirements differ for data versus textual materials.

- For data: If you are generating, retaining, importing, or exporting any electronic data, the audit trail begins from the instant the data hits the durable media.
- For textual documents: If the document is subject to approval and review, the audit trail begins upon approval and release of the document

#### **Are e-mails controlled documents?**

This is a most interesting question. From the controls standpoint, an email can be a document and be used as such; however, from the Part 11 compliance standpoint, it does not meet the requirements of the regulation. Please note that if the text in an email supports such activities as change control approvals or failure investigations, then the emails have to be managed in a compliant manner.

#### **Can a single restricted login suffice as an electronic signature?**

No, the operator has to indicate intent when signing a document. The user has to re-enter the user ID or password, which shows awareness that he or she is executing a signature, and indicate the meaning for the



e-signature. To support this, 21 CFR 11.50 states that signed e-records shall contain information associated with the signing that indicates the printed name of the signer, date and time, meaning for the e-signature, and that these items shall be included in any humanly readable form of the record.

**FAQ EXCERPT ENDS**



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