

***“...Given the wider business benefits that the Rule offers, it is imperative that electronically signed records should be implemented in the context of a company’s information technology strategy...”***

## Electronic Signatures & FDA

### *Electronic Signatures and FDA’s 21 CFR Part 11*

“In the Federal Register of March 20, 1997, at 62 FR 13429, FDA issued a notice of final rulemaking for 21 CFR, Part 11, Electronic Records; Electronic Signatures. The rule went into effect on August 20, 1997. Part 11 is intended to create criteria for electronic record keeping technologies while preserving the agency’s ability to protect and promote the public health (e.g., by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary pursuing regulatory actions). Part 11 applies to all FDA program areas, but does not mandate electronic record keeping. Part 11 describes the technical and procedural requirements that must be met if a person chooses to maintain records electronically and use electronic signatures. Part 11 applies to those records required by an FDA predicate rule and to signatures required by an FDA predicate rule, as well as signatures that are not required, but appear in required records.”

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Source:

**U.S. Food and Drug Administration**

Office of Regulatory Affairs  
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### What is the FDA Final Rule?

The FDA Final Rule provides “criteria for acceptance by FDA . . . of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper.” By giving pharmaceutical companies the approval to use electronic records and electronic signatures, the Rule represents a watershed by allowing major efficiency improvements in their business operations.

### What does the FDA Final Rule say?

• **Subpart A - General Provisions:** defines the scope and implementation of the Final Rule, as well as some key definitions. “Persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met,” and that a docket stating a company’s intent has been submitted to the FDA.

• **Subpart B - Electronic Records:** establishes the system controls that must be in place if electronic records and signatures are to be used. A signed record must clearly indicate, “(1) the printed name of the signer; (2) the date and time when the signature was executed; and (3) the meaning (such as review, approval, responsibility, or authorship) associated with the signature.” Electronic signatures “shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred to falsify an electronic record by ordinary means.”

• **Subpart C - Electronic Signatures:** sets out the FDA’s general requirements for electronic signatures, their components and system controls. Electronic signatures must be “unique to one individual and shall not be reused by, or assigned to, anyone else.” They may be biometrics based or they may be based on identification code/password combinations.

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## Business Benefits:

The Final Rule regulations apply to all FDA program areas and are intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health. But it is important to realize that the use of electronic signatures can dramatically drive down costs for all business processes, not just FDA submissions.

- No need to print documents for signing. Reduce or eliminate printer and paper management costs where documents are printed “for signature.”
- Greatly speed up workflow. E-mail documents for multiple concurrent signatures.
- Automated signature verification. Much faster, more reliable and more objective compared to manual signature verification.

## What are the Electronic Signature alternatives?

Pharmaceutical companies must implement electronic records and electronic signatures without delay. It is undeniable that large business cost savings will accrue from this initiative and that it provides a unique opportunity to gain competitive advantage. Retaining paper documents and signatures is not a viable alternative for the long term. The signature options provided by the FDA are:

## Electronic Signatures

Controls and procedures (set out in Subpart C) must be established to ensure the

technology is equivalent to a handwritten signature.

- Biometrics-based signatures: Must be designed to ensure they cannot be used by anyone other than their owners.
- Identification codes/passwords : Extra system control must be implemented (Subpart C, section 11.300) to ensure their security and integrity.

## Handwritten Signatures

Subpart C does not apply if the technology adopted preserves the act of signing with a stylus, even when applied to electronic documents.

## Implementing Electronic Signatures

Given the wider business benefits that the Rule offers, it is imperative that electronically signed records should be implemented in the context of a company's information technology strategy. A pharmaceutical company must ensure that its chosen technology satisfies both the FDA Final Rule and the conventional use of handwritten signatures on paper. Implementation thus presents the company with some key choices and challenges:

### • FDA Acceptability

Ensuring that the chosen system matches the FDA's definitions and that the required system controls are in place.

### • User Acceptability

Ensuring that users approve of and are quick to adopt the new technology so that the impact on existing business practices is minimal.

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Any popular format.  
The key to paperless  
business processes.**

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## • Legal Acceptability

Ensuring that third-party (including non-pharmaceutical) document recipients will continue to trust and do business on the basis of electronically signed documents and that these documents and signatures will stand up in the court of law.

## CIC Electronic Signature

CIC provides companies with a biometric handwritten electronic signature. A signer's biometric signature is captured at the time of signing (shape of the signature, velocity and acceleration of the signing event and stroke dynamics). A biometric signature since it is based on an individual's biometrics it satisfies the controls and procedures set out in Subpart C.

**Subpart C - Electronic Signatures:** sets out the FDA's general requirements for electronic signatures, their components and system controls. Electronic signatures must be "unique to one individual and shall not be reused by, or assigned to, anyone else." They may be biometrics based or they may be based on identification code/password combinations.

CIC's electronic signature is attached to the signed document in a way to maintain the integrity of the document. This is done by permanently binding the signature to the document and comparing the original document with the contents of the document each time it is opened. If any change is detected, the electronic signature is invalidated. In addition, the electronic signature includes the date and time and location of the signature along with the

reason the document was signed. This illustrates a person's consent, understanding the responsibility toward the document contents. Because the electronic signature is bound to the document permanently it cannot be transferred into another document or used fraudulently.

A biometric signature, is not only similar to a handwritten signature but is also less intrusive than most other biometric authentication techniques, such as retinal eye scan, or fingerprint. The biometrics of a handwritten signature is based not only on the shape of the signature but also the dynamics of the signature. The dynamics of the signature include the velocity and acceleration of the signing event, and stroke dynamics. Signatures have at least three attributes, form, movement, and variation, and since moving a pen on paper produces the signatures, movement perhaps is the most important part of a signature. This is based on the person's muscular dexterity, usually referred to as "muscle memory." Once a person is used to signing his or her signature, the brain without any particular attention to detail controls these nerve impulses.

