

# Digital Signatures for Federal Government

## CoSign® Digital Signatures for Government Agencies

With increasing pressure on government budgets and a need for federal agencies to do more with less, CoSign® makes it easy for government agencies to digitally sign transactions, documents, and forms. By embedding standards-based digital signatures directly into common files and business applications, CoSign produces a FIPS 186-2 compliant electronic signature record for every approval. This **Portable Signature Format (CoSign PSF™)** allows easy and secure validation and proof of signer identity, intent, and document integrity without any costly, complex, or proprietary technology required for verification. The results are sustainable, digitally signed electronic records that are based on published standards and that can be trusted by recipients for data integrity and signer authenticity.

### Value Proposition - CoSign Digital Signatures

**Mitigate risk.** CoSign is tried and tested and used by hundreds of government entities and nearly a million government sector end-users from across the globe.

**Assure security and compliance.** CoSign Central stores the signing key (Private Key) in a centralized and secure hardware device (the CoSign FIPS version is FIPS-140-2 Level 3 certified), ensuring that any tampering attempt with the secured CoSign appliance will be detected. Strong key security combined with a high-level of user identification (which is supported by standard operating procedures for identification throughout the employee recruitment process) enables CoSign to comply with the most stringent federal, state, and industry regulatory requirements such as the FDA's 21 CFR Part 11, HIPAA, and SOX.

CoSign ensures your compliance

- » Federal Information Security Management Act (FISMA)
- » FIPS 140-2 level 3
- » Digital Signature Standard (FIPS 186-2)
- » Government Paperwork Elimination Act (GPEA)

**Add signature capture capability to external facing portals.** CoSign enables digital signing functionality in advanced external-facing applications such as partner-facing web applications, kiosk type point-of-sale applications, and e-invoicing applications.

**Ensure external acceptance.** CoSign digital signatures are embedded directly into the document itself, enabling the document to serve as a self contained e-record. This enables any outside party to independently verify the digitally-signed e-records for signer identity and intent, and data integrity.

**Integrate into existing workflows.** CoSign integrates seamlessly with leading workflow and Enterprise Content Management Systems such as Microsoft® SharePoint®, enabling automated approval processes from within your organization's existing workflow systems.

**Securely control authorized signers.** CoSign works with existing user management systems like Microsoft Active Directory® for controlling signer authorizations, and supports custom user management for external signer authorization for users who are outside of the organization.

**Deploy quickly and manage easily.** CoSign ensures quick deployment and minimal ongoing IT management requirements, translating into a very low total cost of ownership.

## User Benefits

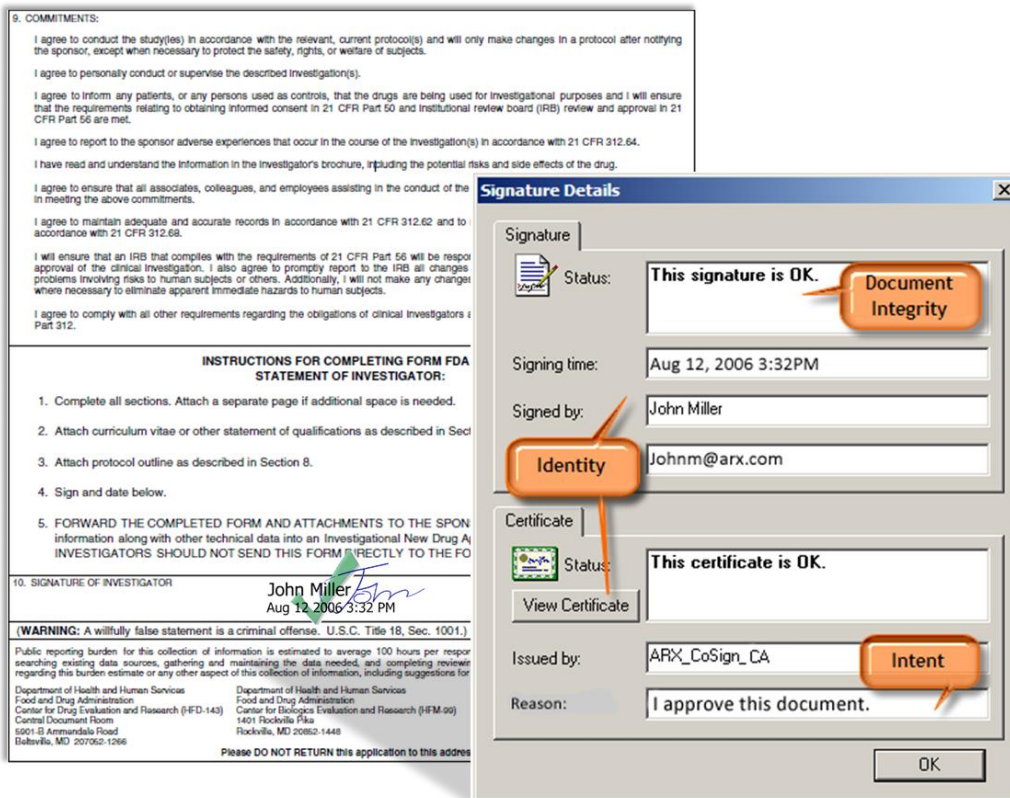
**Turn any document into a signed and sealed PDF.** CoSign's integrated signing feature can convert any electronic document into a signed PDF.

**Add your graphical signature and signing rational.** The signer's graphical signature is placed on the document as well as the rational for signing, such as: 'I approve,' 'I agree,' etc.

**Approve along with your colleagues.** CoSign allows multiple signatures to be placed on a document one after another while ensuring document integrity. It also allows for digital signatures to be applied only to a specific area of the document. This is useful in scenarios that require a series of approvers and an audit trail.

**Make a complete return on investment.** CoSign eliminates the costs associated with paper, printing, scanning, archiving and more. Your system will pay for itself in a matter of months, or less.

**CoSign keeps business moving by fully automating workflows and quickly scaling processes with proper controls.**



9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 56 and Institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the investigation meet the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the approval of the clinical investigation. I also agree to promptly report to the IRB all changes/problems involving risks to human subjects or others. Additionally, I will not make any changes where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators in 21 CFR 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA STATEMENT OF INVESTIGATOR:**

- Complete all sections. Attach a separate page if additional space is needed.
- Attach curriculum vitae or other statement of qualifications as described in Section 8.
- Attach protocol outline as described in Section 8.
- Sign and date below.
- FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FDA.

10. SIGNATURE OF INVESTIGATOR

John Miller  
Aug 12, 2006 3:32 PM

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including reviewing existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information, including suggestions for reducing this burden. Send comments to Washington, DC 20503-2977.

Department of Health and Human Services  
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Food and Drug Administration  
Center for Biologics Evaluation and Research (HFM-09)  
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Please DO NOT RETURN this application to this address

**Signature Details**

Signature | Status: This signature is OK. Document Integrity

Signing time: Aug 12, 2006 3:32PM

Signed by: John Miller  
Identity | Johnm@arx.com

Certificate | Status: This certificate is OK. Intent

View Certificate

Issued by: ARX\_CoSign\_CA

Reason: I approve this document.

OK

Digital Signatures That Keep Your Business Moving

