

Digital Signatures for the Pharmaceutical Industry

"The cost of CoSign will pay for itself in just three months, and it will allow more time for our field reps to concentrate on work, not paperwork."

- Angela Gasper, IT Project Manager at MEDRAD (Bayer-Schering).

A Digital Signature Solution for the Pharmaceutical Industry

In the competitive biopharmaceutical environment, accelerating processes is essential. Being first to introduce new drugs to market is worth millions and therefore life science organizations must be quick and efficient. Migrating to a paperless workflow is a proven way to accomplish the goal of increased efficiency and streamlined business processes. However, in order to lawfully become paperless, a pharmaceutical company must maintain compliance with regulations such as [21 CFR \(Code of Federal Regulations\) Part 11](#), the Food and Drug Administration's regulation on electronic records and electronic signatures. This regulation calls for authenticity and integrity of electronic records in computer systems with portability. To ensure that the standards are maintained, pharmaceutical companies undergo continuous auditing by external parties such as the FDA.

CoSign® makes it easy to sign transactions, documents, and records while maintaining document authenticity and integrity. This is accomplished via a standards based digital signature that embeds signatures directly into applications, leveraging existing business workflows and processes. CoSign produces a signature record for every signature it captures. This Portable Signature Format (CoSign PSF™) allows anyone to seamlessly verify and retain proof of identity, intent, and document integrity without costly, complicated, or proprietary software. CoSign keeps your business running at optimal speed by fully automating and quickly scaling processes with proper controls.

How Do CoSign Digital Signatures Improve Business Processes?

Accelerate business processes. Because the CoSign PSF is a self-contained, portable, and embedded signature record, signed documents can be easily routed through and between organizations in your collaborative network. Records signed with CoSign can be examined rapidly with no need for time-consuming manual routing of physical documents.

Lower costs. CoSign allows users to reduce costs associated with authorizing and signing documentation. It also reduces the costs and quality challenges associated with archiving, audits, and legal requirements. By reducing costs associated with traditional paper-based processes (i.e., paper, printing, scanning, faxing, postage, and processing), organizations realize a quick Return on Investment (ROI).

Eliminate vendor lock-in. By using a standards-based technology, CoSign transforms signed documents into portable electronic records that are maintained in a non-proprietary format. This allows future or external recipients to easily verify signatures in common applications (e.g., Microsoft® Word, Excel®, InfoPath®, Outlook®, PDF, TIFF, AutoCAD®, etc) without costly, complicated, or proprietary software, or dependency on the system that created the digital signatures.

Seamless Digital Signatures

- » A Simple Click. Easy to sign, retain and verify digital documents using business applications.
- » A Faster Pace. Accelerate the pace of doing business with a customer, partner or prospect.
- » A Lower Cost. Ease the cost and burden of using digital signatures in business process automation.

Digital Signatures That Keep Your Business Moving

Legal and regulatory compliance. CoSign allows biopharmaceutical organizations to become paperless while maintaining compliance with regulations such as the FDA's 21 CFR Part 11, as well as HIPAA Security Standards, SOX, and other requirements.

Document integrity. According to the FDA's CFR Part 11, open systems need to employ procedures and controls designed to ensure the authenticity and integrity of electronic records from the point of their creation to the point of their receipt. CoSign seals documents digitally, verifying the document has not been altered after signing, providing proof of the signer's identity, and document integrity over the life of the electronic record.

Digital Signatures Applications in the Pharmaceutical Industry

Typical examples of digital signature use within the pharmaceutical industry include systems and processes such as electronic submissions, RA/QA, Standard Operating Procedures (SOPs), clinical operations, manufacturing instructions, electronic batch records, electronic lab notebooks (ELN), field service operations, secure document exchange with external parties and partners, as well as the wealth of non-FDA regulated business processes in HR, finance, legal, etc.

The ARX CoSign product is the largest and most widely deployed digital signature solution being used today in thousands of FDA regulated applications. The product has been successfully deployed with applications for hospitals and clinics, laboratories, food manufacturing, medical device and biopharmaceutical companies, contract research and manufacturing organizations, as well as the software/service vendors supporting these operations. Clients include 4 of the 10 largest CROs, 4 of the 10 largest Pharmaceutical companies, 3 of the 10 largest medical device companies, over 50 contract labs, and many of the leading software and service vendors in the life sciences industry.

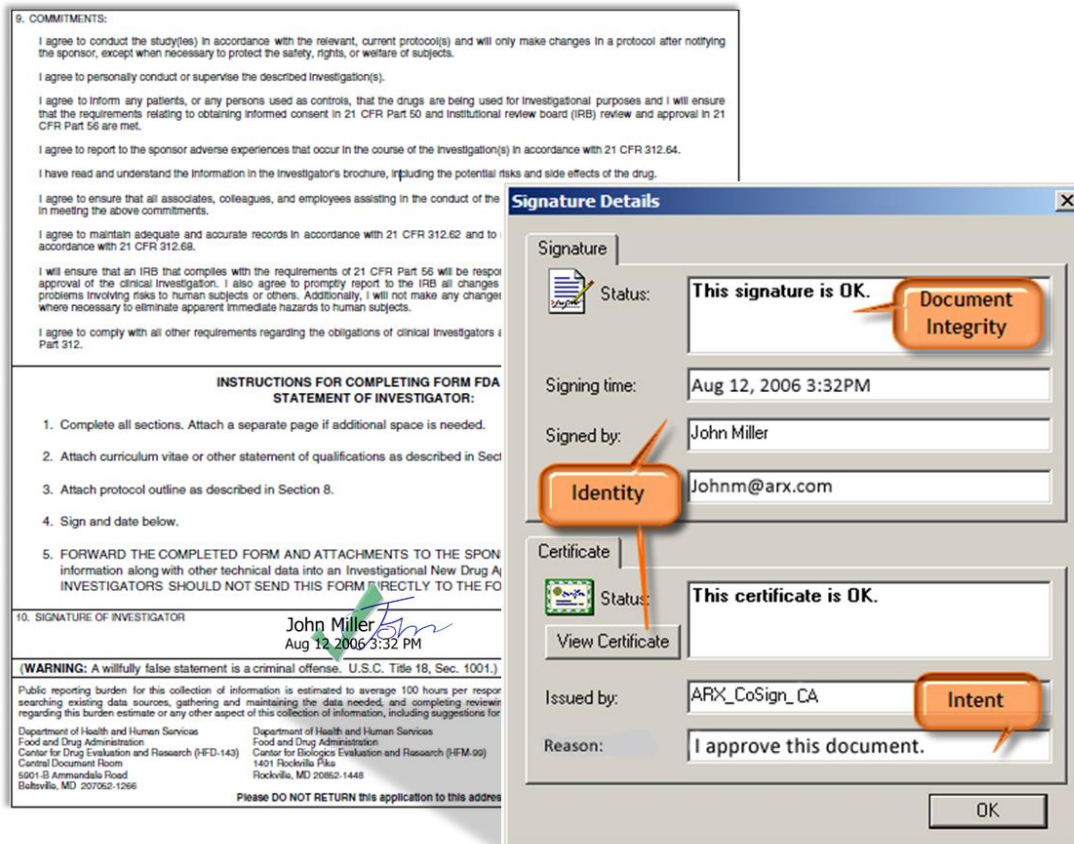


Figure 1: Digital signatures seamlessly integrate into Pharmaceutical documentation, keeping your business moving without losing control.