

**AR e-signature solution
Increasing efficiencies and ensuring data integrity**

CoSign assists Pharmaceutical companies to comply with 21 CFR, Part 11



The solution is in the process

In an era of digital technology, when automation of processes drives productivity and reduces costs, the pharmaceutical industry still generates mountains of paperwork. These paper processes can result in liability concerns and difficulty in controlling and monitoring changes, updates, and approvals. Manually signing these documents is a long process that can take days to complete, thereby significantly hindering pharmaceutical processes.

In a competitive 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. However, being quick is not enough. For pharmaceutical companies to become paperless they require compliance with regulations such as 21 CFR (Code of Federal Regulations) Part 11, the Food and Drug Administration's regulations on electronic record keeping and electronic signatures. Companies undergo continuous auditing by external parties such as the FDA, which mandates evidence that their data is valid and their processes are well defined.

Its time to replace traditional signing methods, with CoSign.

CoSign, the innovative and non-forgeable digital-signature solution ensures data liability and enables organization to comply with regulations worldwide. It also allows organizations to significantly shorten process's cycle times and expedite delivery to market.

With CoSign, it's that simple!

So what does the FDA require?

In order to migrate to more efficient electronic systems, pharmaceutical organizations must comply with 21 CFR Part 11 specific requirements, which **mandate** that companies implement:

- A system in which electronic records and signatures are trustworthy, reliable and secure.
- Electronic signatures that are equivalent to paper records and handwritten signatures executed on paper.
- Signatures that offer integrity as well as ensure that the signer cannot readily repudiate the signed records.
- A system that discerns invalid or altered records.
- Signatures that are linked to an electronic record.

Systems and processes such as drug approval, quality assurance, Standard



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Operating Procedures (SOP's) and client submissions can significantly benefit from digital signatures. This is because they pose the utmost risk in terms of product quality and/or public safety. These systems require constant monitoring, updating and reviewing. By implementing digital signatures into their system, pharmaceutical organizations can benefit from a convenient method of monitoring changes. In addition, authorizations and updates have a clear electronic audit trail for the transaction.

CoSign brings convenience and compliance to Pharmaceutical processes

Up until now digital signatures have been a complicated and expensive solution to integrate and manage. Today, AR has developed a digital-signature solution that is simple-to-use, secure and cost-effective. The Life-Science industry will greatly benefit from the use of digital signatures in terms of efficiency and data integrity. With CoSign, organizations will be able to electronically sign, as well as send and archive electronic records, whilst complying with FDA regulations.

Simplicity and Security of CoSign

CoSign proves an innovative and a trustworthy way to electronically sign documents and transactions. Implementing CoSign's PKI based technology guarantees that your signature cannot be copied or tampered. CoSign is easily integrated with in a growing number of applications such as

MS-Word, Adobe-Acrobat and leading document management systems. In addition, CoSign is the only digital signature solution that signs scanned TIFF images. It can be smoothly deployed within any organizations existing user-management systems. CoSign delivers a zero management and reliable way of implementing digital signatures within major application. Therefore, by implementing this solution pharmaceutical companies that are already migrating to paperless solutions such as content management systems and workflow applications can now eliminate the last paper in their organization. It also enables users to easily verify the validity of the signature anywhere, anytime.



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CoSign provides standards that conform and exceed the 21 CFR Part 11, electronic signature requirements as well as provide added value offerings that enables organizations to streamline time consuming paper-based processes, these include:

- Representation of the signers name, date and reason of the signature.
- Electronic signatures that are inseparable from the document (cannot be extracted).
- Ability to identify and prove that the electronic document has/has not been changed.
- Signatures that allow organizations to create an audit trail of signatures in Acrobat and Word.
- Multiple signature capabilities whereby numerous signers, reviewers and authorizers can sign one document.
- Graphical electronic representation of your handwritten signature, which can easily be viewed by FDA auditors or any other auditing authority.
- Digital Signature that can be verified anytime, anywhere.

*So no more waving pens from
one another*

CoSign allows pharmaceutical companies to easily migrate to a secure and convenient electronic working environment that ensures data integrity and non-repudiation of documents.

CoSign is the digital signature that enables immediate compliance with FDA regulations.

Considering CoSign's technology pharmaceutical companies can significantly become more efficient and productive. Pharmaceutical organizations, CRO's, biological and medical equipment industries can now dramatically save operational costs, expedite delivery, by eliminating the requirement to print the paper forms which in turn helps gain competitive advantage.

CoSign is the digital-signature solution that will not compromise the integrity of your electronic records. Be sure that you will not find your signature elsewhere.

**Signing is now quick with
just a click!**

For more information on AR's digital signatures solution in Pharmaceutical, please contact sales@arx.com or call:

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Your comments and feedback are welcome media@arx.com

