

ClinPhone Complies with FDA Regulations Using CoSign Electronic Signatures

"CoSign provides an elegant solution for both our business and regulatory requirements"

Dr Jonathan Engler, former Joint MD, ClinPhone Group Ltd.



The largest and most experienced Clinical Technology Organization (CTO) in the industry, having supported close to 2000 clinical trials (of which more than 400 are currently live) in over 80 countries and 70 languages. ClinPhone undergoes between 40 – 50 audits annually.

EMPLOYEES: More than 500, working out of offices in the USA and Europe, with corporate HQ in Nottingham, UK.

INDUSTRY: Life Sciences

THE CHALLENGE: Provide an electronic signature solution that would:

- » Eliminate delays when issuing documents,
- » Always meet regulatory requirements,
- » Eliminate Logistic concerns when documents are transferred between sites, and
- » Significantly speed up the filing of documents issued in the field.

DEPLOYMENT SUMMARY: CoSign Enterprise rolled out to all users on day one.

BENEFITS:

- » **Speeds up** the signing process from weeks to minutes.
- » Electronic Signatures, became a **part of the document** and cannot be copied or falsified, unlike the electronic file of a document signed with wet ink.
- » Based on standard technology. Signatures may be **validated well into the future.**
- » CoSign allows **multiple electronic signatures** on a single document.
- » Electronic signatures **comply with requirements** such as GxP & 21 CFR Part 11, among others.
- » Source document is available at all sites, 24/7, reducing the need for faxing or transferring copies.
- » **Reduce cost** of printing, filing, priority mailing between sites.
- » **Rapid deployment.** Inexpensive compared to a traditional PKI electronic signature implementation.
- » **Zero Management.**

ClinPhone, the world's leading provider of Clinical Technology Services was seeking an electronic signature solution that would meet with stringent regulations to ensure the accountability and data integrity of sensitive internal documents. In addition, the company sought to obtain a significant competitive advantage by reducing the time-to-approval process, and reduce costs by introducing a paperless office environment.

In order to meet the different regulative requirements such as FDA's 21 CFR Part 11, GxP (GMP, GCP GLP, GAMP, etc.), Computer System Validation, or the wide spectrum of regulatory applications, many biopharmaceutical and medical device organizations are choosing to implement electronic signatures solutions when moving to electronic records and data systems. FDA 21 CFR Part 11 guidelines for Electronic Signatures and Records emphasize the specific requirements for electronic records and electronic signatures. These requirements mandate user authentication, data integrity as well as stating the appearance of the electronic signature (e.g. include time and reason for each signature).

An electronic signature solution with PKI (Public Key Infrastructure), a standard, mature, and proven technology, is a key part of that commitment .

"We evaluated a number of digital and electronic signature products and found that CoSign provides an elegant solution for both our business and regulatory requirements," said Dr Jonathan Engler, former Joint Managing

Director, ClinPhone Group Limited.

"Our product selection process was eased by the impressive technical knowledge, understanding and helpfulness of ARX's staff. "

CoSign: an easy choice

Dr. Engler looked at CoSign to assist the company in meeting this urgent need ."ClinPhone creates a vast number of documents using Microsoft Word or as Acrobat PDF files," says Daljit S. Cheema, IT Director, ClinPhone. The majority of these are needed to meet our regulatory requirements. These documents help us to demonstrate our systems are validated and controlled. Many of these documents have to be signed by several people, "Other solutions proved to be either time-consuming to deploy or difficult to manage, and were resource-intensive when it came to scalability. CoSign, however, laid these concerns to rest, offering us all this, and more."

An out-of-the-box, easy-to-use electronic signature solution, CoSign eliminates the need for handwritten signatures at ClinPhone. CoSign allows ClinPhone to electronically sign thousands of documents using strong standard electronic signatures. These signatures replace handwritten signatures, sealing and legally-binding them as well as saving on the costs and time associated with paper-based processes .

Combining CoSign's electronic signatures with PKI technology ensures signer authenticity, data integrity and non-repudiation of documents .



A swift rollout

The companywide rollout formally commenced on 3rd March 2005 after installing CoSign in ClinPhone's network.

Rapid deployment was vital to the success of the project. "CoSign had to be successfully integrated within the ClinPhone network, and integrated with ClinPhone's existing user-management system to reduce the complexity and cost of enrolment and management of new users, within a very short space of time," says Cheema .

The rapid deployment of CoSign and its ease of use and tight integration with the network and attached desktops allowed it to be quickly adopted by company employees. Coordination was handled by a single IT department manager and a member of the ARX support team. By the end of the first day the entire company was up and running with CoSign. "We rolled CoSign out to staff working at the office and at home so everyone could be trained on the application. On the first day CoSign was officially 'live', one person actually signed from home."

A seamless implementation

ClinPhone's users were able to start signing documents right away. "The basic concept was easy to grasp," Cheema says, "and the signatures were set to offer a look and feel that emulated the traditional 'wet-signatures' people were comfortable with".

To meet specific requirements in FDA's 21 CFR Part 11, user authentication is performed per signature. In order to sign, and once the user is authenticated, the document's hash (i.e. the document's digital fingerprint) is sent to CoSign and is then signed within the appliance with the user's private key.

CoSign provides the Certificate Authority (CA) which, within ClinPhone, is verified by a two stage process. ClinPhone verifies the identity of the individual before they can log onto the network to activate their account. These procedures have been put in place to meet the requirements of 21 CFR Part 11.

Standard Electronic Signatures

ClinPhone was keen to stress it did not want a proprietary electronic signature solution that was only capable of operating within an environment, such as a DM (Document Management) solution. First of all, it would have locked the company into verifying and validating documents within the confines of an expensive DM system. Secondly, it would have also forced them into a long term legacy system nightmare; requiring ClinPhone to maintain a version of that DM application for the entire lifecycle of every single document within that system.

Using CoSign Standard Electronic Signatures meant that signed documents can be validated without the dependency on a DM system. In fact, using standard based electronic signatures allows users to validate the signatures within applications such as Word and Adobe Acrobat without installing any proprietary software.

ClinPhone can now verify the authenticity, and validate the integrity, of signed documents well into the future, no matter if they chose to replace CoSign with the latest product on the market.

Groupwide benefits

The Approval process has been sped up. "To obtain an approval on a project required us to fax documents from our HQ in the UK to branches around the world," says Cheema. "This could take anywhere between three to four weeks to get signatures

from all the parties. Today, however, the process is completed in 10 minutes; CoSign paid for itself just in terms of increased productivity."

Electronically signing documents also reduced the need for every document to be printed, filed, microfilmed and archived. Documents only need to be printed when they are required, for example, for client audits.

Users also appreciate the way electronically signing documents reduces the need for faxing and making certified copies and reduce the number of original documents that have to be couriered between continents.

Conclusion

ClinPhone is a truly global company whose success rests on its ability to comply with regulations as well as enable speedy business processes. With this in mind, it made sense for ClinPhone use ARX's CoSign electronic signature appliance to support the delivery of its business goals. "CoSign's electronic signatures have enhanced the cost-effectiveness of our systems, allowing us to improve the effective delivery of all our services," concludes Cheema.

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