

PAREXEL's ClinPhone Complies with FDA Regulations Using CoSign Digital Signatures

Overview

ClinPhone, a subsidiary of PAREXEL and 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.

"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."

"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."

A swift Rollout

The company-wide 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 enrollment 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.

"We started very early in the morning to hook up the CoSign appliance to our network," says Cheema.

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*



"CoSign's electronic signatures have enhanced the cost-effectiveness of our systems, allowing us to improve the effective delivery of all our services."

- Daljit S. Cheema, IT Director, ClinPhone

- » Customer - ClinPhone (PAREXEL)
- » Country - Europe, USA
- » Industry - Life Sciences

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 Integration

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 Digital 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.

Group-wide Benefits

As electronic signatures made with CoSign automatically include the user's graphical signature, the date and time of the signature and the reason for the signature, this means anything signed by CoSign will help ClinPhone comply with regulatory requirements, such as 21 CFR Part 11.

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.

Lost documents, Cheema says, are no longer a problem, saving the company considerable time and money. *"CoSign's electronically signed documents are stored centrally in specified directories reducing the chance of documents being lost or misfiled."*

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.

About CoSign Digital Signatures

ARX (Algorithmic Research) is a global provider of cost-efficient digital signature solutions for industries such as life sciences, healthcare, government, engineering, and energy. ARX's CoSign digital signature solution automates approvals affordably in a compliant manner, allowing organizations to go paperless, expedite business processes and save costs. CoSign is the only digital signature solution that is seamlessly integrated with Microsoft SharePoint and other popular DM/ECM solutions. CoSign signatures are globally accepted by external partners without the need for proprietary-validation software. CoSign is also centrally managed through the organization's user directory for reliable control of signature privileges, and ease of use and administration. Learn more about the CoSign [digital signature](#) solution.

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