

EVENT FLASH

AstraZeneca Becomes First Pharmaceutical Company to Submit Completely Digital Signature-Based Communications with the FDA

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IN THIS EVENT FLASH

This IDC Flash looks at a recent announcement from Arcot Systems Inc. and the SAFE-BioPharma Association that states that AstraZeneca has become the first international healthcare company to submit completely digital signature-based communications with the FDA. IDC reviewed the announcement and the impact it will have on the use and deployment of digital signatures across industries in the near future.

SITUATION OVERVIEW

In a recent announcement, Arcot Systems and the SAFE-BioPharma Association revealed that AstraZeneca has become the first pharmaceutical company to submit completely digital signature-based communications with the FDA. This method creates a secure, purely digital signature-based, paperless transmission environment. Although there has been acceptance of fully electronic submissions prior to this, the submissions were not considered completely secured, and additional paper backups with ink signatures were required as well. This announcement signifies the first time such a submission has been made without additional paper requirements. The impact of this submission has tremendous potential for the pharmaceutical industries because it could obviate current transmission requirements, protecting years of work and billions of dollars' worth of pharmaceutical research investment.

The SAFE-BioPharma Association is a nonprofit collaborative pharmaceutical industry initiative that has been operational since 2005. It develops and maintains consistent and industrywide methods for managing and utilizing digital certificates. The Signatures and Authentication for Everyone (SAFE) digital signature standard evolved to provide companies with the ability to sign regulatory and commercial transactions in a tamperproof and legally enforceable way. This submission is believed to be the first instance of a global pharmaceutical company doing end-to-end digital workflow.

AstraZeneca has combined the SAFE standard with the Universal Client from Arcot Systems. The Universal Client digital signing system provides a uniform user interface and digital signature technology and ensures SAFE-compliant signatures. Arcot Systems, based in Sunnyvale, California, provides 100% software-based authentication solutions incorporating strong PKI technology while maintaining a simple username/password-like interface. The technology provides access to various digital identity credentials, including smart cards and Arcot's own software smart card.

The SAFE-BioPharma Association believes that the solution gives the legal community confidence in digital signatures by providing "a framework built upon strong PKI-based digital certificates, a state-of-the-art signing solution, unique standards, and a closed-system rule set." Founding members of the association include industry giants AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Procter & Gamble, and Sanofi-Aventis.

FUTURE OUTLOOK

This announcement underscores IDC's belief that digital proof of identity is becoming an increasing reality for organizations. The use of digital IDs and electronic contracts will become more commonplace over the next several years. Standards will play a pivotal role here by enabling federated communications among organizations, entities, and ecosystems with secure digital ID mechanisms in place. Increasing pressure to meet regulatory compliance, together with advances in technology, is pushing commerce and industry to transition from paper to digital evidence as proof of identity for both individuals and corporate entities. IDC believes that this transformation, when complete, will have significant benefits to companies, individuals, and legal systems on a worldwide basis. These benefits will include:

- Companies, not just consumers, will be protected by regulatory legislation.
- Digital evidence will be accepted as proof in courts of law.
- Online contracts will emerge and become legally acceptable.

IDC believes that the emergence of fully authenticated, digitally binding agreements will help ensure that companies are protected from both internal and external fraud, resulting in tremendous cost savings.

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