SAFE-BioPharma Association

Case Study: AstraZeneca Implementation of SAFE-BioPharma™ Digital Signatures

Background

A paper in the New England Journal of Medicine estimated that of the total pharmaceutical R&D expenditure ($42 billion in the US), approximately 40% is linked to paper-based costs. Recognizing this issue and the fact that the industry is transitioning from traditional paper-based processes to electronic processes, several big pharma players collaborated to develop the SAFE-BioPharma digital identity and signature standard as a way to help companies manage risk associated with electronic business-to-business and business-to-regulator transactions.

AstraZeneca's innovative use of the SAFE-BioPharma standard to sign submissions made through the FDA's Electronic Submissions Gateway is a milestone event that demonstrates to other companies one significant way the SAFE-BioPharma standard can accelerate progress toward the shared goal of greater efficiency and less paper. In recognition of this pioneering achievement, AstraZeneca received BIO-IT World Magazine's 2008 Best Practices Grand Prize.

Situation

On September 18, 2006, AstraZeneca U.S. Regulatory Affairs submitted the first electronic original 356h form (cover sheet for IND/NDA filings) to the FDA. In the past, paper originals were the only way to comply with regulations. By using SAFE-BioPharma digital signatures and the FDA Electronic Submissions Gateway, AstraZeneca completed a landmark milestone. No paper original of the 356h exists.

As background, AstraZeneca U.S. Regulatory Affairs was implementing the FDA Electronic Submissions Gateway (ESG). At the same time, AstraZeneca IT colleagues were participating in ongoing development of SAFE-BioPharma digital signatures. The Regulatory Information Strategy Group became aware of the need for digital signatures, and saw the ESG project as an opportunity to implement SAFE-BioPharma signatures.

Combining the two efforts would lead to the business benefit/objective of a completely electronic submission, eliminating the overhead activities to create, sign, store, and maintain paper originals and providing faster availability to clinical data. Another business benefit/objective would be increased flexibility, because AstraZeneca colleagues could apply SAFE-BioPharma digital signatures to documents from anywhere with an Internet connection. When these colleagues travel, this flexibility can lead to increased speed as well, because documents can be digitally signed immediately rather than waiting for colleagues to return to an AstraZeneca site. Other anticipated benefits included improved cost and time efficiencies for both sponsor and agency (e.g. eliminating need to burn CD, DVD, tape); more efficient transfer of electronic submissions; earlier access to the submission by the review division, and eliminating paper (related reduction in processing and archiving paper and efficiencies associated with electronic processing).

Questions? Contact us

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AstraZeneca Implementation, continued.

Solution/Outcome

AstraZeneca formed two teams to implement the ESG and SAFE-BioPharma signatures. The teams faced a tight time schedule, starting in April 2006 with a delivery date in early fall. The teams faced both business and IT challenges. Business challenges included developing operating procedures, managing credential ownership, defining system ownership, ensuring organizational buy-in, and working within budget and time constraints. Technical challenges included enabling an application, selecting a credential issuer, performing internal validation, planning for support, and delivering credentials to users. The details of these challenges and how the teams resolved the issues are explained in the AZ white paper, "AstraZeneca Implementation of SAFE-BioPharma Digital Signatures," which can be accessed on the SAFE-BioPharma website [www.safe-biopharma.org].

As part of lessons learned, the teams identified the key elements of project success as:

- Business leaders as champions for the project.
- Small, focused team.
- Department-level scope for SOPs, training, and support activities.
- Limited number of users (80) to be provided with SAFE-BioPharma credentials and training.
- Delivery focused on SAFE-BioPharma signatures, not on company-wide identity management.
- Leveraging experiences, tools, and templates from SAFE-BioPharma, other members, and consultants.
- Rigorous structured process for application development, testing, and delivery.

All of these elements combined for a successful on-time and on-budget delivery.

Joe Waldron (Executive Director, US Region, Global Drug Development Information Services) describes the vision as "anywhere we do wet ink signatures today is a place where we can be leveraging SAFE-BioPharma digital signatures tomorrow, and begin to reduce the burden associated with managing paper."

SAFE-BioPharma Association

SAFE-BioPharma Association is the non-profit association that created and manages the SAFE-BioPharma™ digital identity and signature standard for the pharmaceutical and healthcare industries. The SAFE-BioPharma industry standard is used to mitigate legal, regulatory and other business risk associated with business-to-business and business-to-regulator electronic transactions. It facilitates interoperability by providing a secure, enforceable, and regulatory-compliant way to verify identities of parties involved in electronic transactions. SAFE-BioPharma's vision is to be a catalyst in transforming the biopharmaceutical and healthcare communities to a fully electronic business environment by 2012. The Association's members include Amgen, AstraZeneca, Bristol-Myers Squibb, Genzyme, GlaxoSmithKline, Johnson & Johnson, Merck, Organon, Pfizer, Procter & Gamble, Roche and Sanofi-Aventis.

Learn about SAFE-BioPharma's growing Vendor Partner Community at **www.safe-biopharma.org**.

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