Pfizer Implementation of SAFE-BioPharma Digital Signatures for Electronic Lab Notebooks*

In the discovery phase for a new drug, chemists perform experiments to identify new compounds. Historically, they recorded their experiments in a paper lab notebook, signed the experiments, and met with another scientist who witnessed the experiment. Eventually, the chemist provided the completed paper notebook to a Records Management organization for archiving. Signing and witnessing is important, since it provides the date-time stamp for when a new compound was discovered. The date-time stamp can be vital many years later when the company defends the patent for the drug.

Converting this series of activities to an electronic lab notebook has been a dream for many years. Each step of the process that involves paper takes the chemist away from the lab and reduces the time actually spent on science. With CeN and SAFESign, Pfizer has achieved this dream.

On October 6, 2006, Associate Research Fellow Michael Tollefson completed an experiment by entering information into CeN (Chemistry electronic Notebook). He then inserted his Pfizer badge into a slot on his laptop, entered his SAFE-BioPharma passphrase, and applied a SAFE-BioPharma digital signature to the experiment. The system automatically sent an email to a witness, who reviewed the experiment online and also applied a SAFE-BioPharma digital signature to the experiment. The system then automatically sent the signed and witnessed experiment to Records Management for archiving.

Since achieving the milestone of the first completely electronic experiment, use of CeN has expanded at Pfizer to the point where hundreds of experiments are signed every day. Pfizer scientists describe the key business benefits as:

- CeN is non-intrusive and fits with how chemists do their daily work
- Less time is spent managing paper, so more time is spent in the lab
- Process of signing and witnessing is speedy and leads to greater compliance with internal policies
- Completed experiments are available and searchable online, providing cross-site efficiencies that were not possible with paper notebooks
- Because experiments are signed the same day they are completed, and because the SAFE-BioPharma digital signature has a clear identity of who signed and when they signed, Pfizer's longterm patent protection is increased.

The team that built the system involved colleagues and contractors from IT, Discovery, Legal, Records Management, and other groups. In summarizing the elements to success, team members focused on the importance of involving business customers from the beginning of the project. Another element was focusing on the corporate culture and ensuring that the IT solution worked within the culture. The team also learned that small pilots were adequate for testing the business and IT concepts. The team built on some existing Pfizer infrastructure and also enhanced the infrastructure.

As a founding member of the SAFE-BioPharma Association, Pfizer had supported the development of the SAFE-BioPharma standard and was well aware of the potential benefits. However, the company was also aware of potential challenges. As Tony Gazikas, (Vice President, Worldwide Technology Engineering) explains, "The challenge of implementing digital signatures in electronic systems is one of belief. As more biopharmaceutical companies adopt and use this standard, the more acceptance digital signatures will have." This paper discusses the activities to implement SAFE-BioPharma signatures for electronic lab notebooks. The last section of the paper describes other current and potential uses for SAFE-BioPharma signatures at Pfizer. Michael Tollefson summarizes the success from a business perspective, describing acceptance as very high and saying, "It's fast, simple, and fits with how we do our work."

***"Pfizer Implementation of SAFE-BioPharma Digital Signatures for Electronic Lab Notebooks" can be downloaded from the SAFE-BioPharma web site at www.SAFE-BioPharma.org.**

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. For more information, visit **www.safe-biopharma.org.**

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