



***Pfizer Implementation
of SAFE™ Digital Signatures
for Electronic Lab Notebooks***



Signatures and Authentication For Everyone

July 23, 2007

Version 1

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Executive Summary

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 passphrase, and applied a SAFE digital signature to the experiment. The system automatically sent an email to a witness, who reviewed the experiment online, and also applied a SAFE digital signature to the experiment. The system then automatically sent the signed and witnessed experiment to Records Management for archiving.

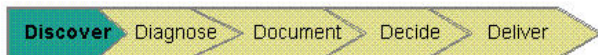
Since achieving the milestone of the first completely electronic experiment, use of CeN has expanded at Pfizer to the point where hundreds of experiments are signed every day. Pfizer scientists describe the key business benefits as:

- 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 digital signature has a clear identity of who signed and when they signed, Pfizer's long-term 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 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 signatures for electronic lab notebooks. The last section of the paper describes other current and potential uses for SAFE 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 “Discovers” SAFE



The first step in any implementation of the SAFE standard is learning about the standard and performing initial research. Today, companies typically learn about the standard by visiting the SAFE web site, attending a conference, or reading white papers like this one.

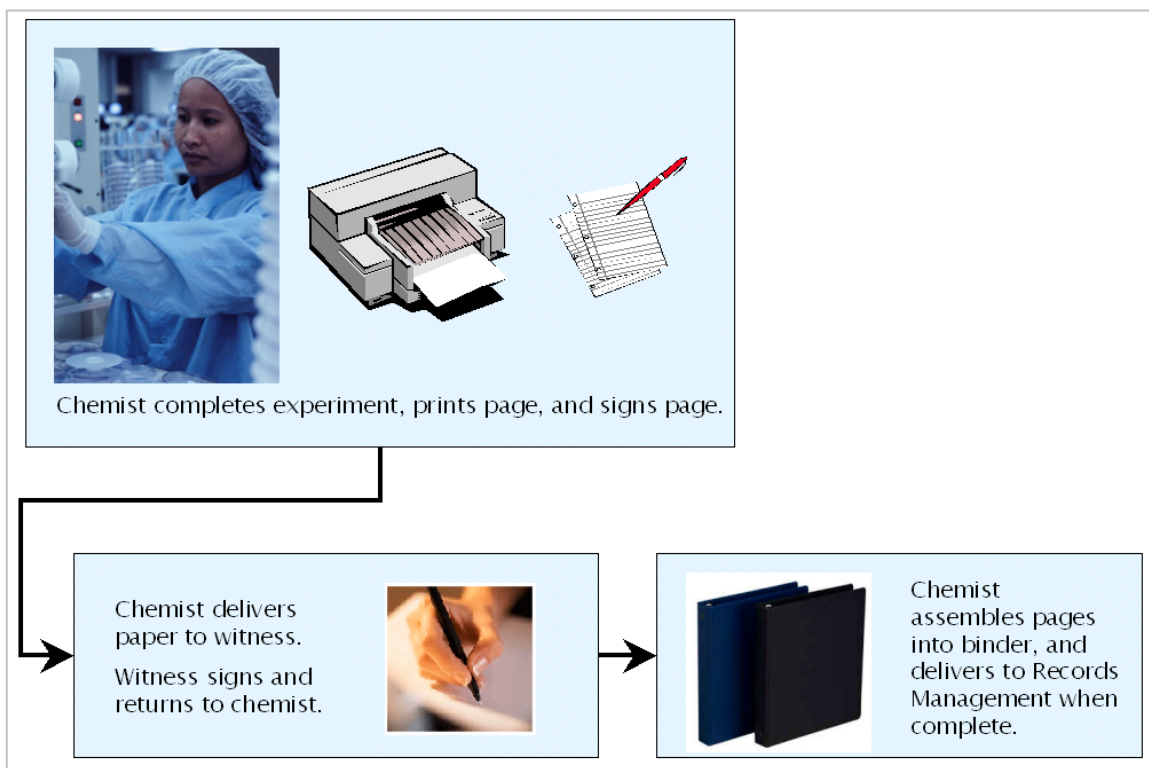
Pfizer is a founding member of the SAFE-BioPharma Association, and is one of the companies who helped develop the SAFE standard. Pfizer participated in early activities through the Pharmaceutical Research and Manufacturers of America (PhRMA). Internally, the company started the IT infrastructure and business processes needed to comply with the SAFE standard. As Tony Gazikas describes, “The electronic form and its digital signature were technically simple to create, but the business implications, policy assessments, and regulatory challenges necessary to make it acceptable were immense.”

Pfizer’s first application of a SAFE digital signature occurred in February 2005, when an investigator applied his SAFE signature to FDA form 1572. The physician applied a digital signature compliant with Version 1.0 of the SAFE standard. Since then, the standard has evolved to Version 2.1. Within Pfizer, use of the SAFE standard has expanded to other areas. This white paper focuses on the team developing electronic lab notebooks, and their experiences in implementing the standard.

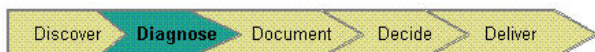
As background for chemistry lab notebooks, scientists perform experiments and document their data and results in a notebook. Historically, all information was on paper. Figure 1 shows the typical paper process for a lab notebook. Pfizer had implemented an early version of an electronic lab notebook, e-chemistry notebook. As its use expanded to over 1200 users, a paradox evolved. With the e-chemistry notebook, scientists might need to print and sign more pages than with the old paper notebooks.

Steve Trudel (Senior Advisor, Scientific Informatics) had been the IT lead on the e-chemistry notebook project. The Chemistry electronic Notebook (CeN) team was responsible for planning and implementing SAFE signatures. However, both teams were aware of the challenges. As Leslie Holbrook (Director, Worldwide Business Technology) explains, “For years, the scientists had wanted to move to electronic lab notebooks and get rid of paper entirely. The sticking point was always the need to sign and witness the experiment, so automation and a true e-lab notebook simply weren’t possible before SAFE signatures.” The IT and business teams began working together to move to the next stage of developing a business case for integrating SAFE signatures into the e-chemistry notebook.

Figure 1 Typical Paper Process for a Lab Notebook



Diagnosing and Learning More



Typically, the second step in implementing the SAFE standard involves diagnosing the situation, developing a business case for using SAFE signatures, and learning more about the potential effort.

For Pfizer as a whole, the business case had been developed much earlier when the company decided to become a founding member of SAFE. The CeN project was able to rely on underlying Pfizer infrastructure, but still needed to decide if SAFE signatures provided enough business benefits to justify implementation.

Developing the ROI for SAFE signatures in CeN was a challenge since these experiments occur so early in the pipeline for a drug. Tam Woodrum (Director, Worldwide Technology Quality & Compliance) noted that one potential business benefit is the increase in screening speed, which could increase the likelihood of finding a viable compound; however, this is extremely difficult to quantify.

Another potential benefit is enabling scientists to spend more time in the lab and less time processing paper. Combining this benefit with the expected reduction in records management activities, the team developed an estimated savings that provided sufficient ROI to proceed.

The intangible benefits were perhaps more important than the financial ROI. Any experiment has the potential to become a vital piece of evidence for defending a Pfizer patent. The ability to provide indisputable proof of when an experiment was signed is key.

With a paper process and “wet signatures” (ink signatures), this ability was easy. Easy, but not without its own challenges. Each experiment must be signed and witnessed, and performing these activities takes scientists away from their work in the lab. As a result, scientists might wait a day or

two before processing experiments. This delay could lead to potential compliance issues with internal policies; or more important, with issues in a patent defense many years in the future.

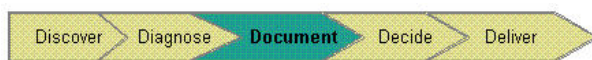
With an electronic process and digital signatures, Pfizer required a legally defensible signature for the lab notebooks. SAFE signatures met this need, and the automatic date-time stamp also provided an indisputable time when the experiment was signed. (See “Key Benefits of SAFE Signatures” for a brief overview.)

Key Benefits of SAFE Signatures

- ✓ **Legal enforceability.** SAFE digital signatures are the legal equivalent of an ink-based signature. SAFE signatures meet three key legal criteria. With authentication, you are sure of the identity of the person who provided the signature. With integrity, you are sure the document has not been altered since it was signed. With non-repudiation, you are sure that the sender cannot deny signing the document.
- ✓ **Regulatory compliance.** The SAFE standard meets or exceeds regulatory guidelines for 21 CFR Part 11 and HIPAA. SAFE designed the standard to meet similar international guidelines, and ensures that new versions comply with emerging regulations.
- ✓ **Strong Security.** The SAFE standard ensures security and data integrity. With two-factor authentication, users need both their SAFE credential and their passphrase to digitally sign a document. This is similar to automatic teller machines, which require people to provide both their ATM card and their PIN. The standard uses public key infrastructure (PKI) to apply digital signatures to documents and to assure the integrity of their content.
- ✓ **Global.** SAFE members are global companies and require a global standard, both for internal and external use.

Michael Tollefson summarizes this phase by saying, “When Steve Trudel introduced us to the concept of SAFESign, it seemed like a viable solution. He described the benefits of using SAFESign to legally sign experiments, and sign in a way that would hold up in court. We decided to work together so that CeN could take advantage of SAFESign as it became available.”

Assessing and Documenting Readiness



Typically, the third step in implementing the SAFE standard involves assessing corporate readiness and creating documentation required for the SAFE standard. This phase involves developing a detailed understanding of the standard, and the business and technical aspects of implementation. Because this phase involves business processes, aligning multiple business groups, and technical tasks, it is composed of two overlapping sets of business and IT activities.

Business Aspects

At Pfizer, the initial team involved IT and business colleagues. Steve Trudel describes how this team developed a draft workflow. They then presented the workflow to business customers, IT, and IT management at multiple Pfizer sites. Steve Trudel explains that the goal of these presentations was to educate a broad group of people, “to get everyone on the same page about what to expect with a completely electronic lab notebook.” From the business perspective, Michael Tollefson comments, “Steve Trudel’s team came up with a workflow that made sense, and made the link between CeN and SAFESign very slick.”

Leslie Holbrook recommends, “Use internal experts and a high-touch approach. This involves meeting face-to-face with people to discuss the ideas.” She recommends in-person sessions over videoconferences, teleconferences, and emails because the face-to-face meetings offer more opportunities to ensure clarity and discuss potential concerns. She also recommends against emphasizing the concepts of non-repudiation and the technical details; pointing out that the attorneys will understand the importance of non-repudiation and the IT staff will understand PKI, but the business audience wants to understand how using SAFE signatures makes their job better.

Alice McNeil (Associate Director, Regulatory Compliance) described using toasters as an analogy, “Bread goes into a toaster, and bread comes out of a toaster. It’s visibly changed, but it’s still bread. This is similar to what happens to a file before and after applying a SAFE signature.”

Steve Trudel understood the potential that colleagues would hesitate to use SAFE signatures, saying, “We all have enormous experience with wet signatures, and have a ‘warm fuzzy’ that our signature is legal. It’s a leap for users to move to digital signatures and we worked to help them make the leap.” The team took the approach of showing users the process and how fast and easy it was to apply a SAFE digital signature. They minimized technical explanations.

Pfizer was able to leverage some existing business aspects of implementing the SAFE standard. However, to use SAFE certificates, the team needed to develop a SOP. Pfizer adopted the strategy of developing a pan-Pfizer SOP. This required multiple review cycles to ensure alignment across Pfizer divisions for Human Health, Animal Health, Manufacturing and so on. However, the payoff is that this SOP applies to all future activities involving SAFE certificates. New teams will be able to rely on the existing SOP. (The SAFE web site describes the required SOPs and policy framework in detail; see www.safe-biopharma.org.)

As the technical activities progressed, the team recognized the need to involve additional groups at Pfizer. Michael Tollefson describes how the team involved Patent and Legal in the middle of 2006. They shared the updated draft workflow that involved CeN, SAFESign, and digital signatures. The team explained the workflow to the attorneys, who requested wording changes in various steps, but were enthusiastic about the overall process. As Leslie Holbrook advises, “have a strong partner in your internal legal organization, and integrate the attorneys as part of the team from the beginning. Allow enough time for the learning curve and recognize that the underlying concepts are not straightforward.” As the Pfizer team learned, attorneys can help with developing the internal policy, records management, risk management, and more. In presentations, the team first ensured their legal partner understood the issues, and then let the attorneys answer the business questions on non-repudiation and other legal issues. Leslie Holbrook recommends, “Avoid having IT staff answer these questions as they tend to delve into too much technical detail.” (For more advice on business aspects, see “Advice from the Pfizer Team” later in the paper.)

As the technical activities progressed, the team also involved Records Management. In working with the draft workflow, the team needed to resolve the issue of where to store digital signatures. Resolving this issue involved breaking new ground for Records Management.

New Ground for Records Management

After the activities in CeN are complete, Records Management activities become important. In the paper world, records management and archiving occurred on a daily and weekly basis. In the electronic environment, after the scientists and witnesses have completed their activities, the Records Management role becomes one of archiving.

The PDF generated in CeN and electronically signed in SAFESign is automatically archived in Pfizer's document management system. The Records Management organization has access to the archived original. Additionally, CeN keeps a copy of the SAFESign flattened version of the PDF within CeN. By keeping both the digitally signed original and the flattened version of the signatures, any CeN user can easily view the flattened version. As Tam Woodrum explains, "the concept of an 'ephocopy' or 'flattened file' is key to the success for long-term archiving. The flattened file contains the document, an image of the SAFE digital signature, and the metadata associated with executing that signature. Combined, the elements of the ephocopy give the reader assurance that the SAFE signature was valid at the time it was executed." Figure 2 shows examples of original and flattened SAFE signatures.

Figure 2 Examples of SAFE Signatures

Archived version with original SAFE digital signatures:

Steven.C.Trudel Steven.C.Trudel
Reason: I am the author of this document.
Date: 2007-05-15 17:11:32 -0400

Michael.B.Tollefson Michael.B.Tollefson
Reason: I have read and understood the contents of this document.
Date: 2007-05-16 08:23:51 -0400

Flattened

Steven.C.Trudel Steven.C.Trudel
Reason: I am the author of this document.
Date: 2007-05-15 17:11:32 -0400
1 Facsimile of Original Digital Signature

Michael.B.Tollefson Michael.B.Tollefson
Reason: I have read and understood the contents of this document.
Date: 2007-05-16 08:23:51 -0400
2 Facsimile of Original Digital Signature

Records Management colleagues are viewed as “the custodians but not the owners of this information.” Since the information must be kept for decades, Records Management is responsible for ensuring that the correct format is maintained through the life of the document. Initially, Records Management confirms that the PDF format is correct. On a long-term basis, the team will assess the ongoing viability of the format, whether it can be read by new technology, and the ongoing viability of the SAFE signature as part of an overall eRecords strategy. As one example, if Records Management decides to update the format in the future, they must still be able to show that the date-time stamp of the SAFE signature is unchanged.

In thinking about managing electronic formats for decades, the media becomes an issue. Remember JAZ or ZIP disks? Floppies? Clinical teams rely on a team with both Records Management and IT colleagues to address this issue, and to revisit it regularly. New forms of storage media emerge, and the team evaluates the ROI and business need for retiring old forms of media or transferring to a new form.

From a Records Management perspective one school of thought is to hold the original electronic file and maintain additional new versions in up-to-date readable formats. Then, the date-time stamp on the SAFE signature in the original file becomes the reference file. Records Management maintains the provenance of the versions of files throughout the lifetime of the original document. As one colleague explained, “this is new ground for Records Management, to think of maintaining an electronic file with an original digital signature for decades. We are moving from managing boxes of paper to managing searchable electronic records.”

Technical Issues

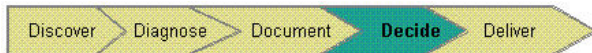
Pfizer was able to leverage existing IT infrastructure for some aspects of their implementation by choosing to incorporate the SAFE certificate on the Pfizer badge (see “Selecting a Credential Issuer” for more detail). As described later in “Enabling the CeN Application,” the team used a series of prototypes and two very small pilots to test the technology. The CeN programming team worked with an internal team (Development Informatics, or DEVi) to resolve issues with the SAFE infrastructure. Where issues could not be resolved internally, the DEVi team worked with SAFE-BioPharma as needed. Enabling the application was ultimately very successful. However, the team experienced some technical challenges in the process.

One challenge was providing a seamless user interface. As Rupen Mehta (Project Manager, SAFESign) explained, “the basic SAFESign approach didn’t provide all the automation that the CeN application required to enable a seamless end-to-end electronic signing process. We needed to enhance the functionality of SAFESign to enable the necessary automation, without customizing it too significantly.” Since Pfizer provided a component of the SAFESign code (USSI) as open source, Rupen Mehta’s team faced the challenge of delivering code that met both the internal Pfizer needs and the needs in the open source environment. Rupen Mehta summarizes, “Before any enhancements were made to SAFESign, we needed to ensure it didn’t conflict with the overall industry need.”

Synchronizing activities was the biggest challenge faced by the technical team. Aspects of the Pfizer infrastructure were being developed at the same time as the CeN code. As one example, applying SAFE signatures in CeN depended on the availability of SAFE certificates. And, the Pfizer infrastructure for SAFE certificates depended on the credential issuer providing those certificates. And, the credential issuer’s ability to provide the certificates depended on receiving certification from SAFE-BioPharma Association. Rupen Mehta describes how a delay in any aspect of these interlinked activities led to delays for CeN; saying, “The coding issues were not as big of a challenge as the synchronization issues.”

See “Selecting the Credential Issuer” and “Enabling the CeN Application” for more detail.

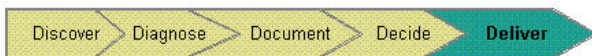
Deciding to Implement the SAFE Standard



Typically, the fourth step in implementing the SAFE standard involves multiple decisions. The team decides on the first application to use the standard, and decides whether the implementation will be Proof-of-Concept (POC), Pilot, or Production. In the third step, the team has typically identified gaps in the corporate business process and IT infrastructure. In the fourth step, the team decides to implement a SAFE solution, revises SOPs, creates new documents for the standard, and aligns business processes.

At Pfizer, the third and fourth steps morphed together. After the team built the business case, the decision to implement the SAFE standard for electronic lab notebooks had been made. Then, as the team identified gaps in business processes, they began the steps to revise or create necessary documents, and to update business processes. As the team presented the draft workflow to a variety of audiences, they revised the workflow on an ongoing basis. As Michael Tollefson explains, “Senior leaders were on board with the SAFE concept from the beginning. They had been enthusiastic supporters of an e-signature world.” Knowing that the senior business leaders endorsed the SAFE solution helped the team move forward with delivery.

Delivering the SAFE Solution



Typically, the final step in delivering the SAFE solution involves four key activities: selecting a credential issuer, enabling an application, developing training materials, and delivering SAFE credentials to users. The next four topics discuss these key activities at Pfizer.

Selecting the Credential Issuer

As background, Pfizer has a single integrated Identity and Access Management (I&AM) system, which is consistent across all Pfizer sites. Colleagues and contractors use their badges for identification, access to buildings, signing on to the Pfizer system from an external location (such as a hotel), signing internal documents with a “basic certificate,” and as a debit card for purchases at the cafeteria (at some sites).

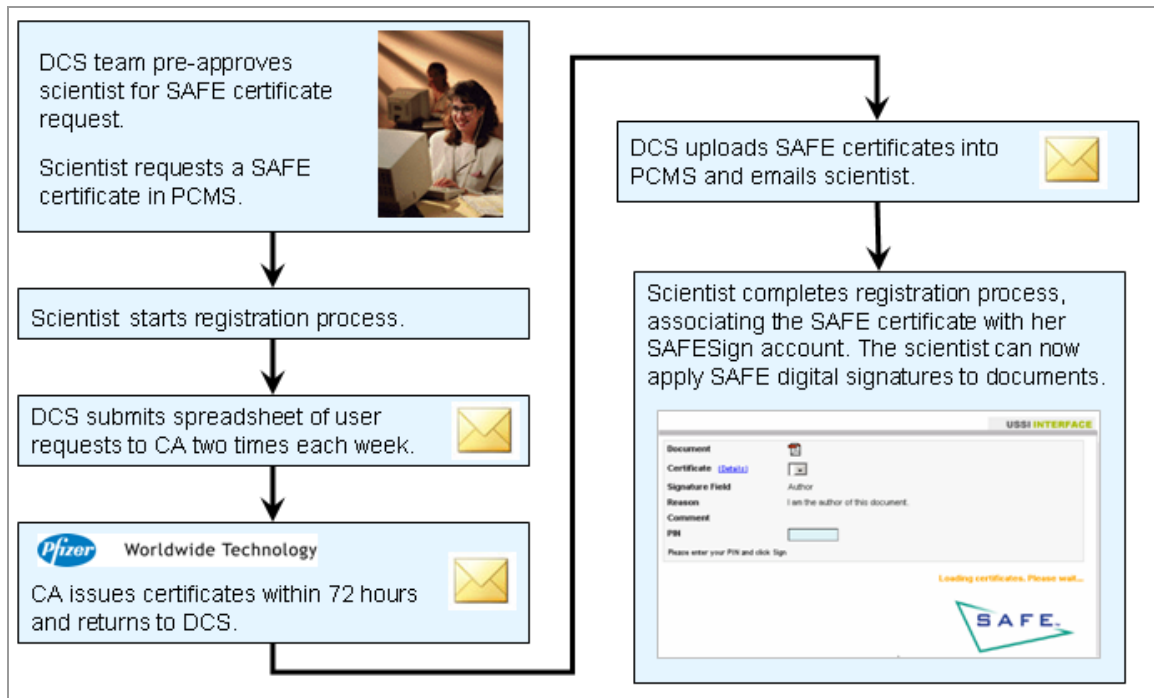
Pfizer chose to integrate the SAFE certificate on each colleague’s badge. The badging approach was also consistent with the Pfizer culture, because employees were comfortable with using their basic certificate to sign internal documents. Adding the SAFE high assurance certificate for signing external documents was a natural progression. Employees cannot use their basic certificate to sign any document that has the potential as an external document—such as a FDA submission or a lab notebook that might be used in patent defense.

In selecting the credentialing authority, Pfizer chose to use an impartial third party Certificate Authority (CA). In part, this was to provide non-repudiation from an uninvolved party. The CA needed to certify its CA infrastructure against the SAFE 2.1 standard, which impacted the timeline for CeN. Until the CA was certified, CeN with an electronic signature workflow could not move to Production.

Credentialing and registration are two aspects of enabling the SAFE standard. The CA provides the SAFE certificate for each user. The Registration Authority (RA) provides a process for ensuring the identity of the user. Pfizer uses an RA application that enables multiple certificates on a single badge, enabling both the basic and SAFE certificates.

Figure 3 shows the interaction between various systems involved in integrating the SAFE certificate on a Pfizer badge.

Figure 3 Providing SAFE Credentials to a User



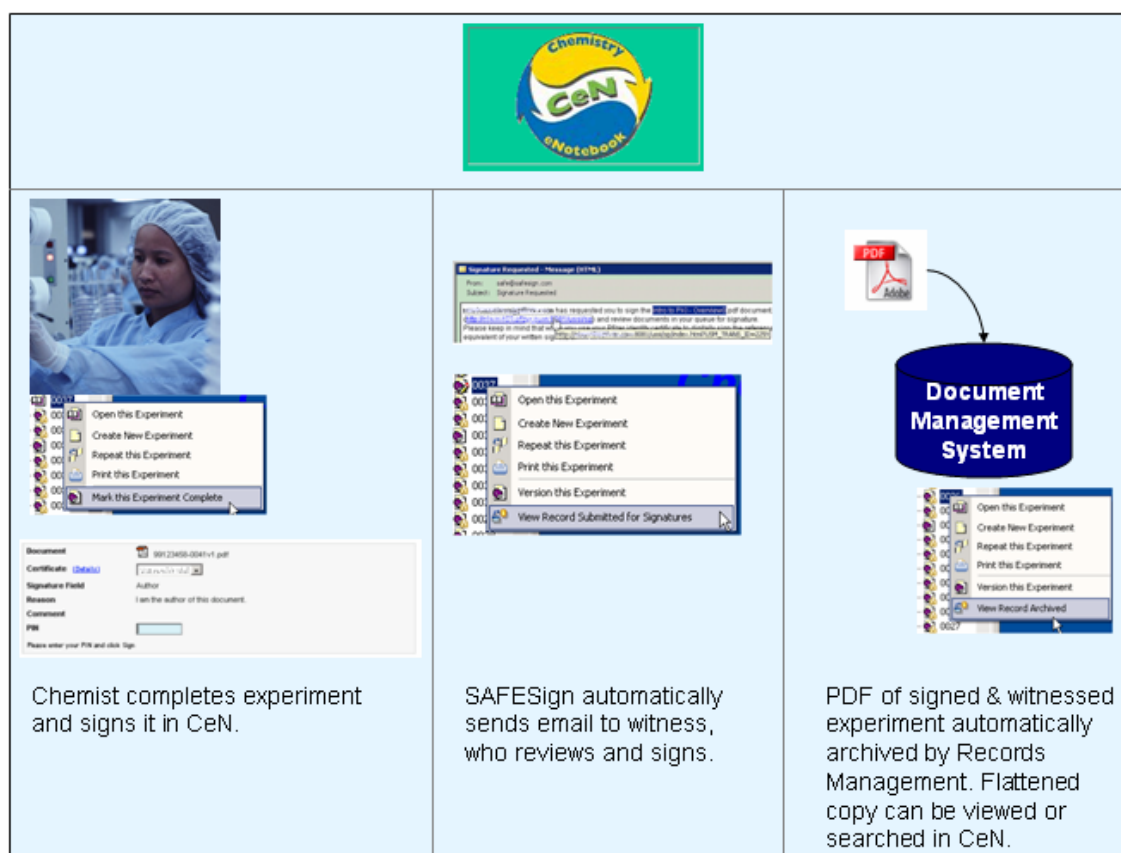
As Figure 3 shows, the Digital Certificate Services (DCS) team pre-approves the scientist for a SAFE certificate. The scientist enters the online Pfizer Certificate Management System (PCMS) and requests a SAFE certificate. She follows the process online. (In very few cases, the scientist will need to first obtain a basic certificate. As colleagues and contractors are on-boarded, and as badges are renewed, basic certificates are added to the badge.) When the scientist reaches a certain step in the registration process, she will need to wait for the certificate to be issued by the CA. DCS submits a spreadsheet of certificate requests for users to the CA twice each week. The CA issues SAFE certificates within 72 hours and returns the certificate information to DCS. DCS then uploads the SAFE certificates into PCMS and emails the scientist that she can complete registration. The scientist then completes the registration process, associating the SAFE certificate with her SAFESign account. She can now apply SAFE digital signatures to documents.

Enabling the CeN Application

As described earlier, Pfizer had implemented a SAFE compliant signature with an early version of the SAFE standard in 2005. Alice McNeil explained that this initial implementation used for the 1572 in 2005 was not scalable to a large group of users. In that early implementation, the team also learned the importance of simplicity and ease of use. The setup for the early implementation was manual and difficult, and training a large number of users with the first approach would not have been cost-effective. As a result, the CeN team was not able to leverage the early work from 2005.

Figure 4 shows the workflow for applying SAFE digital signatures to electronic lab notebooks in CeN from the scientist's perspective. (This workflow omits detailed activities for obtaining a SAFE credential; see Figure 3.) From a technical perspective, CeN and SAFESign interact, but this interaction is seamless to the scientist. Technically, the chemist completes the experiment in CeN and SAFESign provides the mechanism to electronically sign the experiment. For the witness, technically SAFESign automatically sends the email to the witness, requesting that the experiment be reviewed and signed.

Figure 4 CeN and SAFE Signatures



Pfizer developed the code for SAFESign and for USSI (Universal SAFE Signing Interface). The CeN development activity occurred in parallel with the USSI and SAFESign project. As a result, the CeN programmers leveraged the underlying USSI API. However, integrating SAFE signatures into CeN required revisions and enhancements to the original USSI API. Synchronizing the activities led to challenges, as discussed earlier in “Technical Issues.”

In 2006, Pfizer released the USSI components of the digital signature services technology into the Open Source public domain. George Rathbun (Director, Regulatory Compliance) comments, “The development and open-sourcing of the USSI technology, a key component of SAFESign, demonstrates real leadership on the part of Pfizer. Pfizer seeded the environment to foster the use of digital signatures across the industry. Additionally, Pfizer has chosen to divest the SAFESign technology to a commercial vendor, who will bring SAFESign to our industry as a commercial product offering called MySignatureBook. This will afford industries economies of scale as more and more applications leverage digital signatures using this approach. ”

In developing the code to integrate SAFE signatures into CeN, the IT team was able to use the standard SDLC (Software Development Life Cycle) process for the organization. They relied on other

development activities as well. For example, the SDLC documents for SAFESign were required to be in place before CeN could be released.

The CeN programmers built web services around the electronic notebook and integrated SAFESign into CeN. Steve Trudel explained that it was important to eliminate the need for users to learn two systems. One of the key technical goals was to build a seamless link between the two. Michael Tollefson describes the results: “Steve Trudel did a spectacular job of integrating how CeN works with the SAFESign site. It’s seamlessly integrated, and we don’t need to launch a second web site—this is a key feature for the scientists.”

As the IT team developed the code, the team ran a very small pilot with USB tokens for five users. Given the Pfizer culture, it wasn’t a surprise that users found these to be less desirable than the badge solution. As Steve Trudel comments, “Everyone on site already must have their Pfizer badge with them at all times, and providing the USB tokens for the SAFE certificate just gave people one more thing they needed to carry around and keep track of.”

A second pilot, conducted partially in Nagoya, was called the “white badge” pilot because at that time, the badges onsite did not have the ability to store digital certificates. The white badges were used both at Nagoya and at other sites in this second pilot. This approach helped the programming team resolve any issues with integrating SAFE certificates onto a Pfizer badge. By starting on a small scale (about 25 users), and with a separate badge, they ensured no impact to the Pfizer badge in the eventual Production delivery.

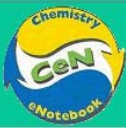
Developing Training Materials

In developing the training, the IT team participated in monthly business meetings and presented the workflow to users. The IT team thought of this as a train-the-trainer approach, and considered the initial group to be “power users.” The team developed multiple slide decks to explain the steps in the process, and adopted an approach of self-directed training. Michael Tollefson attended business line meetings to provide how-to presentations to scientists in St. Louis. He comments, “People were generally receptive to the slide decks, which gave excellent step-by-step instructions. This was especially valuable for the one-time setup activities.”

Figure 5 displays a portion of the first screen in training. Figure 6 displays an example of a training slide that shows selected steps in signing and witnessing an experiment. Figure 7 shows the last screen in training, after someone has completed all four PowerPoint presentations. The page gives a few quick reminders of the process.

In discussing training, Leslie Holbrook recommends against training on the general capability of SAFE signatures. Instead, she advises that signing should be a ‘non-event’ and incorporated into training on the application itself. “If IT understands the business need, and the application handles the details of SAFE signatures, then there’s no need to burden the scientists with understanding the technical differences between using their basic and SAFE credentials.” Leslie calls this “right-sizing the information,” and uses an analogy of explaining the network to business users, where IT staff don’t try to explain network topology to people who don’t need the detail to do their work.

Figure 5 Initial Training Screen



Chemistry eNotebook

electronic Signatures

****** Basic Assurance Certificate ******

Your badge can be used to log into your computer, connect into Pfizer from home, or sign internal documents via USSI (Universal Safe Sign Interface). This is made possible by the Basic Assurance Certificate (Basic Cert), which is assigned internally by Pfizer. A Basic Cert is also a prerequisite for getting a SAFE Certificate (Secure Access for Everyone), which will allow you to sign CeN experiments electronically.

Typically most colleagues at Pfizer will already have a Basic Cert on their Pfizer Badge, however, this capability has only been available for about a year. Therefore, it is possible that some folks may not have Basic Certs. or even the hardware on their desktop or laptop to use it.

The following steps are necessary to get a Basic Assurance Certificate and Pfizer Badge card reader:

* Prerequisite *
Basic Assurance Certificate

* Step 1 & 2 *
SAFE Certificate

* Step 3 & Reference *
SAFESign


eSig Usage
in CeN


Figure 6 Sample Training Screen

5) Author enters PIN for certificate and signs document using his/her personal certificate.

6) SAFESign system sends automatic email to witness designated in Signature Template indicating there are documents to be signed.

7) Witness can click on link in email or use eSig queue via CeN.





SAFESign plug-in is automatically launched just as it was for the Author.

Witness reviews document and signs using his/her personal certificate and PIN.

Note: Current RM rules indicate you must sign on completion and witness must sign within 3 days.

Figure 7 Final Training Screen

Chemistry eNotebook
electronic Signatures

*** Prerequisite *
Basic Assurance
Certificate**

*** Step 1 & 2 *
SAFE Certificate**

*** Step 3 & Reference *
SAFESign**

**eSig Usage
in CeN**

****** eSignature Usage in CeN ******

Welcome to the new age of Electronic Signatures! Now that you have completed all these steps you are now ready to use eSigs in CeN.

Some things to keep in mind while using eSigs:

- Once you enable eSigs via the **Tools | Options** menu you should continue to use eSigs and should not flip/flop back and forth between a wet signature and an electronic signature.
- An IP document is automatically generated when an experiment is marked complete using all data captured in CeN.
- The author will be prompted to sign the IP document after it is created and submitted to SAFESign.
- The witness is notified via email and within CeN when there is a document for him/her to sign.
- The witness **MUST** review the document prior to signing and **MUST** review/sign within 3 days of being notified.
 - When the witness reviews a document and cannot attest to the accuracy and reasonableness of the experiment, the witness should reject the document in SAFESign and notify the author of the reasons.
 - If a document is rejected the author/chemist can request a curation event for the experiment to re-open the experiment, make any necessary edits and then res-submit the experiment for signatures.
- After all signatures the document is automatically submitted to Records Management and, assuming no errors, you will not need to do anything further.

Click on the following slide deck for instructions on how to use eSigs in CeN:

Delivering SAFE Credential and Training Users

At Pfizer, “delivering the SAFE credential” involves adding the SAFE certificate to the Pfizer badge. See Figure 3 and the text following the figure in “Selecting a Credential Issuer.” Since obtaining the credential is a one-time activity, providing training on this one-time activity is important but not sufficient. Users must know how to *use* the credential to apply SAFE signatures. As discussed earlier in “Developing Training Materials,” Pfizer adopted the approach of integrating training on SAFE signatures into training on CeN.

As Michael Tollefson describes the training, “We don’t go into detail about the distinction between SAFE certificates and the basic certificate on the Pfizer badge.” In fact, SAFESign selects the appropriate credential based on the type of document being signed. The end user doesn’t need to worry about choosing which credential to use. He describes the SAFE certificates to others simply as a “special certificate” that requires a PIN like an ATM card, and explains to other scientists how the certificate generates their name at the end of the signed PDF. For others thinking about implementing SAFE signatures, he recommends, “keep it simple, and avoid technical discussions because most scientists don’t really want to know the IT details. Focus on the business benefits of e-signatures versus paper signatures.”

Michael continues, “I point out that the SAFE signature is actually easier than the old way. With paper, you need to print the page, sign the notebook, take it to someone else to get witnessed, put the signed and witnessed page into a binder, and eventually deliver the completed binder to Records Management. Instead of running to sign and witness after every page, it was typical to wait until you had several pages, so days could elapse after an experiment before it was signed and witnessed. Now, we have e-sign-as-you-go. At the end of an experiment, a scientist simply signs the document, and an email notice is automatically sent to the witness. Typically, all activities are complete in less than a day. And, after a scientist signs, their activities are complete. CeN automatically archives the finished document, eliminating several activities. Life is better because scientists like myself can spend more

of our day actually doing science. This gives much better compliance with our internal policy, and more importantly, much better patent protection.”

As scientists transition to electronic lab notebooks, it’s possible to have one hybrid notebook per scientist. Suppose a scientist switches to using SAFE signatures in the middle of a paper lab notebook. The early, paper part of the notebook is handled according to existing policies for paper. Then, the later part of the notebook is electronic and follows the new process. Michael Tollefson notes, “CeN allows for 9999 experiments per scientist, so I think it will be a long time before any scientist needs a new e-notebook in CeN.”

The Pfizer approach and implementation are proving to be successful. As Leslie Holbrook summarizes, “Users are finding SAFE signatures to be fun. Before starting, people expect digital signatures to be a major activity. Instead, they find the tools are so easy and signing is so quick that it’s like a dial tone for a phone. Digital signatures should be non-intrusive; they should just happen.”

Enhancements after Initial Delivery

In the initial release, scalability and speed were challenges. The speed of certificate loading was initially 15 seconds. While this might be a short wait in line for a cup of coffee, it seemed like a very long wait for users staring at a computer screen. In spring of 2007, the team enhanced the code and certificates now load in 1 second. This has won some resisters over—people who were excited about the idea and the process, but frustrated with the timing. Michael Tollefson describes the enhancements, “Now that IT has solved the speed issues, acceptance is very high. It’s fast, simple, and fits with how we do our work.”

The IT team monitors the interaction between the Registration Authority and Certificate Authority now, and plans to increase automation of this process in the future. The credentialing process can be frustrating to some, as it requires a number of steps and wait time while the external Certificate Authority processes the application. By increasing automation, the team hopes to reduce the wait time.

Business Benefits

Michael Tollefson describes some key business benefits by saying, “We always had faith that the paper records would be there on a shelf, but recognize the higher potential benefits with an electronic format. An added bonus is that we can now do electronic searches to facilitate cross-site information sharing among scientists. This is very powerful because we can search and capture information about reactions that have been investigated internally. It’s much more powerful and efficient than external searches. With paper, scientists didn’t have an effective way to do this type of searching—it would have required reading through many notebooks at many Pfizer sites.”

He goes on to explain that a dependable archiving process was key to scientists’ acceptance of the new technology. To help increase confidence in the new approach, he describes how Steve Trudel has cross-checked the archiving in the initial few months. “Steve took this task on not to reassure himself, but to increase our comfort level with the new methods.”

From a Records Management viewpoint, the key business benefit is the ability to produce records without needing to produce all the paper. With the correct metadata, Records Management can move toward systems that make it much easier to search and find specific records. Another key benefit is the legibility of the signature and the ability to associate the signature with a person. As one colleague explains, “with wet signatures, go back a few years and it can be a challenge to identify from a signature who actually performed the experiment and who witnessed it.” With a SAFE signature, this identification will be straightforward now and into the future. See Figure 2, which shows a sample archived version of SAFE signatures by a chemist and witness, illustrating the ease of identifying both the individuals and the date-time stamps.

Some of the benefits are intangible. As Leslie Holbrook comments, “No one wants to be first with new technology because of the potential risk. Using SAFE signatures on something as significant as an e-lab notebook truly adds to the credibility of the idea.”

Advice from the Pfizer Team

Part of the success of SAFE as an organization comes from the willingness of members to share their experiences with others. The Pfizer team provided a few suggestions for implementing SAFE signatures.

Several team members recommended including all potential business organizations on the SAFE team from the beginning. At Pfizer, both the Legal and Records Management groups became involved near the middle of the project. Team members explained that if all organizations are involved from the start, then each area experiences the learning curve for SAFE concepts at the same time. Other team members commented that when multiple IT organizations are involved, it’s helpful to have a single IT sponsor to resolve priorities and resourcing issues.

All team members stressed the importance of involving business colleagues from the beginning, as the CeN team did. They recommended involving the entire team of business users in developing the flow diagram on how SAFE signatures will work in an application. Tam Woodrum explains the underlying reason, saying “the business process change from wet signatures to SAFE signatures has more impact on success than the actual technology nuts and bolts of SAFE.”

Another reason for success was meshing the delivery approach with the corporate culture. At Pfizer, colleagues need their badge for virtually every aspect of their work, and integrating the SAFE certificate onto the badge increased user acceptance. In giving advice about using SAFE signatures, Leslie Holbrook recommends, “Keep SAFE signatures for high value events. In thinking about where to use them, focus on the root cause of why people need to sign the document. Then, apply SAFE signatures in situations that require non-repudiation and legal enforceability especially outside of your own organization such as in a court of law or when sharing with your regulators. Think about a blended enablement of SAFE signatures and electronic signatures based on the business need.” This approach worked well with Pfizer’s decision to provide both basic and SAFE certificates on badges.

In advice on timing, several team members noted the importance of an underlying infrastructure, or the ability to leverage other IT and business activities. As one team member commented, “For Pfizer Global Research and Development, it was useful that the infrastructure for a SAFE credential was already integrated onto the Pfizer badge. Another timesaver was that the infrastructure for SAFE signatures was already in place at Pfizer.” Without both these features, he estimates that the implementation would have required more time.

In advice on selecting the first large-scale SAFE implementation, Tam Woodrum says, “Select the right project with the right scope, where ‘right’ means not too big, and not so small that there is limited ROI.” For a project like e-lab notebooks, she thinks a 6-9 month timeframe is reasonable. While CeN might have seemed like a counterintuitive project because of the importance of patent protection, Tam explained that the scientists are very comfortable with purely electronic approaches and are highly motivated to use SAFE signatures because it makes their jobs easier and gives them more time to focus on science. Leslie Holbrook also noticed the good fit between technology and the user base, saying, “When deploying new technology, be opportunistic instead of over-planning the deployment.”

SAFE Today and into the Future

As of May 2007, Pfizer has about 1100 users in CeN with 405 users actively using SAFE digital signatures, and 700 employees with SAFE certificates on their badges. Since Michael Tollefson’s first signature in early October 2006, over 36,000 experiments have been signed electronically using SAFE digital signatures. The average is over 300 signatures per day, with a few days of over 600 signatures,

and one day with over 1200 signatures. The volume is impressive. As Leslie Holbrook says, “When we first learned about SAFE signatures, most colleagues thought the highest-volume use would be in a clinical application...but it’s in Discovery.” As you might expect, the primary users for CeN are bench chemists.

The chemists are enthusiastic about their experience, and have shared their views with other colleagues. According to Michael Tollefson, “The success of CeN is selling the concept to other areas. There’s at least one initiative for a ‘BioBook’ in the biopharmaceutical area, which will also use SAFE signatures.”

CeN itself has three areas where the team expects changes. Records Management is developing new processes and working with other technology as they begin to implement a new storage solution for digital signatures. This team sees the potential to change from the current document management platform to another technology. If that occurs, the CeN workflow will require updates. As a second area, Pfizer is developing a Corporate Records Management Policy that considers e-records. Depending on the final Policy, CeN may require updates. Third, Pfizer has an ongoing effort to consolidate the electronic Records Management archive to a single system. This effort will ensure consistency in handling electronic archives pan-Pfizer, and will ensure that decisions to upgrade media for storage are consistently applied across Pfizer. For all of these potential areas, Steve Trudel and the business team will continue to work together to minimize any impact on CeN users.

Although CeN has the highest-volume activity for SAFE signatures, Pfizer continues to expand into other areas. Pfizer colleagues believe that more applications will become SAFE-enabled in the future. Tam Woodrum advises, “Expect to see pockets of use for new technology like SAFE signatures. Eventually, you reach a tipping point where the technology simply becomes part of how everyone works.” Leslie Holbrook reminds us all, “No one envisioned how the Internet would be used—not even the builders. I expect we will use SAFE signatures in the future in ways that we cannot even envision now.”

More on Pfizer

Pfizer Inc, founded in 1849, is dedicated to better health and greater access to healthcare for people and their valued animals. Our purpose is helping people live longer, healthier, happier lives. Our route to that purpose is through discovering and developing breakthrough medicines; providing information on prevention, wellness, and treatment; consistent high-quality manufacturing of medicines, consumer products; and global leadership in corporate responsibility. Every day we help 38 million patients, employ more than 100,000 colleagues, utilize the skills of more than 12,000 medical researchers, and work in partnership with governments, individuals, and other payers for healthcare to treat and prevent illnesses—adding both years to life, and life to years.

To learn more about Pfizer please www.Pfizer.com.

More on SAFE-BioPharma Association

The table below briefly summarizes aspects of SAFE Bio-Pharma Association. For more detail, visit the web site at www.safe-biopharma.org.

SAFE-BioPharma Association Overview	
✓	Member-governed non-profit association
✓	Manages and promotes the SAFE standard
✓	Provides a legal and contractual framework
✓	Provides technical infrastructure to bridge different credentialing systems
✓	Provides SAFE identity credentials, both directly and through vendors
✓	Supports Vendors who supply SAFE-enabled products

The figure below shows the typical phases in implementing the SAFE standard, and identifies the goals and selected key actions for each phase.

