

Adobe solutions for the SAFE-BioPharma Association

Supporting industry standards for electronic identity and digital signatures



Adobe solutions for SAFE address electronic authentication challenges in life sciences, including:

- Geographically distributed users
- Different credentials for every company
- Nontechnical end users
- Legal ambiguity of digital signatures
- Diverse preexisting PKIs that lack interoperability
- Strict regulations that vary worldwide
- Requirements to protect privacy and authenticity of information
- Everyday processes that require collaboration with investigators, subjects, regulatory authorities, and partners/joint ventures

The SAFE-BioPharma Association is revolutionizing the information lifecycle in the pharmaceutical industry. Supported by the Pharmaceutical Research and Manufacturers of America (PhRMA) and major pharmaceutical companies, SAFE is transforming electronic document processing by establishing the standards, legal policies, and technologies necessary to ensure document authenticity. SAFE's goal is to reduce the time to market and cost of clinical trials by standardizing and streamlining the way regulatory agencies, pharmaceutical companies, clinical research organizations (CROs), and their investigators manage documents and verify digital signatures.

A new drug may take 10 to 20 years to bring to market and typically accumulates literally tons of paperwork that documents how it meets efficacy, patient safety, and regulatory requirements. Requirements vary by country and govern a wide variety of activities, from how clinical trials are conducted to how products are packaged and labeled. By joining the SAFE-BioPharma Association and adopting the SAFE standard for digital signatures, members can streamline the costly paper-based business processes involved in developing a new drug and remove lingering concerns about the legal standing and acceptance of digital signatures. These standards help SAFE members simplify the complex, billion-dollar process of bringing a new drug to market and enhance their legal protection by improving the documentation of clinical trials, research, discoveries, and patents.

Reduce the inefficiency and cost of paper-based processes

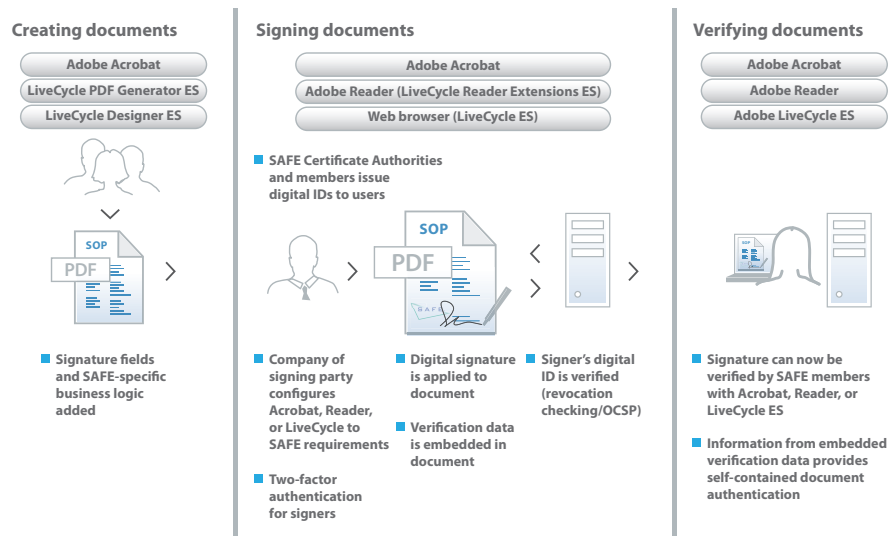
Statistics published by PhRMA in 2004 show that approximately 40% of all pharmaceutical research and development (R&D) costs are spent on paper-based business processes—a total of \$9 billion in the United States alone. For example, the Food and Drug Administration (FDA) employs 700 people to review New Drug Applications (NDAs), which can contain as many as 1,000 volumes of 300 pages each and must be submitted in triplicate. Since 1997, when the FDA first allowed pharmaceutical companies to submit NDAs in PDF, the FDA has benefited from a dramatic reduction in storage space requirements and greater efficiency for reviewers who can mark up and provide comments electronically in the PDF file.

Today, the pharmaceutical industry spends more than US \$1 billion per year on various models that aim to provide independent validation of digital signatures and other credentials. The goal of SAFE is to deliver unique and globally valid electronic identity credentials for legally enforceable and regulatory-compliant digital signatures.

By increasing confidence in electronic documents, SAFE enables companies to take advantage of the benefits of this medium, including immediate infrastructure cost reduction/avoidance and longer term innovation and productivity improvements, such as reduced time to submission and improved protection of sensitive information.

Adobe products supporting SAFE standards:

- Adobe® Acrobat® Adobe Reader® (with Adobe LiveCycle® Reader Extensions ES), and LiveCycle Digital Signatures ES have been certified to comply with the SAFE standard.
- Adobe LiveCycle Digital Signatures ES allows the deployment of SAFE-enabled signature functionality in enterprise applications.
- Adobe Acrobat and Reader enable access to Adobe PDF files that include native support for the PKI digital signature standards required by SAFE.
- Adobe LiveCycle Forms ES supports the deployment of more secure electronic forms for data capture.
- Adobe LiveCycle Process Management ES orchestrates LiveCycle services around business processes.
- Adobe LiveCycle Reader Extensions ES adds digital signature functionality into Adobe PDF files for Adobe Reader users.
- Adobe LiveCycle Rights Management ES provides dynamic and persistent control of document access and permissions.
- LiveCycle Content Services ES provides content management capabilities, enabling organizations to better share, manage, and archive their forms and documents.



Using SAFE digital signatures in Adobe PDF files

Adobe SAFE-compatible solutions streamline the movement of authenticated information

Adobe’s support for the SAFE digital signature standards allows life sciences organizations to more efficiently and cost-effectively conduct business by enabling a more secure movement of authenticated information across lines of business, between headquarters and clinical investigators, and among businesses and government regulators. Ultimately, Adobe solutions can help pharmaceutical companies maximize their patent windows by accelerating and streamlining the paperwork and processes involved in bringing pharmaceuticals to market. Adobe solutions enable electronic workflows and fortify them with persistent document security capabilities so that organizations can confidently:

- Reduce costs by eliminating paper, printing, document storage, and transport costs
- Locate and transport the right documents at the right time for more rapid completion of the trials process and timely granting of patents
- Establish a legally enforceable and auditable electronic document of record that is usable across organizations
- Improve ease of use by combining multiple documents and forms in a variety of native file formats into single Adobe PDF package

Adobe PDF

Adobe PDF is the predominant document format in life sciences because its accuracy, portability, and collaborative features are well suited to the variety of content types and platforms in bio-pharmaceutical workflows. Adobe PDF documents have supported digital signatures since 1999; Adobe Acrobat, Adobe Reader, and Adobe LiveCycle ES (Enterprise Suite) software include native support for the PKI digital signature standards required for SAFE transactions and are certified to conform to the SAFE standard.

IT managers can now easily integrate SAFE-enabled solutions with Adobe Reader so that end users can sign documents natively in Adobe Reader without having to purchase or install any additional hardware and software. In Adobe Reader, the signing experience is simple, intuitive, and self-contained. There are no “receipt” files or infrastructure to maintain. The signature resides persistently in the document and is always associated with it.

Adobe LiveCycle ES software

In addition to working directly on the desktop with Adobe Acrobat and Reader, SAFE signing capabilities can be incorporated into more advanced enterprise applications that integrate directly with existing systems and services. Adobe LiveCycle ES components provide SAFE signature capabilities as part of its enterprise application platform. For server-based and enterprise applications, SAFE-enabled organizations can deploy LiveCycle Digital Signatures ES software for signature creation and verification. Automated signature creation and verification is only one of the many features offered by LiveCycle ES. Additionally, the LiveCycle Process Management ES and LiveCycle Forms ES components support the development of applications for processes built around document review, approval, and electronic forms as well as data capture. Adobe LiveCycle Reader Extensions ES software can be used to extend enterprise applications beyond an organization's firewall by activating digital signature functionality in free Adobe Reader software, enabling people to use Adobe Reader to create SAFE digital signatures and reducing deployment costs.

LiveCycle ES also includes capabilities to protect the privacy, confidentiality, and accountability of electronic document workflows. LiveCycle Digital Rights Management ES software provides dynamic and persistent document rights management (DRM) and auditable content protection. LiveCycle Content Services ES provides content management capabilities that enable organizations to better share, manage, and archive their forms and documents. Finally, in addition to regulated workflows around product development, Adobe LiveCycle ES solutions can be used for many of the other workflows already in use internally at pharmaceutical organizations, including those for documents describing internal processes and SOPs, quality assurance and maintenance records, human resources files, financial records, and virtually any other process or workflow.

For more information

For more details about Adobe solutions for SAFE members and SAFE, visit www.adobe.com/lifesciences/safe.html.



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