

Focus research on innovation and reduce administrative burdens

Preserving intellectual property rights by protecting electronic laboratory records



SEALR capabilities

- EU-qualified and U.S. Federal Bridge cross-certified signing credential services
- PDF generation and signing
- Archival and lifecycle management

Adobe and Science Applications International Corporation (SAIC) have joined forces to reduce the shortcomings of electronic laboratory records technology with an integrated, end-to-end solution that applies high-assurance digital signatures to help protect valuable intellectual property contained in electronic form and avoid the delays and costs of paper-based signatures. The Solution for Electronic Authentication of Laboratory Records (SEALR) for the desktop is designed to more securely and reliably record, manage, and preserve critical research information now and in the future.

Paper lab notebooks are inefficient, cumbersome, and prone to many risks. They require manual transcription of data, often generated electronically. They do not store electronic experiment results such as audio, images, or video, and they are difficult to search, index, or share with colleagues in different locations. They also are susceptible to physical loss, damage, and tampering. These drawbacks increase the administrative burden on researchers and prevent them from performing their core function—research.

Electronic lab records systems solve many of these challenges. They help reduce the difficulty of managing the research and development (R&D) lifecycle by recording the invention process and the details and results of experiments. Electronic lab records can capture research and test results electronically as many different types of documents or files—images, reports, audio, video, data, and spreadsheets. Electronic lab records can couple the files with authentication, access control, and disaster recovery mechanisms to help secure them against tampering and loss. Electronic lab records free valuable information from the physical world, enabling researchers to search, index, and access the content in any location at any time.

However, electronic lab records leave unsolved several challenges related to how organizations capture critical approval and agreement signatures and retain signed R&D records over time. These records are fundamental to regulatory compliance and patent applications. How will electronically signed R&D records stand up to scrutiny

under regulatory investigation, patent disputes, or judicial legal-admissibility standards? How should they be preserved to ensure accountability and protect intellectual property rights while adhering to legal standards and complying with regulatory requirements?

Electronic lab records solutions can record who invented what and when but do not address the challenges of detecting falsification and manipulation of electronic records that show no artifacts of change. Electronic lab records must mitigate the risks by incorporating intrinsic information assurance mechanisms that ensure that R&D records and their signatures are irrefutable and admissible in a court of law. Otherwise, critical intellectual rights may be lost, and the expense of defending them could skyrocket.

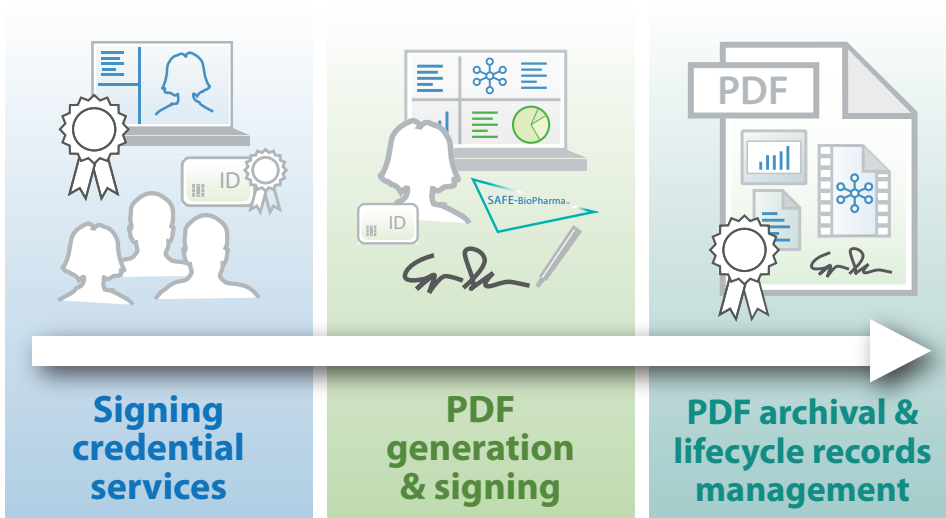
Consequently, electronic lab records must do more than just create and store records—they must also retain definitive evidence about the identity of the inventors, researchers, and signers of the documents. Electronic lab records must reliably preserve information for very long periods, ensuring that documents can be retrieved, accurately and completely rendered, and shown to be authentic even decades after their creation.

Fortunately, reliable, easy-to-obtain signing credentials and easy-to-use digital signature technology are available from SAIC and Adobe, respectively. These solutions are designed to deliver identity and information assurance capabilities for any electronic lab records system, without modification, as simply as printing to PDF. SEALR for the desktop incorporates digital signature and information management capabilities into a complete Electronic lab records assurance solution that captures and preserves evidence in three areas:

Signing credential services—Recording who invented, witnessed, and approved a given record.

PDF generation and signing—Identifying which records were signed, when they were signed, and whether they have been altered.

Archival and lifecycle management—Managing how records are stored and secured.



SAFE-BioPharma

Members can obtain turnkey high assurance globally compliant identity credentials from SAFE Bio-Pharma. Enjoy the benefits without the worry of infrastructure and operations.

Based on a simple identity registration process and an expedient provisioning process, users get sole control of a reliable identity credential (secure signing device containing a digital certificate) for authentication and signing purposes.

Adobe Acrobat

- Generate Adobe PDF files
- Create PDF digital signatures using SAFE identity credentials
- Collaborate on PDF files with shared comments
- Create PDF/A documents for archiving
- Verify PDF signatures for authentication

Signing credential services

The high-assurance signing credentials incorporated into SEALR are European Union (EU)-qualified (guaranteed admissible in an EU court of law) and U.S. Federal Bridge cross-certified. They can be obtained as a fully managed service through SAIC Identity Life-Cycle Management Services (SILS) or as turnkey credentials from SAFE-BioPharma™ Association.

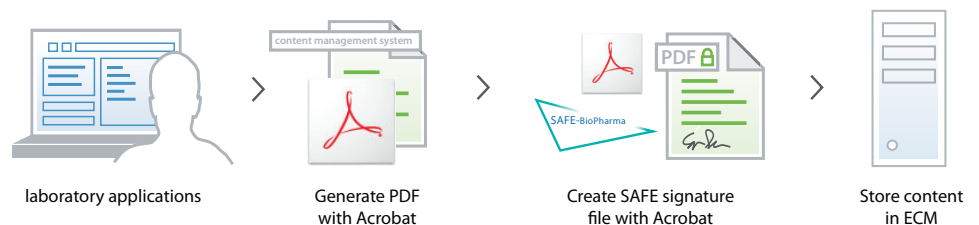
SILS is a turnkey managed service that provides identity registration, credential provisioning, and credential management services to issue and manage the lifecycle of signing credentials. SILS requires no internal deployment, is easy to operate, and integrates with various types of identity and signing technology. SAFE-BioPharma is a nonprofit association that manages the SAFE-BioPharma digital identity and signature standard for the pharmaceutical and healthcare industries. Simply join and start receiving ready-to-use, high-assurance credentials for your researchers and partners.

PDF generation and signing

Adobe's SAFE-compliant and industry-standard Adobe® Acrobat® software provides content rendering and signing for desktop PDF creation, assembly, collaboration, and control. Acrobat enables the creation of reliable PDF content from desktop applications for exchange and collaboration, without requiring users to have access to the original applications.

Acrobat enables your organization to:

- Create PDF or PDF/A files from source applications on the desktop
- Assemble multiple file types, including office documents, multimedia, and 3D files, into a single, compact PDF portfolio
- Digitally sign PDF files with high-assurance signing credentials to preserve the identity of the signer and the integrity of the document
- Apply trusted time stamps when digitally signing content
- Easily share Adobe PDF files with contributors and research partners, who can use free Adobe Reader® software to comment on and review documents
- Control access to documents with password protection



Archival and lifecycle management

SEALR for the desktop archives records and provides authoritative record life-cycle management strategies through a combination of SAIC services and Adobe software solutions.

Paper notebooks and existing electronic lab records systems do not adequately mitigate the risks to an organization's ability to work effectively, promote and defend its work, and innovate electronically from end to end. Reduce the risks and the difficulty of managing records with SEALR for the desktop, the information solution that transforms electronic intellectual property into authoritative source records with long-term preservation capability. Contact Adobe and SAIC today to learn more.

For more information

For details about SEALR, visit www.adobe.com/lifesciences or e-mail SEALR@saic.com.

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