

Accelerate the pace of innovation, focus on research, and reduce administrative burdens

Preserving intellectual property rights by protecting 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 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) is designed to work at the enterprise or desktop level 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 are susceptible to physical loss, damage, and tampering. They do not adapt well to modern research environments that increasingly rely on collaboration and large electronic datasets. They require researchers to use valuable time to transcribe information and perform administrative chores. In addition, the information remains captive to physical searches or massive transcription efforts, greatly delaying the pace of innovation.

Electronic laboratory records solve many of these challenges. They 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 data files—images, reports, audio, video, data, and spreadsheets. Electronic lab records can also include 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 an unlimited number of researchers to search and access the content in any location at any time.

However, electronic lab records leave unsolved several critical challenges related to how organizations capture critical approval and agreement signatures and retain signed R&D records over time. These records are fundamental to new drug 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 deemed 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 these identity and information assurance capabilities for any electronic lab record, without modification, as simply as printing to PDF. SEALR for the enterprise and desktop incorporates digital signature and information management capabilities into a complete ELN 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.

Signing credential services

The high-assurance signing credentials incorporated into SEALR are European Union (EU) qualified (presumed admissibility in an EU court of law) and U.S. Federal Bridge cross-certified. Signing credentials 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 managed service that provides identity registration, credential provisioning, and credential management services to issue and manage the life cycle 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.

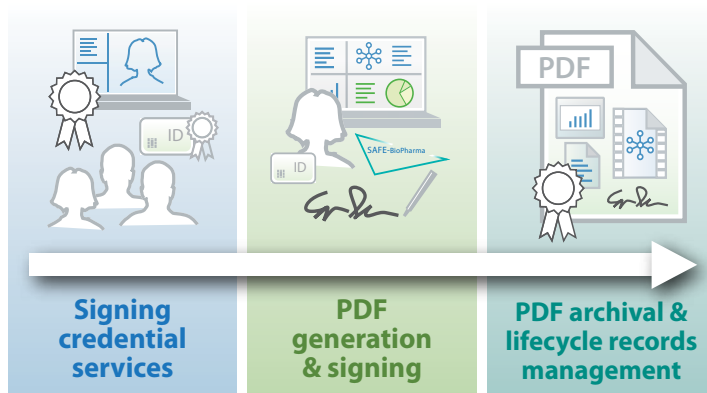
PDF generation and signing

PDF creation, assembly, collaboration, and control for laboratory records are provided either by Adobe® Acrobat® software on the desktop or through Adobe LiveCycle® ES (Enterprise Suite) in enterprise environments. Adobe LiveCycle ES is an integrated server solution that blends digital signature services, information assurance, document output, and process management. Both Adobe Acrobat and LiveCycle ES are certified to comply with the SAFE-BioPharma standard.

Archival and lifecycle management

SEALR archives records and provides authoritative record lifecycle management strategies through a combination of SAIC services and Adobe software solutions.

Paper notebooks and existing electronic lab record 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 with SEALR, the information solution that is designed to transform 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.

Adobe helps people create, manage, and deliver the highest quality digital content in the world.

Adobe Systems Incorporated
345 Park Avenue, San Jose, CA 95110-2704 USA
www.adobe.com

SAIC is a FORTUNE 500® scientific, engineering, and technology applications company that uses its deep domain knowledge to solve problems of vital importance to the nation and the world, in national security, energy and the environment, critical infrastructure, and health.

For more information, visit www.saic.com. SAIC: From Science to Solutions®.

Adobe, the Adobe logo, Acrobat, and LiveCycle are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries. SAIC, the SAIC logo, and "From Science to Solutions" are trademarks or registered trademarks of Science Applications International Corporation in the United States and/or other countries. SAFE-BioPharma is a trademark of the SAFE-BioPharma Association in the United States.

© 2008 Adobe Systems Incorporated. All rights reserved.

