Cutting Costs, Saving Time: Improving Life Sciences Operations with Digital Signatures
10 Ways to Improve Life Sciences Operations with Digital Signatures
Going paperless with signature approvals does not require an organization to have an electronic document management (EDM) system in place. Even some larger organizations use secure network folders and other methods to secure and manage their electronic documentation rather than relying on an EDM.

Regardless of whether an organization has an EDM in place, every life sciences organization has policies, procedures and documentation to support ISO, FDA and other regulatory audits. Examples include Standard Operating Procedures, work instructions, training records, project- and task-specific documentation, etc. This documentation requires signature approvals from a variety of responsible parties, including quality managers, department heads and the departmental staff involved in various activities.

Demonstrating compliance with FDA’s 21 CFR Part 11 guidance for electronic signatures and electronic records is a key component of any GxP program. Standard digital signatures are the proper way to drive consistent document and signature controls throughout an enterprise. In fact, 21 CFR Part 11 requires the use of proper digital signatures in any open system. A digitally signed document is a self-contained, portable and fully sustainable source electronic record that can be verified and trusted by internal and external parties independent of the organization or supplier of the digital signature technology.

"To obtain an approval on a project required us to fax documents from our HQ in the UK to branches around the world. It could take anywhere between three to four weeks to get signatures from all the parties. Today, with digital signature functionality, the process is completed in 10 minutes."

Daljit S. Cheema, Director, ClinPhone
What makes a digital signature different from an electronic signature – and why does it matter?

An “electronic signature” refers to any digital substitute for the traditional, handwritten signed name. “Digital signatures” are an important subset of electronic signatures built on a standard Public Key Infrastructure (PKI) that guarantees signer authenticity, data integrity and the non-repudiation of signed documents. Unlike electronic signatures that rely on proprietary software, digital signatures are based on open standards that work across all applications and document formats. For lasting security, digital signatures are the appropriate choice in industries, such as life sciences, that must meet stringent regulatory demands within complex operating environments.

"We wanted to eliminate the high costs and management associated with the proprietary, inflexible system of electronically signing database records in an EDM. Digital signatures are both standards-based and flexible enough to create ‘containerless e-records’ that can stand on their own (outside of an EDM) while ensuring FDA compliance."

Marty Sargent,
Director of Regulatory Affairs & Quality Assurance, Aspyra
Maintaining electronic lab notebooks for automating research and patent operations

Today, research-based companies are leaving their old spiral bound lab notebooks behind. Intellectual property documents, such as those proving scientific discovery and product inventions, are now being captured in electronic lab notebooks (ELNs) to maintain vital information digitally.

Digital signatures coupled with an ELN solution allow processes to remain electronic throughout, avoiding the need to print documents solely for the purpose of obtaining signatures. Through an ELN with standard digital signatures, documents proving scientific discovery and product invention (which may be used in patent applications) can be approved and trusted, and distributed electronically to an unlimited number of researchers from remote locations for years to come.

“By taking our lab notebooks online, our researchers now have direct access to more than 250 existing projects, in one language, across time zones, which is a tremendous benefit in terms of knowledge sharing and securing our rights to innovation. With digital signatures enabling us to sign-off on experiments, we’re able to enjoy the full benefits of our ELN solution and keep our documentation digital throughout its full lifecycle.”

Peter Wagner, Senior Manager, Novozymes

Novozymes drives global scientific collaboration and mitigates risk

Novozymes, a bio-solutions sister company to top 25 pharma enterprise Novo Nordisk, coordinates scientific research across multiple time zones throughout the world. The firm enhanced their homegrown, SharePoint-based ELN with digital signatures in order to enable more than 1,000 employees to sign electronic scientific notes, reports, studies, and more while achieving enhanced security. With digital signatures, Novozymes saves the time it takes for teams of scientists to assemble and authorize documents, and gains authorized electronic documents that can be verified and trusted by internal and external parties well into the future. Using an ELN coupled with standard digital signatures, Novozymes is also able to capture proof of invention as early as possible in the discovery process, which is crucial in patent processes and control of intellectual property.
Maxxam Analytics makes report delivery instantaneous

Project managers throughout fifteen labs at Maxxam, the largest private lab network in Canada, create and submit reports for Maxxam Analytics’ clients in applications spanning from bioanalysis and drug screening to food safety and forensics. Signature approvals on lab reports must stand on their own without requiring additional software for validation or access to the Maxxam LIMS. They must also meet legal requirements in order to stand as evidence in court. With digital signatures, Maxxam not only meets each of these requirements, but also delivers approved reports in seconds rather than days, generating a considerable advantage over the competition.

Whether in their own labs or at contract central labs, life science companies must demonstrate and document good laboratory practices. Lab reports, created locally or within a laboratory information management system (LIMS), must be signed and rapidly returned to clients. In addition, SOPs and lab procedures, as well as sample-handling and chain-of-custody documentation, require numerous signatures that must be applied and broadly trusted.

Digital signatures allow labs to share signed reports immediately by removing the delays associated with paper-based signatures and by making LIMS more effective. Some laboratory information management systems may offer a proprietary electronic signature solution. Only digital signatures, however, allow external parties to verify signed documents without the need for access to the legacy system used to create the signatures.

“While paper and postage were a major expense for Maxxam, the human processing cost was even greater. Each laboratory processes an average of over 100,000 samples every year. Each of the one hundred Maxxam project managers sign and seal around 15,000 reports every month. Digital signatures work seamlessly with the PDF-based reports created in our workflow.”

Sorin Bobariu, Application-Development Manager, Maxxam
In the medical device industry, remote field service staff create and sign reports that must be collated and stored within the central enterprise in order to support audits. The FDA requires that all periodic and annual maintenance and calibration reports of installed medical equipment be signed and included as part of the validation records for instruments and machines.

Priority mail is not cheap, and the priority routing of these reports generates excessive organizational costs. Fortunately, digital signatures eliminate the need for costly express delivery services and allow documentation to be instantly signed and delivered electronically. In addition, in cases where signatures from clients and other third parties are required, digital signatures can be used in point-of-sale/point-of-service applications where graphical consents (i.e., handwritten signatures) can be notarized with digital signatures from field staff acting as witness.

“Through our use of a digital signature solution, MEDRAD significantly cuts costs in shipping, paper-related products and workload, producing an estimated annual savings of over $150,000. Additionally, our field service representatives are now able to concentrate on work, not paperwork.”

Angela Gasper, IT Project Manager, MEDRAD
Monitoring trip reports

Throughout the course of any clinical study, Clinical Research Associates (CRAs) are required to prepare trip reports recording their findings from clinical site visits. Typically, these reports need to be created, signed, and delivered to the trial sponsor within only ten work days under contract. This 10-day limitation creates considerable burden, specifically surrounding the need for the trip reports to pass multiple reviews and receive signature approvals before being delivered. With digital signatures, CRAs can immediately sign electronic documents in their native formats (such as Microsoft Excel® or Word), or even sign within a clinical trial management system before submitting the documentation electronically, significantly reducing process times and delivery costs.

Watch this short video to see how digital signatures can be used for Clinical Operations.

Top three CRO saves more than $750,000 from eliminated courier costs

A leading CRO that manages clinical trials around the world faced a serious paper crisis. In 2008, the company processed roughly 5,000 site visit reports monthly, 75% of which required expedited courier shipments for reviewing and signing. Routing these reports cost the company roughly $750,000 that year.

Determined to shift to an electronic transmissions process that would reduce costs and assure timely delivery, the CRO looked for an appropriate digital signature solution that would be easy to deploy, would integrate with existing authentication methods, and would work with the document types used in the organization.

“Since going into production, over 200,000 signatures by several thousand employees have been pushed through the system. According to our numbers, we saved more than $750,000 in the first year alone and recovered our entire investment in less than three months.”

Project manager, top 3 CRO
Successful clinical studies demand efficient collaboration between a number of parties, including sponsors, CROs, academic affiliates, site coordinators, independent review boards (IRBs), and others. Site initiation requires a comprehensive sign-off process on an FDA regulatory packet that includes forms, agreements, and other documentation. A site cannot be “green-lighted” unless all required documents are signed and submitted.

As recently discussed in an article in the eClinical supplement of the Applied Clinical Trials magazine, pharma and CROs are investing in eClinical portals to achieve secure document exchange and fully electronic FDA regulatory documentation. These portals are yielding enhanced collaboration and faster site initiation. With standards-based digital signatures, all participants in the clinical trial can sign FDA regulatory documentation and eliminate delays, costs, and low-level security associated with paper-based documentation, realizing the full value that can be gained from eClinical portals.

“The combined solution enables clinical trial professionals to fully automate the regulatory workflow and enjoy dramatically reduced study start-up times, in addition to measurable cost savings. In addition, CRAs are able to monitor site and study progress and significant milestones, such as completion of all regulatory packet documents, and also maintain trial-related communication in an internal, study-specific messaging center.”

Vito Losito, PhD, Director of Clinical Trials, Entralogix Group
Recording manufacturing instructions, recipes and electronic electronic batch records

During manufacturing, whether for clinical supply or bulk commercial manufacturing, companies must establish and follow master recipes, and manufacturing instructions for each product. In addition, they are required to capture electronic batch records including material tracking, personnel involved, equipment used, cleaning and manufacturing steps followed, inventory tracking and shipping, etc. Each of these records requires a substantial number of signatures.

The complexity of the process, which sometimes involves secure, clean-room environments and strict requirements for the traceability of all products, exposes manufacturers to errors that can cause, and have resulted in, very large, potentially billion-dollar fines and/or shutdown of operations. In fact, of all areas of documentation, failures in manufacturing record-keeping are the most common triggers for regulatory fines and cease and desist orders.

Digital signatures integrated into the electronic batch records system (EBRS) or manufacturing execution system (MES), can capture necessary signatures at every step in a complicated process.

Allergan gains control of Excel spreadsheets used for EBRS

Allergan found itself drowning in complex Excel spreadsheets that were being used to document every step of the laboratory and manufacturing process. The company added digital signature functionality and deployed an electronic validation system that enables the digital signing of Excel rows and fields. With employees signing through secure, key-swipe authentication in multiple clean-room kiosks, Allergan is able to meet regulatory requirements for batch documentation without inhibiting laboratory and manufacturing speed or compromising clean-room standards.
Outside of GxP regulated operations, digital signatures in life sciences are used with contracts and agreements that require approvals by both internal staff and external parties. Since these documents can be called into evidence in a legal dispute, the organization must be able to demonstrate the non-repudiation of every signer’s identity and intent, and that the document content that has not been altered.

Standard digital signature technology enables the creation of compliant and legally enforceable electronic records. As such, digital signatures integrated with a contract management solution enable contracts to be executed faster, even when signers, including third parties, are outside of the office.

Further, since signed legal documents need to be trusted and verified by multiple parties (often years or decades in the future), digital signatures provide the only solution that guarantees that records can be validated throughout their entire lifecycle and retention period.

“Enabling business partners to create, digitally sign, and manage business-critical documents without ever needing to print and thus slow down processes, all while natively leveraging Microsoft SharePoint, generates substantial advantages in terms of efficiency, collaboration, and especially ROI.”

Tim Sparks, CEO, CLM Matrix
In addition to GxP regulated operations with specific FDA requirements, and contract signing applications with specific legal considerations, companies have a plethora of other documents that are regularly signed within executive management, human resources, finance, IT, purchasing, legal, and other departments.

As part of any electronic workflow, digital signatures cover “the last mile,” overcoming the need to print and distribute paper documents solely for the sake of obtaining signature approvals.

AIIM, a leading authority in the field of enterprise automation, published a report outlining the enterprise applications and benefits of using digital signatures.

A top 3 pharma makes executive approvals anywhere, any time, from any mobile computing device

Several executive management approvals are often required on major purchases. But with staff located in multiple offices and traveling constantly, obtaining signatures can turn a simple capital appropriation requisition into a weeks- or even months-long ordeal.

By integrating digital signature capability into one large pharma’s home-grown (NET) workflow application, executives and department heads gained the ability to immediately approve documents from the road – even using smartphones and iPads. Not only is the digital signature technology based on a standard, so too are the APIs that can be used to quickly and efficiently perform a systems integration process.

“At 9:30 AM yesterday we finished installing the digital signature system and by 2:30 PM we were electronically signing documents in our web application without having read any documentation beforehand.”

Business Analyst, top 3 pharma company
10 Things to Look for in a Digital Signature Solution

Not all electronic or digital signature solutions are alike. To find one that meets the rigorous demands of an FDA-regulated environment while delivering optimal business flexibility, look for:

1. **Open standards**
   Proprietary software can hold your signatures hostage. The FDA-regulated market has embraced standards-based digital signatures for both open and closed system applications. With digital signatures, the resultant electronic records are source documents that are self-contained, portable, and sustainable — independent of the vendor. Even if the vendor goes out of business, the previously signed records can still be verified and trusted.

2. **FDA experience**
   Within the digital signature market, verify that the vendor has experience in FDA-regulated applications, and supports 21 CFR Part 11 compliance. These requirements leave little room for error and there is much risk in going with an unproven supplier. Choose a vendor whose system has been used by thousands of FDA enterprises and GxP applications.

3. **Low total cost of ownership**
   Identify all of the costs — obvious and hidden — in putting a digital signature system into place and operating it over time. Ideally, the solution is a turnkey product from a single vendor with no hidden costs. A hodgepodge of technologies and services from multiple suppliers that need to be integrated and maintained may be the most complex and costly solution available. Consider initial investment, ease of installation, integration, management and system administration over a three- to five-year total cost of ownership (TCO).

4. **Multiple application support**
   The best option should work with the broadest range of desktop applications, including PDF, Office 2003+ Word and Excel, PowerPoint, InfoPath, CAD, and others. Find out if the digital signature technology requires that you have Adobe Acrobat in order to sign PDFs. Ask if support is provided for multiple and sectional signing of Word and Excel files, and if batch signing is supported.

5. **Advanced business system integration**
   The solution should support standard APIs such as MS CAPI, PKCS#11, JCA and OASIS DSS Web Services. The system may even offer a high level API. Verify that the API is well-documented and easy to use, enabling quick integration within your EDM/ECM, ERP, CRM, LIMS, CTMS, ELN, etc. Since custom integration might also increase the level of effort and validation activities, check with the vendor to see if some standard connectors are available for common business systems like Microsoft SharePoint.
6. **SharePoint readiness**  
Given its widespread adoption in the life sciences, SharePoint is a critical application that any viable digital signature technology must work with. Confirm that the digital signature technology being considered already has advanced, out-of-the-box support for SharePoint and common add-ons like Nintex or K2 workflow. Also examine the Microsoft partner network in the life sciences market and see which VARs and Microsoft solution providers the vendor is partnered with to support digital signatures.

7. **Seamless fit**  
The digital signature solution should fit smoothly in your existing and future infrastructure and be easy to install. Choose a product that easily integrates with your existing computing platforms, desktop authoring tools and business systems, as well as user directory service like Microsoft Active Directory or other LDAP structure. The system should not force you to change your existing infrastructure or business processes.

8. **High assurance trust**  
The digital signature solution should provide High assurance of signer identity, driven by integrating the signer credentialing and authentication of your existing user directory structure (Active Directory or LDAP) with your existing HR on-boarding practices and IT security policies. Medium assurance trust, using ID proofing via e-mail verification, may be good enough for allowing external parties to sign documents, but should not be used for internal employees.

9. **Quick installation**  
You should be able to install and operate the system in 2 hours at most without requiring extensive on-site services and staff. Perform a quick test or trial of the system to confirm that it is easy to install and easy to use. Ask for references in your industry.

10. **Minimal validation efforts**  
Go with a standard product from a single vendor requiring minimal custom integration and, hence, computer system validation. Ask for documentation about the vendor’s experience with Qualification and FDA Audits, 21 CFR Part 11 compliance, GxP regulatory support, and typical computer validation activities and support for FDA-regulated installations.
Put digital signatures to work in your organization

Make your operations – and FDA compliance – easier and more efficient. Try the digital signature solution that meets all 10 crucial requirements for FDA-regulated life sciences enterprises with our solution.

About digital signatures

DocuSign/ TSCP digital signature solution fully automates approval work-flows, allowing organizations to go paperless, expedite business processes, and eliminate the expenses and time allocations that paper-based signatures require. Our solution is the most widely-deployed digital signature solution in the life sciences industry, employed by over 20,000 FDA-regulated organizations including 8 of the top 10 pharmaceuticals and 6 of the top 10 CROs. Via its standards-based underpinnings, the digital signature solution ensures signer intent, document integrity and compliance, while significantly streamlining business processes. We create a truly collaborative environment for the multiple parties involved in the life sciences ecosystem, enabling trust of electronic documentation spanning geographic locations and across organizations.

Learn more at www.docusign.com
Technical Specifications

Applications and File Types
- Microsoft Word, Excel, PowerPoint and Outlook
- Microsoft SharePoint and InfoPath
- AutoCAD, Bentley MicroStation
- PDF, TIFF, XML, and many more

Document/Workflow Management Systems
- Microsoft SharePoint, K2 and Nintex
- OpenText, Oracle, Alfresco and Laserfiche
- Siemens Teamcenter, SAP, Adobe LiveCycle
- Agile Frameworks, Box, Google Drive, NextDocs
- Additional ECMS and industry-specific applications

Signature Features
- Standard digital signatures (TSCP Bridge)
- Easily verifiable Digital Signatures
- Proof of identity, intent and integrity
- Multiple signers per document
- Customizable signature block
- Unattended and batch signing
- Audit trail and secured time stamps

Authentication Methods
- User Name/Password
- Single Sign On
- One-Time Password (OTP)
- Tokens (Smart Cards, USB-based security tokens)
- Biometric
- RADIUS or OATH-based authentication
- ID Dataweb
- SAML 2.0

Certification Authority (CA)
- TSCP Bridge Cross Certification
- DocuSign DSA Internal (controlled-trust)
- Subordinate CA or External CA
- Signing Key and X.509 Certificate Management
- Key-Management; Private-key Operations
- SHA 256 Document Encryption
- Policy & Procedure Employee
- Provisioning/Revocation
- Certificate Revocation List, Time Stamp Authority

Supported APIs
- DocuSign DSA Signature API (SAPI*) Web Services
- Ready (OASIS DSS, Adobe Roaming ID ASSP, and SPML)
- Microsoft CAPI and CAPI-NG PKCS#11
- JCA/JCE

User Directories
- Microsoft Active Directory
- LDAP-based Directories
- Active Directory Federation Services (ADFS)
- Directory Independent Installation

Security and Digital Standards
- NIST FIPS 140-2 level 3 validated appliance
- FIPS 186 and ETSI TS 101 733
- DoD JITC PUBLIC KEY INFRASTRUCTURE (PKI)
- Common Criteria EAL 4 + evaluation for SSCD (Secure Signature Creation Device) certification
- eSIGN, eIDAS, UETA, FDA 21 CFR Part 11
- TSCP Information Labeling Data Handling Specification

Additional Features
- High availability and load balancing
- Supports unlimited number of signers
- High performance signing

Physical Dimensions (DocuSign DSA)
- 1U Rack-Mountable - 18.9” x 22.0” x 1.8” / 47.9cm x 55.9cm x 4.5cm (28 lbs / 12.7 kg)
- 4U Rack-Mountable - 19.0” x 17.5” x 7.0” / 48.3cm x 44.5cm x 17.8cm (30 lbs / 13.6 kg)

Organization or Subordinate CA Cross Certification