

DocumentSign™ - Compliance with CFR 21 Part 11

Certified Document Services (CDS) provides a cost effective PDF digital signing solution.

Who needs to be aware of CFR 21 Part 11?

Pharmaceutical stake holders such as drugs manufacturers, medical device manufacturers, biotechnology companies and biologics developers together with any enterprises regulated by the FDA need to be aware of the requirements for CFR 21 Part 11 compliance. In the competitive world of life sciences it is crucial to benefit from the efficiencies offered by electronic communications. If your organisation is involved in clinical trials, virtual office communications and the movement of any sensitive electronic information including medical device quality control records or any type of electronic submissions to the FDA, then you need to carefully consider this important federal regulation.

CFR 21 Part 11 Background

Part 11 was developed in response to the soaring costs associated with managing the distribution, storage, and retrieval of records used in conjunction with the FDA. Additionally, security concerns surrounding wet ink signatures surfaced as it became apparent these signatures including the content they were attesting to could be easily falsified. Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11) outlines the standards for use of electronic records and signatures in FDA-regulated activities, including clinical trials and pharmaceutical manufacturing. Part 11 in particular applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act (the Act) and the Public Health Service Act (the PHS Act), even if such records are not specifically identified in Agency regulations

CFR Electronic Signature and Records Requirement where DocumentSign can help Organisations comply

- 11.10 Controls for Closed Systems
- 11.30 Control for Open Systems
- 11.50 Signature Manifestations
- 11.70 Signature/Record Linking
- 11.100 General Requirements
- 11.200 Electronic Signatures - Components and Controls
- 11.300 Controls for Identifications Codes/Passwords

International Standards and Best Practice

Implementation of any IT process to mitigate a security risk must itself be weighed against multiple acceptance criteria. These may include, amongst others, Best Practice, the ability to meet International Standards and suitability for stakeholders. PKI (Public Key Infrastructure) is a pervasive service, meaning investments in PKI to address requirements in the Pharmaceutical vertical will allow additional ROI to be leveraged in other areas of synergy. Whilst 800M+ users worldwide have access to the Adobe PDF reader, is PDF not a proprietary standard? The answer is no, in that PDF is an International Standards Organisation (ISO) standard. (ISO 32000-1) and equally importantly the signature mechanisms built into Adobe Acrobat, Reader and LiveCycle ES conform to a European Standard. ETSI/ESI Technical Standard (TS) 102 778, better known as PAdES (pronounced with either a long or short a), highlights how the digital signature format described in ISO 32000-1 meets the needs of the 1999 EU Signature Directive.

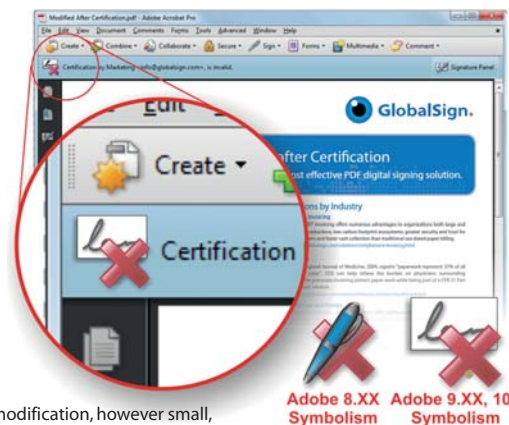
- Part 1: "PAdES Overview - a framework document for PAdES";
- Part 2: "PAdES Basic - Profile based on ISO 32000-1"; (Best Practice)
- Part 3: "PAdES Enhanced - PAdES-BES and PAdES-EPES Profiles";
- Part 4: "PAdES Long Term - PAdES-LTV Profile";
- Part 5: "PAdES for XML Content - Profiles for XAdES signatures".

For more information about GlobalSign solutions, please call Belgium +32 16 89 19 00 or UK +44 1622 766766.

Visit www.globalsign.eu or www.globalsign.co.uk for more information

Maintaining Integrity and Proving Authenticity

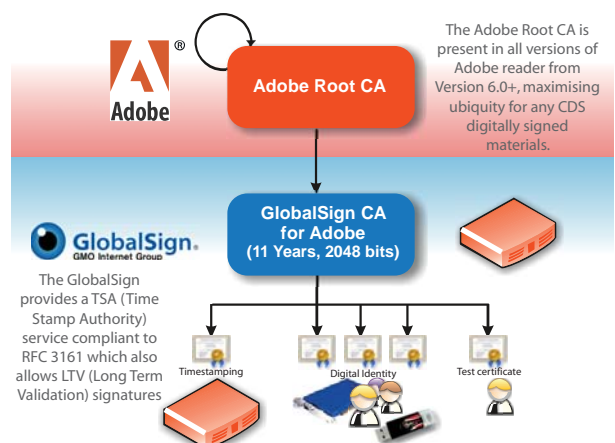
DocumentSign Digital IDs are highly vetted and secured digital IDs that tie critical transactions to key personnel. When authors, approvers, and reviewers of Adobe PDF documents apply a digital signature to an Adobe PDF, they bind their identity within an organisational affiliation to precise content. Within the context of the document an exact date and time is embedded, providing auditors an easy to follow and non repudiated audit trail surrounding key and often time sensitive business decisions. This trail is embedded into the signature properties of the PDF and easily retrieved in human readable format. Digitally signed PDFs signed with a CDS compatible digital ID are validated using just the free Adobe reader, providing organisations an easy and cost efficient method to distribute important documents outside the controlled environment of their network whilst avoiding the complex requirements related to maintaining an external verification services.



Any modification, however small, causes an Integrity check failure.

The 'Integrity' checking mechanisms within the PDF document clearly highlight whether any modification of the content has occurred since the signature was applied - the result is a strong audit trail of accountability.

How is 'authenticity' handled? the answer is that each Digital Identity is chained through the GlobalSign intermediate issuing CA to the Adobe Root CA which is distributed into Adobe 6.0 onwards, allowing 800M+ users to take advantage of the PKI capabilities built into their viewer.



DocumentSign™ - How it Works & Solutions by Industry

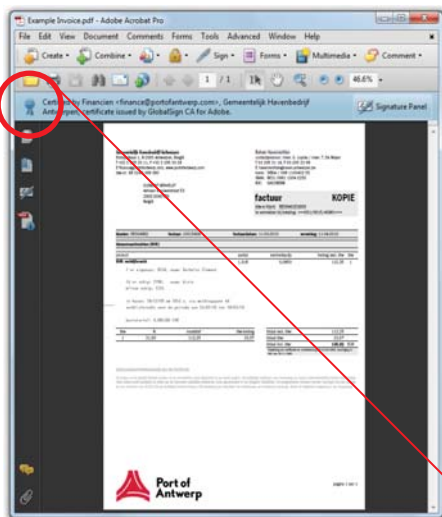
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How it Works...

Certified Document Services (CDS) is a service which is enabled by the Adobe root certificate authority and was introduced into the Adobe® Acrobat® product range from version 6.0 onwards. CDS empowers document authors to digitally sign Portable Document Format (PDF) files, using an industry standard X.509 digital certificates chained to the Adobe Root Authority to allow automatic validation of authenticity of the author using the free Adobe Reader software. No additional client software or configuration is required.

A major advantage to any organisation with stakeholders in multiple countries, is the built-in international language support within the PDF reader itself. Available in over 30+ languages, Adobe Reader ensures a consistent digital signature experience worldwide. CDS was designed specifically to enable any organisation providing documents to large and disparate recipients, who may be in multiple countries, to increase the assurance level of the document. The document's integrity and authenticity are digitally preserved by the addition of the CDS signature to the PDF. Document authors are able to increase this assurance level without requiring recipients to deploy additional processes - it simply works, ensuring an effective ROI through a vast reduction in the investment normally associated with supporting a proprietary security system.

Following a thorough verification of the 'Applicant' requesting a Document-Sign certificate, GlobalSign will issue a 'pickup' link which allows a certificate to be generated and securely stored on a SafeNet® hardware cryptographic device. Authors can digitally certify PDFs using certificates "chained" up to the trusted Adobe Root. Recipients simply need to open the document using the Adobe free reader to instantly verify the authenticity and integrity of the document. Adobe's simple to interpret "Blue Ribbon, Yellow Warning Triangle, and Red X" trust messaging allows even novice users an easy to understand method to determine if the document is legitimate.



Valid and certified!
Authenticity and
Integrity are verified
Pass



Error!
Authenticity Check
Fails



Error!
Integrity Check
Fails

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Visit www.globalsign.eu or www.globalsign.co.uk for more information

Solutions by Industry

Electronic Invoicing

Electronic VAT invoicing offers numerous advantages to organisations both large and small – cost reductions, low carbon footprint ecosystems, greater security and trust for all stakeholders and faster cash collection than traditional out-dated paper billing.

<http://www.globalsign.com/solutions/industry-solutions/e-invoicing.html>

Healthcare

The New England Journal of Medicine, 2004, reports "paperwork represent 31% of all healthcare costs". CDS can help relieve the burden on physicians surrounding cumbersome processes involving patient paper-work while being part of a CFR 21 Part 11 compliant solution.

<http://www.globalsign.com/solutions/industry-solutions/healthcare.html>

Manufacture and Design

Architecture, Engineers, and Construction (AEC) professionals benefit from CDS with faster design collaboration, more efficient and less expensive electronic document storage, and stronger protection via tamper evident engineering and product documentation as documents are exchanged among customers, partners, contractors, and building departments.

<http://www.globalsign.com/solutions/industry-solutions/manufacturing.html>

Education

More and more educational institutions are increasing student and alumni satisfaction as universities and colleges disseminate sensitive documents like transcripts and admissions letters electronically in a fraction of the time and costs seen with their paper equivalent.

<http://www.globalsign.com/solutions/industry-solutions/education.html>

Government

CDS supports both local and federal government initiatives including the Government Paperwork Elimination Act helping reduce costs, enhance citizen accessibility to government information, and reduce unnecessary environmental waste while at the same time providing high assurances to its citizens that the information is legitimate.

<http://www.globalsign.com/solutions/industry-solutions/government.html>

Financial Services

Industry best practices coupled with government imposed regulation like Sarbanes-Oxley make CDS an attractive option as a thorough audit of the signature properties are embedded in the document itself. Well after the Digital ID expires, the signature characteristics are preserved providing relying parties strong authentication of both the organisation and individual or role that signed the PDF, whether the content is still intact, and the exact date and time of the transaction as determined by a RFC 3161 compliant time-stamp.

<http://www.globalsign.com/solutions/industry-solutions/financial-services.html>

The Notarial and Legal Professions

CDS provides unequalled support of trusted documents in multiple languages. This alone facilitates cross border transactions as both sides are able to interrogate the authenticity of a document in their local language; the ideal solution for e-Notarisation.

<http://www.globalsign.com/solutions/industry-solutions/notary-legal.html>

The SafeNET iKey 4000

GlobalSign's Certified Document Services Certificates are usually provided with a SafeNET iKey 4000. As an extension of smart card technology, the iKey 4000 plugs into any USB port to provide strong portable user authentication without the need for costly reader devices. Certificates installed onto the iKey 4000 ensure regulatory compliance with the FIPS 140-2 Level 3 requirements of the Adobe CDS program but also provide a Common Criteria EAL 2 chip to allow storage of other credentials.

For organisations with high volume signing requirements or the need for automation, GlobalSign is able to provide HSM (Hardware Security Module) in either PCI, PCI(e) or Network attached. In addition, GlobalSign's ePKI (Enterprise PKI) solution is available for companies that require multiple digital identities.

