

FDA Electronic Submission Gateway (ESG) WebTrader

Choosing an x.509v3 Digital Certificate provider

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SUMMARY

The FDA Electronic Submissions Gateway (ESG) is an agency wide solution for accepting electronic regulated submissions. The ESG provides a solution for Pharmaceuticals, Biotech, Food, Tobacco, and other regulated manufactures to electronically submit a wide range of forms electronically including AERS reports to the FDA.

The FDA requires the use of a digital certificate to upload documents electronically using the ESG. A digital certificate can be presented electronically to prove your identity or your right to access information or services online.

Digital Certificates can be obtained through a Certificate Authority, an entity that is trusted to associate a public key to the information on the subject, contained in the certificate.

There are many items that should be taken into consideration before ordering a digital certificate for the FDA ESG. including the type of digital certificate to use. You may want to consider the digital representation, validity period, ease of use, and support options to just name a few.

What is the Electronic Submission Gateway (ESG)?

As stated by the FDA "The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach their final destination.

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

ESG provides Pharmaceuticals, Biotech, Food, Tobacco, and other regulated industries that perform research, product development, testing, or manufacturing of FDA regulated products a method to electronically submit a wide-range of forms including AERS – Adverse Event Reports to the FDA. One requirement to establishing a WebTrader account, the on-line mechanism participants use to upload their electronic submissions to the FDA, is to acquire an x.509v3 digital certificate. This white paper provides the selection criteria organizations regulated by the FDA should follow when selecting a digital certificate provider to be used in conjunction with their ESG WebTrader account. Although the efforts to establish a WebTrader account may at first seem daunting, with the proper guidance steps are really quite manageable and worthwhile as the benefits to electronic signatures are tremendous.

Submissions via the ESG WebTrader provide organizations involved in health, food, drug, and safety the following benefits:

- Speed of submission
- Automatic routing to appropriate FDA regulatory organization
- Increase in productivity
- Decrease in costs via reduce manual effort and courier expense
- A cleaner environment associated with reduced paper.

Preparing for ESG is not the faint of heart

Most likely you are the Compliance Officer or at the very least an IT representative, with little or no experience in Public Key Infrastructure, the underlying policy and technology utilized behind digital certificates, let alone familiar with terms like .cer and PKCS12 abundantly referenced in FDA ESG user guides. ESG readiness includes numerous steps ranging from installing and configuring Sun's Java Runtime plug-ins to submitting letters of non-repudiation needed to comply with CFR 21 part 11. Acquiring and preparing x.509v 3 digital certificates to authenticate and sign submissions through the ESG is just one of several readiness tasks that separate you from being able to move from costly and slow paper intensive submissions to the speed and efficiency of electronic submissions.

Who is affected?

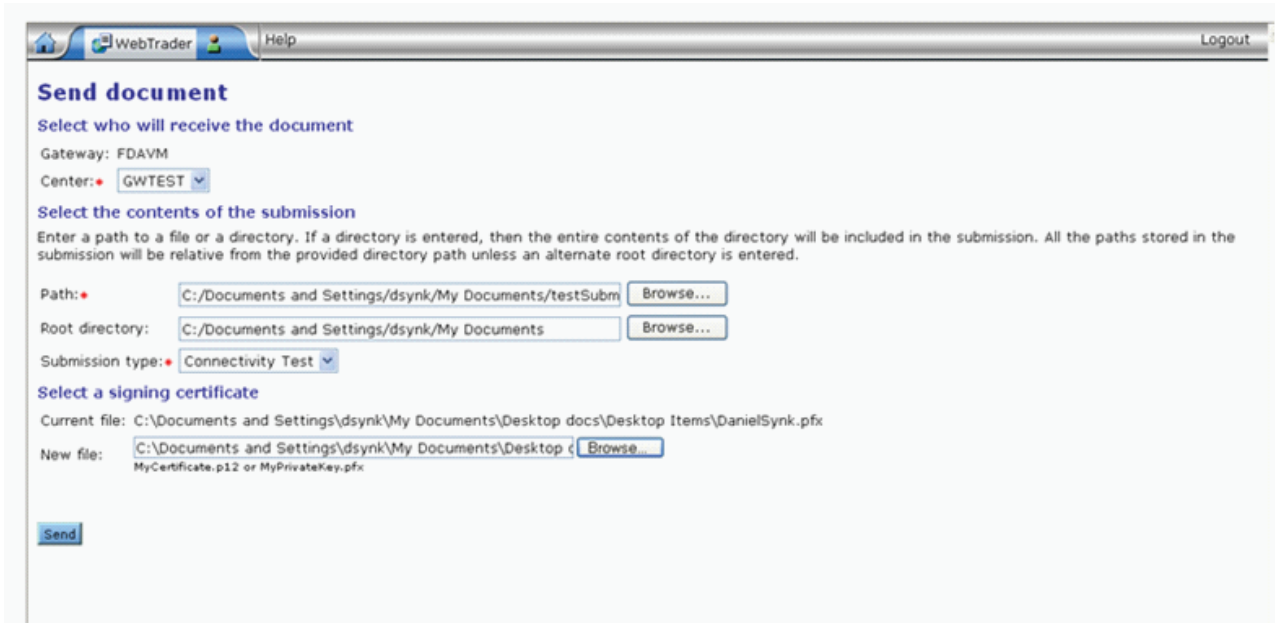
Currently the FDA supports several Centers that regulate hundreds to thousands of organizations involved in areas such as Blood, Vaccines, Biologic Products, Pharma, and Veterinary. Specifically, ESG supports the following FDA Centers:

- Center for Biologics Evaluation and Research (CBER)
- Center for Drug Evaluation and Research (CDER)
- Center for Devices and Radiological Health (CDRH)
- Adverse Event Reporting System (AERS)
- Center for Veterinary Medicine (CVM)
- Office of the Commissioner (OC)
- Center of Tobacco Products

What is an X.509 V3 Digital Certificate

As stated in the FDA Electronic Submissions Gateway (ESG) User guide, in Section 3.2 Preparatory Activities – Obtain Digital Certificate, participants in the ESG WebTrader must acquire an X.509 V3 digital certificate. The FDA has approved several CAs including GlobalSign as a source of FDA ESG compliant digital certificates. In the simplest of definitions digital certificates issued to individuals and / or organizations, also known as Digital ID's, are the electronic counterparts to driver licenses, passports and membership cards. A digital certificate can be presented electronically to prove your identity or your right to access information or services online. Digital certificates bind an identity to a pair of electronic keys that can be used for encrypting and signing digital information. A digital certificate enables individuals and organizations to secure business and personal transactions across communication networks. A stricter definition is as follows - The public key of a subject and the associated information, digitally signed with the private key of the issuer of the certificate.

Below is an illustration on how ESG will prompt the WebTrader account holder for a digital certificate.



The screenshot shows the 'Send document' page in the WebTrader application. The page has a header with 'WebTrader' and 'Help' on the left, and 'Logout' on the right. The main content area is titled 'Send document' and contains several sections:

- Select who will receive the document:** Gateway: FDAVM; Center: GWTEST (dropdown).
- Select the contents of the submission:** Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.
 - Path: C:/Documents and Settings/dsynk/My Documents/testSubm (with a 'Browse...' button)
 - Root directory: C:/Documents and Settings/dsynk/My Documents (with a 'Browse...' button)
 - Submission type: Connectivity Test (dropdown)
- Select a signing certificate:** Current file: C:\Documents and Settings\dsynk\My Documents\Desktop docs\Desktop Items\DanielSynk.pfx; New file: C:\Documents and Settings\dsynk\My Documents\Desktop c (with a 'Browse...' button) and a note 'MyCertificate.p12 or MyPrivateKey.pfx'.

A 'Send' button is located at the bottom left of the form.

What is a Certificate Authority

A Certificate Authority, such as GlobalSign is an entity that is trusted to associate a public key to the information on the subject, contained in the certificate. As a WebTrust approved CA, most popular operating systems and browsers, like Microsoft trust digital certificates issued from their trusted certificate hierarchy because of the stringent policies and controls that surround the issuance, security, and life cycle management of the digital certificates issued. Below is an illustration of a trusted certificate hierarchy as presented via the Microsoft Internet Explorer browser:

What type of certificate should I choose?

The minimum requirement for a digital certificate for use with the FDA Electronic Submissions Gateway is a Class 1 Personal Identification Certificate. The FDA recommends choosing a certificate with a validity period of three years.

Below is a chart showing the different types of Digital Certificates for the FDA ESG that GlobalSign offers.

	PersonalSign 1	PersonalSign 2	PersonalSign 2 Pro
Type Certificate	X.509 Class 1	X.509 Class 2	X.509 Class 2
Digital ID binds to	-E-mail address only (joe.smith@abc.com)	-E-mail address -Individual identity (Joe Smith, joe.smith@abc.com)	-E-mail address - Individual identity -Organization identity (Joe Smith, ABC Company, joe.smith@abc.com)
For those customers requiring...	Digital ID for general use	Digital ID used to represent themselves as an individual	Digital ID used to represent an individual at a company.
Pricing- 1 year	\$20	\$60	\$90
Pricing- 2 year	N/A	\$70	\$120
Pricing- 3 year	\$49*	\$80*	\$150*

Summary

GlobalSign has issued many hundreds of FDA ESG compliant digital certificates over that past several months and are the industry experts based on our wealth of experience in this critical area to electronic submissions for the FDA. Contact GlobalSign for additional information including detailed "how to" end user guides.

For more information about GlobalSign solutions, please call 1-877-SSL-GLOBAL or

Visit www.globalsign.com/authentication-secure-email/digital-id/personalsign-for-FDA.html

About GlobalSign

Established in 1996 and as a WebTrust accredited public certificate authority, GlobalSign offers publicly trusted SSL Certificates, EV SSL, Managed SSL Services, S/MIME email security and Code Signing for use on all platforms including mobile devices. Its Trusted Root solution uses the widely embedded GlobalSign Root CA certificates to provide immediate PKI trust for Microsoft Certificate Services and internal PKI, eliminating the costs of using untrusted Root Certificates. Its partnership with Adobe to provide Certified Document Services (CDS) enables secure digitally signed PDF documents, certified transcripts and e-invoices. These core Digital Certificate solutions allow its thousands of authenticated customers to conduct secure online transactions, data transfer, distribution of tamper-proof code, and protection of online identities for secure email and access control. The company has a history of innovation within the online security industry and has offices in the US, UK, Belgium, Japan, and China.