

CVM eSubmitter Frequently Asked Questions

This Frequently Asked Questions (FAQ) is meant to provide support for those Industry users interested in submitting an electronic submission to the Center for Veterinary Medicine (CVM). If you experience problems or you are not able to find a question that matches your scenario, please send your question to us at cvmesubmitter@fda.hhs.gov.

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Installing the Software and System Requirements

Q1. What are the computer and system requirements to run the CVM eSubmitter software?

- Windows Operating System (Windows XP, 7, 8, and 10)
- Adobe Acrobat Reader v5.0 or greater
- 30 MB of disk space
- Software capable of viewing HTML, such as a Web browser, Microsoft Word, or Adobe Acrobat (you will need the full install version to view HTML in Acrobat)

Q2. Can CVM eSubmitter be used on a Mac operating system (Mac OS X)?

CVM does not directly support the Mac at this time. However, there is a work-around if you need to install CVM eSubmitter on a Mac OS X, please contact the CVM eSubmitter Help Desk at cvmesubmitter@fda.hhs.gov.

Q3. How do I receive software updates from the CVM?

As long as your computer is connected to the Internet and your company does not have a firewall that prevents automatic updates of software, the software auto-updates each time it is opened. There is nothing that needs to be done by the user once CVM eSubmitter has been updated to CVM's latest version of the software.

Q4. What if my company has a firewall that prevents automatic updates of software?

A solution may be to install the software on a company server that allows for auto-updates. Users can access the application from the server.

Q5. What steps must be followed to permit more than one user to access CVM eSubmitter (i.e., install on a shared network)?

The CVM eSubmitter application can be installed on a shared network or server location to be accessed by multiple users. To do this, when downloading the software, change the default location (your local hard drive) to the location of the server from which you wish to work. There is a file locking feature so two users do not access the same submission file at the same time and potentially overwrite each other's work. If you decide to use a server it is important to remember that all files that are attached to questions in the submission MUST be saved to the server.

Q6. Can the shared network location be restricted, therefore limiting access to the application?

The shared network location where CVM eSubmitter is installed can be restricted through standard user rights/permissions. Thus, the application will not be visible or the data files protected based on user permissions for the specified network location. CVM eSubmitter does not require a username or password so those users with access to the network location will have access to the application.

Q7. Can CVM eSubmitter be switched from my workstation to a network location?

For the application itself, this would require separate installations. However, the data and output locations can be switched between local and network locations if desired.

Q8. Can the submission be prepared from multiple workstations and later consolidated into one final

No, but you can install CVM eSubmitter on a network and enable file locking to allow multiple people to access the same submission file (at different times). See the response to "What steps must be followed to permit more than one user to access eSubmitter?"

Installing the Software and System Requirements (continued)

Q9. Is the eSubmitter software Part 11 compliant?

Yes, the software has the ability to maintain all the data files that are produced and submitted to the FDA.

Q10. As CVM eSubmitter requires Windows OS and Adobe Reader 5.0 (or full Adobe Acrobat), does it require any special permissions for a user on a Windows machine? What exactly does the installer unpack?

The CVM eSubmitter application is Java based. The installation program will unpack the application into the user designated location. All files installed will reside in the aforementioned designated location. The files installed include the application, support files, Java runtime engine (JRE), and install/uninstall information. The JRE installed is specific to this application and should not interfere with other possible JRE's installed (i.e., JRE is not recognized by the OS but instead called by the CVM eSubmitter application directly). There are no special permissions required.

Q11. Does CVM eSubmitter introduce any new Digital Linked Library's (DLLs)?

No.

Q12. Does CVM eSubmitter require any specific version of DLLs that are standard on the machine?

No.

Q13. Does CVM eSubmitter communicate outside the local box? Does it use any TCP ports?

Yes. The application uses an internet connection to perform auto-updates of the application and support files (e.g., enhancements, fixes). The auto-update process is called at start-up every time the application is executed. However, if no internet connection is available the application will still execute correctly but no updates will be received. If you use a proxy server there are settings within a configuration of the application to give the application permission to contact its auto-update site.

Q14. Does CVM eSubmitter introduce any vulnerabilities of which you (the developers) are aware?

None of which we are aware.

Q15. Are there any issues that might affect our environment of which I should be aware?

None of which we are aware.

General Information

Q16. What types of submissions can be submitted to CVM using the CVM eSubmitter software?

- Office of New Animal Drug Evaluation (ONADE): Investigational New Animal Drug (INAD) file, New Animal Drug Application (NADA), Generic Investigational New Animal Drug (JINAD) file, Abbreviated New Animal Drug Application (ANADA), Veterinary Master File (VMF), and General Correspondence (GC) file submissions
- Office of Surveillance and Compliance (OSC):
- Drug Experience Reports (DERS)
- Division of Animal Feeds (DAF): Food Additive Petitions (FAP), Investigational Food Additive (IFA) files, and Generally Recognized As Safe (GRAS) Notices
- Office of Minor Use and Minor Species (OMUMS): All submission types for the Indexing program.

Q17. How can several people work on an individual submission from different computers?

There are two ways that users can collaborate on one submission:

- 1) CVM eSubmitter can be installed on a network and accessed by multiple users. To do this, see the response to the question: "What steps must be followed to permit more than one user to access CVM eSubmitter (i.e., install on a shared net-work)?" OR
- 2) The data file can be passed from one user to another. The submission can be accessed by placing the data file in the data folder and opening it from the CVM eSubmitter application.

Q18. Can I create a submission, edit it, save it and return to it to finalize it in multiple sessions?

Yes. You may save and close a submission file at any time. To return to the submission file, click Open Existing Submissions in CVM eSubmitter to select the submission file in progress.

Q19. Does CVM eSubmitter perform an "auto-save"? If it does, can it be turned off?

Yes, the CVM eSubmitter application has the ability to set an auto-save feature. This feature can be customized by going to File>Preferences. When this option is enabled, CVM eSubmitter automatically saves your submission while you work. You can also set the interval for how often you want to save. By default, auto-save is turned off.

Q20. What if a question or section does not apply to my product?

Questions containing business rules were put in place to disable questions that do not apply to certain products. If a question still does not apply to your product, enter "NA" with an explanation as to why the question does not apply. There are numerous questions within the CVM eSubmitter templates that allow you to provide an explanation of why you are not including a section of the submission that CVM has deemed mandatory.

General Information (continued)

Q21. Can I cut and paste text into the text boxes in the CVM eSubmitter software?

Yes, but be sure to review the formatting of the pasted text. Pasted text from a Word Document may include unwanted formatting tags. A way to prevent unwanted tags is to first copy the text into a Text file (e.g. NotePad) and copy and paste the text from the text file into the appropriate CVM eSubmitter question.

Q22. Can an old submission be reused to generate a new submission by editing it to include the new information for a similar product?

Yes, to do this you will need to open the old submission and go to "File>Save As" to create a new submission. The data from the old submission will be copied over to the new submission with the new file name. The template will also be updated into the latest version. If new questions were added to the eSubmitter template, they will need to be completed. If questions were removed from the template, the data from those questions will be removed.

Q23. What does it mean when I get a message indicating that the CVM eSubmitter template will become "inactive"?

Updates can occur to the templates monthly. Questions are removed or added; new business rules are implemented; and new templates are developed. In order for the CVM to ensure that users are using the most updated templates, the templates are set to expire six months after a new version is released. If you have been working on an submission using the old template you must submit the submission within six months of the last template update or you will not be able to package it with CVM eSubmitter. Otherwise, you can do a "File>Save As" to update to the latest version of the template.

Attaching Files and File Specifications

Q24. How do I attach files?

Attaching a file to a CVM eSubmitter question is very similar to attaching a file to an email. Instructions on attaching files in CVM eSubmitter can be found within the CVM eSubmitter Quick Guide, which may be launched from within the CVM eSubmitter tool's Introductory Screen under Menu Options.

Q25. What types of files can I attach?

The CVM eSubmitter tool supports attachment of the following file types:

- Adobe Acrobat files (.pdf)
- SAS System XPORT files (.xpt) Extensible Markup Language (.xml, .dtd)

However, questions may be restricted to only allow certain file types (e.g., PDF only) based on the question and/or program for which you are submitting.

Q26. How should I name the attached files?

Use a descriptive name so the reviewer can easily identify the content of the file. As a best practice, do not use punctuation, spaces, or other non-alphanumeric symbols in file names when naming the files for attachments.

Q27. Is the descriptive information section in the File Attachment Dialog also shared with CVM when submitted?

Yes, this information is collected as part of the submission.

Attaching Files and File Specifications (continued)

Q28. Should I set security settings or passwords on my PDF files that are attached to the questions in the submission?

No, please do not set any security settings on the attached PDF files. This could cause issues when CVM reviewers access the file, and could result in the rejection of submitted files.

Q29. Which PDF versions are supported by the CVM eSubmitter software?

Adobe Acrobat 5.0 or greater. Please note that there are features in Adobe Acrobat 8.0 or greater that cannot be supported; if you are submitting Adobe Acrobat 8.0 or greater files, please contact technical support at cvmesubmitter@fda.hhs.gov

Q30. Can I use bookmarks in my PDF attachments?

Yes. In fact, using meaningful bookmarks in the PDF files is very useful to CVM reviewers. It facilitates a faster review time, especially when the attached files are large.

Q31. Can I attach pictures or plug-ins to the questions in the CVM eSubmitter submission?

Although it is acceptable to use plug-ins to assist in the creation of a submission, the review of the submission should not require the use of any plug-ins other than any provided by Adobe as part of Acrobat, and must be compatible with Adobe Acrobat 5.0 or greater.

Q32. Can I scan documents and include them as attachments?

Yes, but please run Optical Character Recognition (OCR) to make the PDFs searchable and allow for copying and pasting of the text.

Q33. What is the recommended font for the PDF attachments?

Times New Roman 12-point is the preferred font. Fonts smaller than 12-points should be avoided whenever possible.

Q34. What if I get a message that says my file cannot be viewed because it cannot be located?

This message may indicate that the file is not in the same location as it was when it was first attached. There are two ways to fix this error:

- 1) Move the file back into the original location OR
- 2) Remove the file from the file attachment list and reattach the file from its current location

Q35. What if I want to make a change to an existing file after it has been attached to a question in the submission?

If you need to make a change to the file after it has been attached, you must go to the file at its current location, make the change and save it to the same location. The content of an attached file can change but the location of the file cannot.

Warning: You will not be able to package correctly if the location of the file changes after it has been attached to a question in CVM eSubmitter and prior to packaging. Should you need to change the location of a file after it has been attached in CVM eSubmitter, you will need to re-attach the file in CVM eSubmitter to the question response after the file has been moved.

Q36. Can file attachments (or data and output files) be stored in SharePoint, or must they reside on the local PC or a network share?

No, CVM eSubmitter cannot access files from a web-based application such as SharePoint during packaging. The files must be accessible from the file system so they can be located and incorporated into the final submission package.

Completing and Packaging Submissions**Q37. Is the .ZIP output file the only format for electronic submission?**

Yes, the only packaged output from CVM eSubmitter is a .ZIP file.

Q38. How can I verify that all my file attachments are included in the submission zip file?

The attached files will be listed during Step 2 of the packaging process. In addition, they are also stored within the zip file that is generated after the submission has been packaged properly. The zip file can be opened and reviewed using a variety of available applications.

NOTE: DO NOT ALTER THE ZIP FILE IN ANY WAY when you review the attachments. This will cause issues loading your submission and will require that you resubmit.

Completing and Packaging Submissions**Q39. What do I do if I "package" the submission and then decide to make a change?**

Open the submission and make the change then simply repackage the submission. Do not add files directly to the zip file without attaching them to the appropriate question in CVM eSubmitter. Files manually added to the zip file will not be considered part of the submission.

Q40. What happens if I change the location of the submission data file or attached files after packaging and I try to re-open the submission in CVM eSubmitter?

If the data file is not in the original location, the software will not be able to list it when attempting to open a submission file. To fix this, you should restore the files to their original location. To determine this location, go to File > Preferences > File Location tab in the CVM eSubmitter application. The file path of the location where your data files should be stored is displayed.

You can move the files back into this location OR change the file path location by clicking on the Select Location folder icon and navigating to the new location where your data files are stored. The new path should display in the text field.

If the location of any attached files are changed the application will no longer be able to locate them for viewing or packaging. To fix this, you should either restore the attached files to their original location, or manually re-attach them to the appropriate question responses.

Q41. How can I store the submissions for record keeping in my company?

The complete packaged zip file (which contains the submission data [.xml] file and any file attachments) can be named and stored just like any other electronic document.

Q42. Can a submission be retracted if in error?

If you have created a submission in CVM eSubmitter, you may delete it locally at any time if created in error. However, if you have transmitted a submission to CVM, it cannot be retracted. You must contact the CVM eSubmitter Help Desk at cvmesubmitter@fda.hhs.gov to assist in resolving the issue.

Completing and Packaging Submissions (continued)

Q43. Is there a limit to the size of a single submission (attachments and images included)?

We have successfully tested up to 4 GB. However, it does take time to package anything greater than 2GB, but it will work. It just takes more time to process and package.

Q44. Can digital signatures be used to sign my submission and any other required signed documents?

Digital signatures are required when utilizing the FDA Electronic Submission Gateway (ESG) to transmit CVM eSubmitter electronic submissions to CVM. Digital signatures are also required when signing a submission during the CVM eSubmitter packaging process (can be an Adobe self-sign during packaging).

Note regarding FDA Electronic Submission Gateway: The ESG authenticates and validates electronic submissions and routes it to the appropriate Center. Please visit <http://www.fda.gov/esg/> to register as a trading partner for an initial ESG test account. Upon successful transmission of the test submission, your account will be promoted to a production account.

Q45. Can the digital signature password that was issued to one person be used by another as long as it is for the same company?

The digital signature accepted in CVM eSubmitter is an Adobe self-signed digital signature. The signature is for a single individual and the password is determined by the user during the creation of the Adobe digital signature. The signatures and passwords are not determined by FDA. For more information on how to create your digital signature and how it is used within the CVM eSubmitter packaging process, see the applicable quick guides located within the manual folder under the application installation folder.

Q46. Are there any other rules for digital signatures?

For information and guidelines on digital signatures, see the applicable quick guides located within the manual folder in the CVM eSubmitter installation folder. These quick guides may also be launched from within the Packaging Wizard in CVM eSubmitter.

Q47. Can CVM eSubmitter be used to compile a submission prior to finalizing our FDA Electronic Submissions Gateway (ESG) account set up?

Yes, the FDA ESG and the CVM eSubmitter application are two separate systems. You will need the ESG account setup finalized prior to actually transmitting the packaged submission generated in CVM eSubmitter. However, you may begin working on your electronic submission using CVM eSubmitter prior to completing the FDA ESG account setup requirements.

Q48. Is the submission available for viewing by the submitter once submitted to FDA?

The submission is always available for viewing from your internal records as it resides on your local machine or network. FDA does not, however, provide access to view submission content previously submitted due to security purposes.