

## **eSubmitter and WebTrader tutorial video script**

### **Video #1:**

This video will demonstrate how to prepare a low-volume submission for electronic medical device reporting (eMDR) using eSubmitter software or eSubmitter. It was created by the staff from the MDR Team supporting the eMDR Helpdesk to assist those who submit low volume of MDR reports electronically to CDRH.

### **Video #2:**

To begin, you should have eSubmitter installed and opened on your computer. To download eSubmitter application go to <https://www.fda.gov/industry/fda-esubmitter> . Registration of eSubmitter is optional; Click, "Register later".

### **Video #3**

From the eSubmitter "Welcome" Screen, click on the "Create New Submission" button under the "Menu Options" section. The first step is to select the appropriate submission type from the list of available options. eSubmitter is available to users for a variety of submission types. Scroll down and then select CDRH MedWatch Form 3500A. Once highlighted, information appears in the "Description of Selected Submission Type" dialog window about the selected form. Click "Next."

### **Video #4:**

The second step is to provide a "Descriptive Name" and "File Name" for the submission, both of which are required fields. Please note that the blue dot next to certain fields denotes that such information is required to complete the submission. Other fields without the blue dot indicate optional information. The "Descriptive and File name" used are intended for you to use to organize the eSubmitter files. FDA will index the files by "core ID" and "report number" when they are received. Submission files should be named appropriately so that you can recognize the submission by its name to reopen it later, if needed. For purposes of this tutorial, we will name this submission "Sample3500AForm". Click "Create."

### **Video #5:**

At the bottom of the screen there is a navigational bar which allows the submitter to click a left facing arrow to return to the previous screen. The "outline view" allows you to return to the list of fields. The right facing arrow allows you to proceed to the next screen.

Click "Next."

**Video #6:**

From the drop-down arrow in the grey box located on the right-hand side of the "Report Number" screen select the option that best describes you as a submitter. The options include "manufacturer," "User Facility," and "Importer." If you are a manufacturer Select "MFR Report Number," select "User Facility Report Number" if you are a user facility, or if you are an importer, then select "Importer Report Number." For MFR or importer report number, please select "CFN" if your firm's registration number is 7 digits long. If your firm's registration number is 10 digits long, you should select FEI. For User facilities, please use your 10 digit Centers for Medicare & Medicaid Services (CMS) number, followed by a 4 digit year, followed by a 4 digit sequence number. For the purpose of this tutorial, we are selecting "MFR Report number" and entering a MFR report number.

Complete the fields named "Form Code" and "Exemption Number" if FDA assigned you a form code or any type of exemption. Click "Next."

**Video #7**

On the "Patient Information" screen, enter all patient information in Part A. click "Next."

**Video 8**

Complete the information requested for the fields on the "Adverse Event or Product Problem" Screen, Part B (B1 to B4). Enter all the information that is available. click "Next."

**Video #9**

Complete the information requested for the B5 field named "Describe Event or Problem." The completion of this field is required. For example: It was reported that the pump had a broken display. No adverse patient effects were reported. Click "Next."

**Video #10**

Complete B6 field named "Relevant Tests or Laboratory Data" screen. Enter all information that is available. click "Next."

**Video #11**

Complete, B7 field named "Other Relevant History." Enter all information that is available click "Next."

**Video #12:**

On the "Suspect Products" screen, select "No" in response to the question "Is this a combination product?" then proceed to Section D. If the response is yes, this action enables the questions in Section C, named "Suspect Products information." For the purpose of practicing, we select "Yes". Click "Next."

NOTE: By selecting 'Yes' to this question you are declaring that the product that was involved in the Adverse Event is a of Combination Product, and the corresponding checkbox in Section G4 of the report, will automatically be checked and you will not have the ability to edit it. To be able to remove the selection from the "G4 Combination Product" checkbox, you must select 'No' in response to this question.

### **Video #13**

Enter information related to "suspect product" in fields C1 through C9. The green plus (+) button allows you to enter more than one suspect product. Drug Sequence Number is required. Enter 1 for your first suspect product. If your suspect product is a drug, a maximum of 20 suspect drugs can be added to a submission. Click on the yellow bulb to display the hint for drug sequence number. The next yellow bulb displays the hint for drug dose. Click "Next". A dialog box appears, and you will be given an option to add another suspect product if any. If not, then to move to the next screen. Click "ok".

### **Video #14**

Since in our example, we don't have any "Suspect product information" to include, we will go back to the C section to select "No" in response to the question "Is this a combination product?" Click on "Previous" and delete the item we just created by clicking on the "Delete Item" button. A dialog box appears to confirm your deletion. Click "Yes" then click "Previous" to go back to the "Suspect Products" screen. Select "No" in response to the question "Is this a combination product?" and then click "Next", which takes you to a new screen named "Suspect Medical Device" (D1 – D2). Please note that D2, "Common Device Name" and "Device Product Code" are required fields for mandatory reporters and should be completed. In our example, FRN is the product code I'll use. You'll notice that the device information pops up if the product code is correct. If you don't know the device's product code, you can search it by clicking on the green plus button located on right-hand side and it will take you to the product code filter dialog box where you can search for a product code and select the corresponding product code for the device. Click "Next."

### **Video #15**

On the "Suspect Medical Device" (D3) screen, enter the corresponding manufacture's name, address and phone number. click "Next".

### **Video #16**

On the "Suspect Medical Device" (D4 – D6) screen, enter "Additional device information", "Operator of Device" and whether the device was "implanted or explanted including the dates." Click "Next"

### **Video #17**

Continue completing Fields D7– D9 on this screen. Click "Next"

### **Video #18**

Complete D10 by providing information related to “concomitant Medical Products” and “Therapy Dates.” Concomitant products are any other medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products, or medical devices, etc.) that the patient was using at the time of the event. Do not include products used to treat the event. Click “Next”

The “List Data Message Dialogue” box appears. Select the appropriate button to add another item or to move to the next screen. Then Select “Ok”.

#### **Video #19**

Complete the information about the Initial Reporter in Part E1 of this screen. Provide the name, email address, mailing address, and phone numbers of the person who initially reported the adverse event to the user facility, manufacturer, or importer, and who can be contacted to provide information on the event if follow-up is necessary. Once completed, click Next

#### **Video #20**

Include a response to Answer the questions in the E2 and E4 fields. Select the appropriate response for the question in the E3 field using the options from the dropdown menu located on the righthand side. Click Next

**Video # 21** Section F (F1 – F14) is only used by User Facility or Importer.

You will notice There is no Section F. that is because section F is only used by User Facility or Importer.

#### **Video #21**

Section G is required for Manufacturer submitters. The G1 field pertains to information that identifies the “name and contact information for the contact office (and manufacturing site for devices”) or “compounding outstanding facilities.” click “Next”

#### **Video #22**

This screen is a continuation of the G1 field, which is intended for information about “office contact” or “manufacturing site.” After completing this screen, click “Next”

#### **Video #23**

Manufacturer submitters would complete the G2 and G3 fields on this screen. The G2 field identifies the “report source”. The submitter would select the appropriate box to identify the source from which the manufacturer learned about the event that is the subject of the report. The submitter must select from the list provided. If the source is not listed, then they should check the box identified as “Other” and

include such information. The G3 field should be completed with the “date the manufacturer received the information or learned about the event” from the source identified. click “Next”

#### **Video #24**

Manufacturer submitters would complete the G4 and G5 fields on this screen. The G4 field named “Premarket Identification” includes a list of premarket submission information/ types. The fields related to the suspect product identified in section C are not filled on this screen; instead, they are filled for each suspect product on the screen for section C. You should fill the Device BLA and PMA/510k fields with identifying information pertaining to the suspect medical device described in section D. Click “Next”

Click “Next”

#### **Video #25**

Manufacturer submitters would complete the (G6-G8) fields. The G6 field, is intended for all (manufacturer) reports. Medical device manufacturers must identify the report as “initial,” “follow up or 5-day reports.” If the report submitted is a “follow up” report, the submitter must identify the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report = follow-up #1, second follow-up report = follow-up #2, and so on). If the report represents an event that must be reported as a 5-day report, then the submitter would select the corresponding 5-day box. The remaining values are available for Drug sponsors and for the reporting of Combination Product reports. In this example, we are checking the initial box, because it is our first submission, not a follow up.

Complete the G7 field, if applicable. This field is used for drug and biologic, including human cell, tissue, and cellular and tissue-based product ( ), manufacturers only.

The information for the G8 field was previously provided on the “Report Number” screen. Therefore, no entry is required. Click next

#### **Video #26**

Part H is required to be completed by device manufacturer submitters. The H1 field identifies the “type of reportable event.” This is a required field and must be completed. The submitter must select from the options listed. The options include “Death,” “Serious Injury,” and “malfunction.” If the type of report represents a “summary report,” then the “summary report” box must be selected, and the “total number of events being summarized” must be entered in the corresponding available field. For example, if the report represents a malfunction report that summarizes 500 individual events, the submitter will check the “malfunction” box and the “summary” box. The submitter would also enter the value 500 to identify the total number of events being summarized. If the report represents an individual event, then the “summary report” box remains unchecked. Since our example does not represent a “summary report,” we’ll uncheck the “summary report” box.

The H2 field pertains to the “type of follow up” and should be completed for supplemental reports. Check the box(es) that most accurately describes the nature of the follow-up report.

The H3 field identifies whether the device subject of the report was evaluated by the manufacturer. Click "Next"

#### **Video #27**

Complete the H4-H6 fields. The H4 field pertains to the date the device was manufactured.

The H5 field is intended to identify whether the device is labeled as "single use." The submitter should check the box that provides the answer to the question.

The H6 is intended for documenting the codes associated with the "Adverse Event Problem" and "Investigation." The submitter should click on the green plus buttons under each corresponding field to select the code that appropriately identifies the event being reported. For "Adverse Event Codes," please refer to the FDA's Medical Device Coding Resources page at <https://www.fda.gov/medical-devices/mdr-adverse-event-codes/coding-resources> . click "Next"

#### **Video #28**

Complete the H7-H9 fields. The H7 field pertains to identifying the type of remedial action, if one was initiated. If applicable, the submitter would make a selection from the list provided.

The H8 field is intended to identify the usage of the device. The submitter should select from the list provided.

The H9 field, pertains to actions reported to FDA under Corrections and Removals. If applicable, then the submitter should indicate the reporting number for such action. click "Next"

#### **Video #29**

The H10-H11field is intended to allow the manufacturer to provide additional narrative or additional data related to the event that is the subject of the report. The information included in this field should not be duplicative of information included in other sections of the report being submitted.

Click" Next"

#### **Video #30**

This is the File Attachments screen where you can attach additional information that would help FDA understand the circumstances related to the event and the device involved. To add attachments to a report, the submitter should click on the green plus button located on the left-hand side of the screen. Follow the prompts for uploading the attachments. After attachments have been uploaded, Click "Next"

#### **Video #31**

- You have finished the process for the completion of the report Submission. If the report was not successfully completed, you will receive a "Warning" pop up box that will alert you that there is data

missing that should be provided for processing the report. When this happens, you will not be able to package a submission file to submit a report to FDA. You must complete the missing information before proceeding. Click "Close"

- To identify the fields that need to be completed, select the "Missing Data Report" from the "Output menu" located on the Toolbar at the top of the screen.
- Click "OK" to open the Missing Data Report. Here the report lists two missing data: Report Number and D section. Close the page.
- Another way to identify which fields need completion is by clicking on the "Outline View" button located at the bottom of the screen.

#### **Video #32**

- The required Missing data fields will be identified by a question mark (?) next to the missing data field. In our example, the first missing data requires to be completed before packaging is the "Report Number", as it is identified by the question mark.
- Highlight the report Number and click "Select" at the bottom of the screen to complete the specific data field.

#### **Video #33**

- In this example, the "Sequence Number" was omitted. This is a required data field, as indicated by the blue dot. Add the "Sequence number". click Next.

#### **Video #34**

- Click on "Outline View" button again. to identify the next required missing data. Select the next missing data (D.Suspect Medical Device (D1-D2)) by highlighting it and click on "Select."

#### **Video #35**

- The "Common Device Name" is a required data field. Therefore, it must be completed. Infusion Pump is the common name in our example. click "Next"

#### **Video #36**

- Click on the "Outline View" button again to identify the next missing data field. Do the same until all missing data fields have been completed.
- Once you have completed all the required missing data fields, the system will allow you to package your file.
- Click on the "Package Files" button from Icon tool bar located at the top of the screen.

### Video #37

- The Packaging Files Dialog box will appear. The packaging process will result in a single ZIP file per submission. The ZIP file generated by eSubmitter should not be altered in any way prior to transmitting to FDA.
- Note: The Package Output Location, located on the bottom of the dialog box, indicates the folder on your computer where the zip file will be saved. You will need to access the file from that location at a later time. For additional instructions, select the yellow lightbulb in this dialog box.
- Click “Next” in the “Packaging Files Dialog” box. Click “Next” again and then click the “Package Submission Files” button to complete the packaging. Click “Next” again in the dialog box.
- You will receive the message “Submission Package Created Successfully.” Click “Done.”

### Video #38

- To submit your zip file to CDRH, you need to login to your WebTrader account. The next video will walk you through that process.

## How to send a Low-Volume submission to eMDR using WebTrader

### Video #39:

**This video will demonstrate how to submit a low-volume eMDR using WebTrader. It was created by the staff from the MDR Team supporting the eMDR Helpdesk to assist those who submit MDR reports electronically to CDRH.**

Before sending a WebTrader test submission, ensure you have setup your WebTrader test account using the instructions located at <https://www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist>.

### Video# 40:

In order to send a submission using WebTrader, please perform the following steps:

1. Go to the Electronic Submissions Gateway (ESG) test login screen at <https://esgtest.fda.gov/>
  - a. Enter your User ID
  - b. Enter your Password
  - c. Click the check box next to “I agree to the terms set forth in the Rules of Behavior. and click the “Log in” button

A welcome dialog box will appear, please review the messages and click the “Close” button.



#### **Video #41:**

To create a submission, click the "Send Document" button located in the left-hand window frame:

On the Send Document page, perform the following steps:

- a. Select CDRH for Center
- b. Select Adverse-Events for Submission Type
- c. Click on "Add documents" to locate the zip file you produced by eSubmitter to be uploaded. Click "Select"
- d. Select the signing certificate by clicking on the Signing Certificate link. If you have already selected your certificate, it will be displayed on the send screen. If this is your first submission, you will have to click the link and locate it on your computer.
- e. Enter the signing certificate password (this was provided when you created your ESG account)
- f. Click the "Send" button

You will receive a message at the top of the screen indicating your upload has been added to the queue. At the bottom of the screen you will see the message, "Uploads in Progress".

Wait approximately 10 minutes after sending your submission, then go to "Sent Items" page to confirm that your submission was received.

#### **Video #42:**

On the Sent Items page, you will find the zip file you just submitted with an Acknowledgments bar on the same row.

**\*Note:** You will get three acknowledgments when you submit your MDR electronically.

Acknowledgment 1 (also referred to as Receipt) is sent by the Electronic submission Gateway or ESG and confirms that the submission was successfully received by the ESG. Acknowledgment 2 is sent by the ESG and indicates that the submission reached CDRH. Acknowledgment 3 is sent from CDRH and indicates that your submission was successfully loaded or notifies you of any errors that occurred during validation and loading. If the submission was successfully loaded, your "passed" acknowledgement3 serves as proof that your submission was received and accepted by eMDR.

**\*\*Note:** If you do not see the 3 Acknowledgments, please wait up to 24 hours and check again. If there is no Acknowledgement after 24 hours, follow the instructions on the [eMDR Help and FAQs page](#) to request support.

Click on the zip file to open all the Acknowledgements (ACK)s. In the Document Details box, ACK3 is provided in both HTML and XML formats; ACK2 usually appears under ACK3 in a text format, and ACK 1 appears under ACK 2 as RECEIPT. Please note that sometimes ACKs are displayed in different order. In our example, ACK2 is the first acknowledgment from the top.

Please note that the 3 Acknowledgment files you receive in Webtrader are your proof that the submission was received. However, you need to read ACK3 to determine if your report “passed” or “failed”. You should save the passed/successful ACK3 for all your submissions in your firm’s reporting records.

If your submission failed, you will see an error message describing the issue. You should reopen your submission in eSubmitter, correct the issue, repackage and resubmit. You will then receive a new series of ACKs.

Let’s review the ACK3 file. Open the ACK3 in the html format by clicking on the down arrow to download it; save it on your computer and then open to read.

In the Submission Summary box, the Summary Line indicates that your submission “passed”. If you open ACK3 in the xml format, you will see the same message but in a different format.

Let’s now open ACK2 file and review the message it provides. You can view, download or print ACK2 file. Click on “Download arrow” and open to read. ACK2 will only state that “CDRH has received your submission” but won’t indicate whether your submission passed or failed. So, it is important to always save and read ACK3 to ensure your submission passed.

#### **Video #43**

Once determined that your report has passed, you will then need to send the successful ACK3 to the eMDR helpdesk [emdr@fda.hhs.gov](mailto:emdr@fda.hhs.gov) and request approval for a production account. If you need further assistance, please contact the eMDR helpdesk at [emdr@fda.hhs.gov](mailto:emdr@fda.hhs.gov).