



U.S. Food and Drug Administration
Protecting and Promoting Public Health

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Electronic Medical Device Reporting (eMDR)

**FDA Small Business
Regulatory Education for Industry (REdI)**
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Learning Objectives

- Learn the basics of the "Medical Device Reporting: Electronic Submission Requirements Final Rule"
- Review the basic process for preparing and submitting electronic Medical Device Reports (eMDRs)



Poll #1

DEV-D2S7 Poll #1 

View Votes

Edit

End Poll

Has your company submitted eMDRs to FDA yet?

<input type="radio"/> Yes	<div></div>	0%	(0)
<input type="radio"/> No	<div></div>	0%	(0)
<input type="radio"/> I do not know what eMDR is	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results



eMDR Final Rule & Guidance Overview

eMDR Final Rule

- Manufacturers must submit initial and supplemental reports to FDA in an electronic format that FDA can process, review, and archive.
- Requirements of final rule took effect on **Aug 14, 2015**
- The final rule does not change what must be included in a report or when the report should be submitted.

eMDR Final Rule Continued

- Record Keeping Changes:
 - Amends 803.18(b)(1)(ii) to require keeping copies of all reports submitted to FDA, whether paper or electronic (entities may choose method).
 - Requires the retention of all acknowledgments that FDA sends to the manufacturer or importer (803.18(b)(1)(iii)).
 - You will need to produce a human readable copy of any reports sent to FDA if requested by an investigator.



Submitting eMDRs to FDA

WebTrader Account

- Obtain a Web Trader Account from the ESG.
- Detailed instructions are accessible via FDA's "Setting up a Web Trader Account Checklist" webpage.
- Contact ESGHelpDesk@fda.hhs.gov in order to:
 - Request a WebTrader account.
 - Request assistance with the registration or testing process.
 - Ask policy questions.

Poll #2

DEV-D2S7 Poll #2

View Votes
Edit
End Poll

Does your company have a WebTrader Account?

<input type="radio"/> Yes		0%	(0)
<input type="radio"/> No		0%	(0)
<input type="radio"/> I do not know what WebTrader is		0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

Electronic Submission Gateway (ESG)

- The FDA ESG is the central transmission point for sending information electronically to the FDA. ESG then relays the product specific report to the appropriate FDA center
- Digital certificate required for submitters.
- A secure entry point for all electronic submissions to the Agency.

Electronic Submission Gateway (ESG)

- Acknowledgment 1: Indicates submission was received at the FDA ESG.
- Acknowledgment 2: Indicates submission reached CDRH.
- Acknowledgment 3: Indicates submission was successfully loaded into MAUDE or that submission contained errors.
- If there are no errors, the three acknowledgment letters will be generated within **24 hours** of submission.

Electronic Submission Gateway (ESG)

- Contact the ESG Staff at ESGHelpDesk@fda.hhs.gov if the ESG system status website indicates the ESG is operating normally and you did not receive Acknowledgment 1 or 2.
- Contact eMDR@fda.hhs.gov if:
 - the eMDR System Status website indicates that eMDR is operating normally and you did not receive Acknowledgment 3.
 - help is needed to interpret Acknowledgment 3 error messages for an adverse event reports submitted to CDRH.

eSubmitter



- Standard software that eases the technical burden.
- This option is suitable for reporters that want to submit MDRs individually.
- Software generates an electronic version of Form 3500A in zip file format that is sent via ESG. Attachments can be included with submission.
- Please utilize the link in the “Resources Websites” section for the eSubmitter software and instructions for installation.

Health Level Seven (HL7)

- Standard for the capture of the information needed to support the submission of MDR reportable events.
- eMDRs can be submitted in large batches or one at a time.
- Allows for the extraction of information directly from the reporter's database to populate an eMDR and for the transmission of the eMDR to the FDA ESG.

Health Level Seven (HL7)

- Firms may choose to develop a custom eMDR solution using HL7.
- Firms are encouraged to develop capabilities for saving and printing submitted reports and the submission of attachments.
- Please utilize the link in the “Resources Websites” section for additional information regarding HL7.

Other considerations

- FDA considers an MDR report filed as of the date it is accepted at the ESG, as long as the report is later accepted by the CDRH database. The date of the report is the local date (not the hour) similar to the postmark date used for mailed paper reports.
- If a submitter is unable to submit a report on time due to an outage affecting the ESG or eMDR processing system, then the submitter may document its attempts at timely filing in Block H10.

Other considerations

- Updating a report. For all updates, you should include the initial report number and state that the type of submission is a follow-up report. Limit your additional entries to those where you need to update or correct previously provided information.
- Third-party companies can submit eMDRs on client's behalf if the third-party company has permission from the client. A third-party company may not use its client's WebTrader account to submit the reports and will instead have to use its own WebTrader account to submit eMDRs.

Summary

- Please do NOT wait until your company receives an MDR reportable complaint to get an ESG account!
- The method for submitting MDRs to FDA has changed; other MDR requirements generally have not changed.
- eSubmitter & HL7 are two methods to submit eMDRs to FDA.

Resource Websites

- Medical Device Reporting (MDR):
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>
- Guidance Document: Medical Device Reporting for Manufacturers:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm>
- eMDR Final Rule:
<http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03279.pdf>
- eSubmitter Download and Installation
<http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>
- Health Level Seven (HL7) Individual Case Safety Reporting
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/ucm127948.htm>
- Setting up a Web Trader Account Checklist:
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Questions?

- **General MDR questions: Division of Industry and Consumer Education (DICE)**

Email: DICE@fda.hhs.gov

Phone: (800) 638-2041

(301) 796-7100

- **Interpretations on MDR policy: MDR Policy Group**

Phone: (301) 796-6670 (voice)

Email: MDRPolicy@fda.hhs.gov

Please complete the session survey:

surveymonkey.com/r/DEV-D2S7