



# Medical Device Reporting 21 CFR Part 803

**November 4, 2014**

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# Learning Objectives

- Learn the basics of the Medical Device Reporting (MDR) Regulation
- 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)



# Medical Device Reporting (MDR) Regulation (21 CFR 803)



# Authority for Medical Device Reporting

- The Federal Food, Drug, and Cosmetic Act, Section 519 (Records and Reports on Devices) grants the FDA authority to require mandatory medical device reports from:
  - Manufacturers
  - Importers
  - Device User Facilities
  
- A report does NOT constitute an admission that the device, reporting entity, or the entity's employee caused or contributed to the reportable event.



# When do MDR Requirements Apply?

## MDR Reportable Events:

1. User facilities report when they become aware of information that reasonably suggests that a device may have caused or contributed to a patient death or serious injury.
2. Manufacturers or importers report when they become aware of events that reasonably suggest that one of their marketed devices:
  - May have caused or contributed to a death or serious injury, or
  - Malfunctioned and ... would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.



## Report Types and Timeframes

Mandatory reporting timeframes begin on the day after the user facility, importer or manufacturer becomes aware of a reportable event.

Additionally, for manufacturers, the reporting timeframes for:

- 5-day reports begin on the day after becoming aware of a request from FDA for 5-day reports or identification of a remedial action.
- Supplemental or Follow-up reports begin the day after a manufacturer acquires the additional/corrected information.



REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr.)	Deaths, Serious Injuries, Malfunction	FDA	Within 30 calendar days
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days
	Supplements (Follow-up Reports)	FDA	Within 1 month
User Facility	Deaths	FDA and Mfr.	Within 10 working days
	Serious Injury	Mfr. (FDA if unknown)	Within 10 working days
Importer	Deaths and Serious Injuries	FDA and Mfr.	Within 30 calendar days
			Within 30 calendar days



# **Medical Device Reporting: Electronic Submission Requirements: Final Rule**





# eMDR Final Rule

- Requirements of final rule will take effect on **Aug 14, 2015**
- Manufacturers must submit initial and supplemental reports to FDA in an electronic format that FDA can process, review, and archive.
- Importers must also submit initial reports to FDA in an electronic format.
- User facilities will continue to submit reports to FDA and the manufacturer in a paper format on FDA Form 3500A.
- The final rule does not change what must be included in a report or when the report should be submitted.



# eMDR Final Rule

## 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)).



# Electronic Medical Device Reports (eMDRs) to FDA



# Electronic Submission Gateway

## 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
- A secure entry point for all electronic submissions to the Agency.
- Digital certificate required for submitters.



# Electronic Submission Gateway

- 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

- Contact the ESG Staff at [ESGHelpDesk@fda.hhs.gov](mailto: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](mailto: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.



# Web Trader

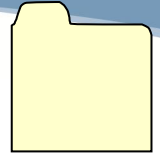
- Obtain a Web Trader Account from the ESG.
- Detailed instructions are accessible via FDA's "Setting up a Web Trader Account Checklist" webpage.
- For policy questions and to request a WebTrader account, contact [esgprep@fda.hhs.gov](mailto:esgprep@fda.hhs.gov).
- For assistance with the registration or testing process, contact [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov).



## eSubmitter

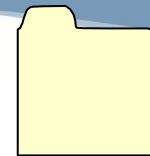
- Standard software that eases the technical burden.
- This option is suitable for reporters that want to submit MDRs individually.
- Software generates an electronic version of Form 3500A in zip file format that is sent via ESG. Attachments can be included with submission.
- Please utilize the link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

# Summary

- Please do NOT wait until **August 14, 2015** 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

- Draft Guidance Document: Medical Device Reporting for Manufacturers:  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm>
- eMDR - Electronic Medical Device Reporting Guidance Document:  
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm175805.htm>
- Medical Device Reporting: Electronic Submission Requirements Final Rule  
<http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03279.pdf>

# Resource Websites

- Electronic Submissions Gateway (ESG) - System Status  
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm367545.htm>
- eMDR System Status  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/ucm179299.htm>
- Setting up a WebTrader Account Checklist  
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

## Resource Websites

- 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>
- Medical Device Reporting (MDR) webpage  
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>

# Providing Industry Education

## Four Resources

### 1. CDRH Learn – Multi-Media Industry Education

- over 80 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

<http://www.fda.gov/Training/CDRHLearn>

### 2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance>



# Providing Industry Education

## Four Resources

### 3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- Phone: 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30 pm EST)

**Web Homepage:**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>



# Providing Industry Education

## Four Resources

### 4. MDR Policy Group: Interpretations on MDR policy & requests for exemptions

- Phone: (301) 796-6670 (voice)
- Email: [MDRPolicy@fda.hhs.gov](mailto:MDRPolicy@fda.hhs.gov)
- Or write to:
  - Food and Drug Administration
  - Center for Devices and Radiological Health
  - MDR Policy Branch
  - 10903 New Hampshire Avenue
  - WO Bldg. 66, Room 3217
  - Silver Spring, MD 20993-0002



# Thank you