U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!

We'll get started in a few minutes

Today's Topic:

In Vitro Diagnostic Products (IVDs) - MDR Requirements, Corrections and Removals Reporting Requirements, and Quality System Complaint Requirements

August 22, 2024

In Vitro Diagnostic Products (IVDs) - MDR Requirements, Corrections and Removals Reporting Requirements, and Quality System Complaint Requirements

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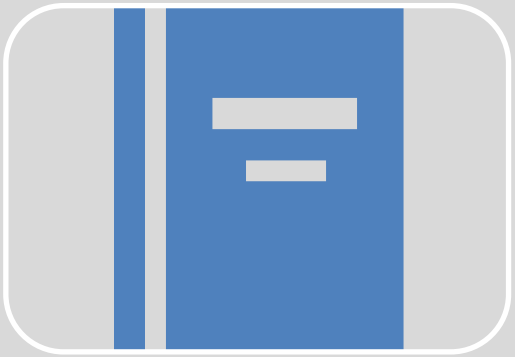
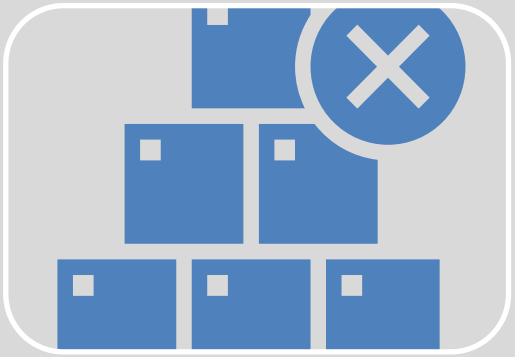
Phaseout Policy: Stage 1



MDR Requirements (21 CFR pt. 803)



Corrections and Removals Reporting Requirements (21 CFR pt. 806)

Complaint Files [Quality System Requirements] (21 CFR 820.198)

Gathering this information early in the phaseout period is particularly important for IVDs that do not have the safeguards associated with compliance with other FDA requirements (such as Quality System requirements and premarket review)

Why is Medical Device Reporting Important?

Transparency for patients and providers regarding adverse events and malfunctions associated with tests upon which they rely

Complaints enable developers to identify problems with tests
(for example, design or manufacturing problems)

Complaints can provide developers with valuable customer feedback
(for example, device performance or ideas for future design changes)

Help FDA identify specific tests that raise concerns
(for example, concerns regarding insufficient validation or inaccurate results)

Enable FDA to track and trend data to detect issues that a single laboratory may never see

Process Overview

Complaint received

or

Issue with device identified

Follow internal procedures (including complaints, MDRs, corrections and removals)

Determine whether complaint, issue, or correction or removal is reportable to FDA

Report to FDA (when required)

Maintain records

Quality System Complaint Requirements

What is a Quality System?

A Quality System is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management

The requirements in the Quality System Regulation govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use

Quality System Regulation
21 CFR 820
(QS Regulation)

- General
- QS Requirements
- Design Controls
- Document Controls
- Purchasing Controls
- Identification & Traceability
- Production & Process Controls
- Inspection, measuring, and test equipment

Quality System
Stage 3

- Acceptance Activities
- Non-conforming Product
- Corrective & Preventative Action
- Labeling & Packaging Control
- Handling, Storage, Distribution, & Installation
- Records*
- Servicing
- Statistical Techniques

Complaints
Stage 1

CFR = Code of Federal Regulations

Why is a Quality System Important?

A quality system specifies requirements to help manufacturers ensure that their products consistently meet applicable customer and regulatory requirements and specifications.

A quality system is a mandatory and flexible framework.

A quality system requires manufacturers to develop and follow procedures and processes, as appropriate to a given device, according to the current state-of-the-art for manufacturing and designing such a device.

Successful compliance with this regulation provides the manufacturer with a framework for achieving quality throughout the organization.

Definitions

Manufacturer

Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the function of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions. (21 CFR 820.3(o))

Complaint

Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. (21 CFR 820.3(b))

Complaint File Requirements

Each manufacturer is required to:

Maintain complaint files.

Establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit.

The procedure(s) *shall* ensure that:

All complaints are processed in uniform and timely manner;

Oral complaints are documented upon receipt; and

Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting.

Complaint Investigation

Each manufacturer must review and evaluate **all** complaints to determine whether an investigation is necessary

Investigation may or may not be required

If no investigation is made, the manufacturer must document the reason for not conducting an investigation and the name of the individual responsible for that decision.

An investigation is necessary for **any** complaint involving possible failure of a device, labeling, or packaging to meet **any** of its specifications

Investigation required

Unless a similar complaint has already been investigated, and another investigation is not necessary; document and retain rationale.

Complaint Investigation Records

Required documentation includes:

The name of the device

The nature and details of the complaint

The date the complaint was received

The dates and results of the investigation

Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used

Any corrective action taken

The name, address, and phone number of the complainant

Any reply to the complainant

Complaints Deemed Reportable

Required to be promptly reviewed, evaluated, and investigated

Required to be maintained in a separate portion of the complaint files (or otherwise clearly identifiable)

Contain the requirements of 21 CFR 198(e) and a determination of:

1. Whether the device failed to meet specifications;
2. Whether the device was being used for treatment or diagnosis; and
3. The relationship, if any, of the device to the reported incident or adverse event.

Complaint Files Accessibility

Records must be available to the test developer

- When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

Records must be available in the United States

- Can be at a U.S. location where the manufacturer keeps records; or
- The location of the initial distributor

Amendments to the QS Regulation

The amended QS Regulation incorporates by reference ISO 13485

Under the phaseout policy in the preamble to the LDT Final Rule, FDA intends to exercise enforcement discretion for complaint file requirements for developers that are in compliance with complaint requirements under ISO 13485

The scope of ISO 13485 is substantially similar the QS Regulation for Complaints:
→ If a lab complies with the current QS Regulation for QS Complaints, they will meet the amended QS Regulation requirements for QS Complaints

May 6, 2025:
LDT Final Rule
Stage 1 phaseout policy:
Compliance with QS Complaints

February 2, 2026:
Effective date for amended QS Regulation

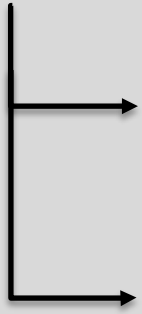
May 6, 2027:
LDT Final Rule
Stage 3 phaseout policy:
Compliance with other QS requirements

Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions | FDA

Medical Device Reporting (MDR) Requirements

What is an MDR Reportable Event?

An event that manufacturers become aware of ***that reasonably suggests*** that one of their marketed devices:



May have ***caused or contributed*** to a death or ***serious injury***, OR

Has ***malfunctioned*** and that the device or a similar device marketed by the manufacturer would ***be likely to cause or contribute to*** a death or serious injury if the malfunction ***were to recur***

Adverse Events

Serious Injury or Illness

Life threatening; or

Results in permanent impairment or damage to a body function or structure; or

Requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure

Malfunction

The failure of a device to meet its performance specifications or otherwise perform as intended

- Performance specifications include all claims made in the labeling for the device
- The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in 21 CFR 801.4

Reportable malfunctions are malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur

Mandatory Reporting Timeframes for Manufacturers

Deaths, Serious Injuries

- To FDA, within 30 calendar days of becoming aware of an event

Malfunctions

Individual Reports:

- To FDA, within 30 calendar days of becoming aware of an event

Summary Reports:

- To FDA, quarterly (VMSRP) if eligible and self-selected

Remedial Actions

An event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health

- To FDA, within 5 business days of becoming aware of an event

Supplements: To FDA, within 30 calendar days

VMSRP = Voluntary Malfunction Summary Reporting Program

What You Need in Order to Submit

FEI Number

- The Facility FEI (FDA Establishment Identifier) Number data element is a number assigned by the FDA for tracking inspections
- The FEI number can be requested at no cost from FDA at feiportal@fda.hhs.gov

Device Product Code

- Classification product codes are a method of classifying and tracking medical devices
- Are used for internal tracking purposes, such as adverse event monitoring or compliance actions
- Are assigned and maintained by the Agency

Adverse Event Codes

- 7 Categories
- Required to submit at least one code per category
- Select the lowest level, most detailed code or codes necessary to describe the event

How to Code an MDR Adverse Event Report | FDA

How to Request an FEI Number

You can request one by contacting feiportal@fda.hhs.gov and providing the following information:

- The legal name of the firm being registered;
- Whether you are representing the firm as an Agent (third party);
- Any alternate firm names, including those used for "doing business as" purposes;
- The physical address of the firm being registered;
- The designated mailing address for the firm being registered;
- The name and contact information of the designated contact person at the facility being registered;
- A comprehensive list of activities conducted at this specific location;
- Any registration numbers associated with other FDA Centers (if applicable);
- Any former names the firm was known by; and
- Any previous addresses linked to the firm.

LDT Product Codes

SCE

IVD offered as LDT, first marketed before May 6, 2024, not modified beyond scope described in preamble to LDT Final Rule

Currently marketed in vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that were first marketed prior to May 6, 2024, and not modified following that date or not modified beyond the scope described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCF

LDT, unmet need within an integrated healthcare system

Laboratory developed tests (LDTs) manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system as described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCG

Modified version of another manufacturer's FDA-authorized test within scope described in preamble to LDT Final Rule

When a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meeting CLIA's regulatory requirements to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, and in compliance as described in section V.C.3 of the preamble to the LDT Final Rule, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification as described in sections V.C.4 and V.C.5 of the preamble to the LDT Final Rule (89 FR 37286).

LDT Product Codes

SCH	**LDT, approved by NYS CLEP** Laboratory developed tests (LDTs) that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP) described in section V.B.2 of the preamble to the LDT Final Rule (89 FR 37286).
SCI	**IVD offered as LDT, not an LDT or under a targeted enforcement discretion policy described in preamble to LDT Final Rule** In vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that are not designed, manufactured, and used within a single laboratory, are within the scope of the phaseout policy and are not subject to a targeted enforcement discretion policy described in the preamble to the LDT Final Rule (89 FR 37286).
SCJ	**LDT, not under a targeted enforcement discretion policy described in preamble to LDT Final Rule** Laboratory developed tests (LDTs) within the scope of the phaseout policy and not subject to a targeted enforcement discretion policy described in section V.B of the preamble to the LDT Final Rule (89 FR 37286).
SCK	**LDT, Non-molecular antisera for RBC antigens when there is no alternative IVD** Non-molecular antisera laboratory developed tests (LDTs) for rare red blood cell (RBC) antigens when manufactured and performed by blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative in vitro diagnostic product (IVD) available to meet the patient's need for a compatible blood transfusion within the scope described in Section V.B.3 of the preamble to the Final LDT Rule (89 FR 37286).

Adverse Event Codes

Device Codes	**Medical Device Problem:** Annex A	Problems (malfunction, deterioration of function, failure) of medical devices
	Medical Device Component: Annex G	The parts and components which were involved in, or affected by, the medical device adverse event/incident.
Evaluation Codes	**Cause Investigation - Type of Investigation:** Annex B	What was investigated and what kind of investigation was conducted to specify the root cause of the adverse event.
	Cause Investigation - Investigation Findings: Annex C	The findings in the specific investigation that are the keys to identify the root cause of the event.
	Cause Investigation - Investigation Conclusion: Annex D	The conclusion regarding the root cause of the reported event.
Patient Codes	**Health Effects - Clinical Signs and Symptoms or Conditions:** Annex E	The clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident.
	Health Effects - Health Impact: Annex F	The consequences of the medical device adverse event/incident on the person affected.

eMDR Account Setup

How to Enroll in eMDR Program

1. **Choose how you plan to submit your MDRs**
   - **Can choose whatever best suits your needs**
2. **Follow the enrollment process for the method you choose**

Low-volume submitters report a new MDR electronically by using eSubmitter to create a MedWatch 3500A electronic submission zip file and then logging into the WebTrader internet site to submit the file.

High-volume submitters use their own AS2 gateway software systems to submit MDRs electronically.

eMDR Account Setup

1. Request Electronic Submissions Gateway (ESG) WebTrader Account

- Setting up a WebTrader Account Checklist
- ESG User Portal

Submission Summary	
Environment:	Ack3: This submission has been sent to the TEST system and has been processed by the FDA. Please refer to the Summary section below to determine if this submission has passed or failed.
Submission Type:	Form 3500A - ICSR R2
Core ID:	ci1650401571231.99858@fdslv05766 te1
Batch ID:	1057985-20220419165242
Date Entered:	Tue Apr 19 16:55:42 EDT 2022
Summary:	passed: 1, Failed: 0

Report List:	
Report Number:	1057985-2021-05106, passed.

3. Submit Complaint Test Submission through WebTrader: Tutorial

4. Send a copy of the "pass" acknowledgement (Ack3) to the eMDR HelpDesk (eMDR@fda.hhs.gov) and request approval for a production account

eMDR Submission Process

1. Create the MDR in eSubmitter

- Use your assigned FDA Establishment Identifier (FEI) number
- Prepare and package into .zip file

2. Submit the MDR through WebTrader: Tutorial

- Log into WebTrader Production using the same credentials as Test
- Click “Send Document” to begin the submission process
- Select “Adverse Events” as the submission type and submit the .zip file generated by eSubmitter
- Will receive 3 acknowledgements; confirm the Ack3 (the HTML file) shows “Pass”

3. Save Acknowledgment 3 (Ack3) in internal MDR event files for the corresponding complaint

eSubmitter Best Practices

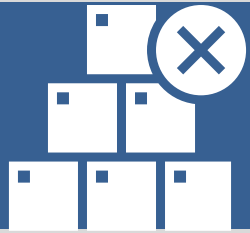
Only submit a zip file generated by FDA's eSubmitter application.

Ensure that you send the zip file, and not a folder containing the zip file in WebTrader.

The ZIP file generated by eSubmitter should not be altered in any way prior to transmitting to FDA.

eMDR is only reachable through WebTrader; you cannot mail a CD or submit through eSubmitter.

Corrections and Removals Reporting Requirements



Device Problem Identified

Problem Identified

Could come from:

- Complaint(s)
- Internal quality check(s)
- Other

Investigate the Problem

What is the cause?

What is the scope?

- Are other lots impacted?
- Are other products impacted?

Determine Actions and Next Steps

- To fix the problem
- To prevent recurrence
- Is the correction or removal reportable to FDA?

What is a Recall?

Recalls are actions taken by a manufacturer to **remove** or **correct** a marketed device that:

- FDA considers in violation of the laws it administers; and
- Against which FDA would initiate legal action

Removal

The physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection

Correction

The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location

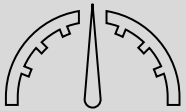
FDA Recall Classifications

Relative degree of health hazard presented by the product being recalled

Class 1

Reasonable probability that the use of, or exposure to, a violative product **will cause serious adverse health consequences or death**

Report Required



Class 2

Use of, or exposure to, a violative product **may cause temporary or medically reversible adverse health consequences** or where the probability of **serious adverse health consequences is remote**

Report Required

Class 3

Use of, or exposure to, a violative product is **not likely to cause adverse health consequences**

Record Keeping Required

Manufacturer Recall Steps

Decide to correct or remove the device

Plan a recall strategy

Notify stakeholders

- Consignees (Customers, Healthcare Professionals & Patients as needed)
- Submission to FDA

Plan for what to do with the device

(e.g., modify the test system)

Conduct effectiveness checks

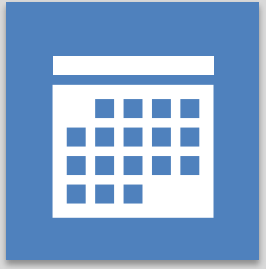
- Have consignees received notification?
- Have they acted appropriately?

Provide status reports to FDA

Manufacturer Notification to Consignees

- Communicate that the product in the consignee's possession is the subject of a recall
  - Include complete product identification, such as lot number, size, model, UDI
- Outline the reason for the recall and health risk
- Provide instructions to return or correct the product
  - For example, indicating to physicians that they should not use a test result
- Include a way to verify effectiveness of notification strategy
  - For example, asking physicians to confirm receipt of the notification

Manufacturer Notification to FDA



Report within 10 days

1. Email report (806 report) to relevant recall division
2. May use eSubmitter

→ Consider using the new Correction and Removal Fillable Form

Submit to your relevant recall division:

ORADevices1Recalls@fda.hhs.gov - CT; DC; DE; IN; KY; MA; MD; ME; MI; NH; NJ; NY; OH; PA; RI; VA; VT; WV

ORADevices2Recalls@fda.hhs.gov - AL; FL; GA; IA; IL; KS; LA; MN; MO; MS; NC; ND; NE; PR; SC; SD; TN; US Virgin Islands; WI

ORADevices3Recalls@fda.hhs.gov - AK; AR; AZ; CA; CO; HI; ID; MT; NM; NV; OK; OR; TX; UT; WA; WY

Must provide:

- Report number (can use FEI number)
- Name, address, and telephone of the recalling and manufacturing firm(s)
- Names and intended use of the product, marketing status, identifying numbers (catalog & lot number, UDI)
- Reason for removal, any injuries
- Actions taken and to be taken
- Quantity of product distributed
- Distribution dates, expiration date, consignees' information
- Copy of related communications to consignees

FDA Recall Responsibilities

FDA Division Recall Coordinator

- Receives your status reports
- Terminates the recall, based on effectiveness

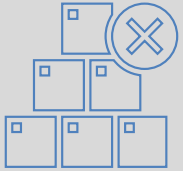
CDRH Reviews and Classifies

- Does the notice to consignees explain the problem?
- Does the strategy mitigate risk?
- What is the severity & probability of harm?

Recall is posted on fda.gov

Recall Summary

Recalls are classified based on the relative degree of health hazard presented by the product being recalled



Class I and Class II recalls must be reported to FDA

Reports of Correction or Removal may be submitted via email or eSubmitter

Case Studies

Case Study – MDR

Event	Complaint received from clinician: Patient's negative test result did not match clinical symptoms
Immediate Action	Test developer enters complaint into Complaint handling system and begins an investigation
Complaint Investigation	Investigation, including re-testing: result was inaccurate (real result=high positive) due to a problem with one of reagents
	For this test, treatment based on a false negative result may lead to significant consequences for the patient (delay in critical therapy, or inappropriate therapy leading to decompensation)
FDA Report	Device malfunction: likely to cause or contribute to a death or serious injury if the malfunction were to recur Event should be reported to FDA as an MDR





Case Study – Recall

Background	LDT contains buffer reagent; designed & validated expiration date of 3 months from manufacture (when stored at room temp)
Event	While this buffer is in use as part of the LDT, control runs begin to fail and the lab investigates
Investigation	The developer determines that the buffer has become contaminated, even though it has only been in use for 2 months
Immediate Action	The developer cannot determine when the contamination began, and initiates corrective actions, including: → Evaluating all test results run while this buffer lot was in use, and correcting any inaccurate results that were reported → Discarding the remainder of the contaminated buffer → Redesigning the buffer to include preservatives to better prevent contamination
FDA Report	Developer reports these actions to FDA in an 806 Report because they were taken to address a test which did not meet specifications and to reduce a risk to health related to inaccurate results

Next Webinar

[Laboratory Developed Tests | FDA]

Date
September 24, 2024

Time
1:00-2:00 PM ET

Topic
Labeling Requirements for In Vitro Diagnostic Products (IVD), Including LDTs, Under 21 CFR 809.10(b)

Please submit questions in advance to:
CDRHWebinars@fda.hhs.gov

Resources and References

Slide Number	Resource	URL
4, 5, 6, 18	Final Rule Regarding LDTs	www.federalregister.gov/public-inspection/2024-08935/medical-devices-laboratory-developed-tests
8	Quality System Regulation	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
8	Quality System Requirements	www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp
11-16	Complaints Files (Presentation)	www.fda.gov/media/109411/download
11-16	Complaint Requirements	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.198
17	Final Rule: Medical Devices; Quality System Regulation Amendments	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments
17	Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions	www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp/quality-management-system-regulation-final-rule-amending-quality-system-regulation-frequently-asked
19-29	Medical Device Reporting Requirements	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803
22	How to Code an MDR Adverse Event Report	www.fda.gov/medical-devices/mdr-adverse-event-codes/how-code-mdr-adverse-event-report
26	MDR Adverse Event Codes	www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes
27	How to Enroll in eMDR program	www.fda.gov/medical-devices/emdr-electronic-medical-device-reporting/how-enroll-emdr-program
27	Health Level Seven (HL7) Individual Case Study Report (ICSR)	www.fda.gov/medical-devices/emdr-electronic-medical-device-reporting/health-level-seven-hl7-individual-case-study-report-icsr
27	Health Level Seven (HL7) Individual Case Safety Reporting (ICSR) File	www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/health-level-seven-hl7-individual-case-safety-reporting-icsr-files

Resources and References

Slide Number	Resource	URL
28	Setting up a WebTrader Account Checklist	www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist
28	ESG Appendix C: Digital Certificates	www.fda.gov/industry/about-esg/esg-appendix-c-digital-certificates
28	Appendix G: Letters of Non-Repudiation Agreement	www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement
28	ESG User Portal	https://esgportal.fda.gov/
28	Install eSubmitter (video)	www.youtube.com/embed/dUBKVD9ksHw
28	eSubmitter and WebTrader Tutorial (video)	www.youtube.com/watch?v=EdKy5wl8F18
28	Setting up an AS2 Account Checklist	www.fda.gov/industry/create-esg-account/setting-as2-account-checklist
27-29	eMDR Implementation Package	www.fda.gov/media/120509/download
32-39	Medical Devices: Reports of Corrections and Removals	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806
32-39	Recalls, Corrections and Removals (Devices)	www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#5

Resources and References

Slide Number	Resource	URL
37	Electronic Submission of 806 Reports of Corrections and Removals	www.fda.gov/media/107333/download
37	Correction and Removal Fillable Form	www.fda.gov/media/174165/download
38	Enforcement Reports	www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
38	Medical Device Safety Communications	www.fda.gov/medical-devices/medical-device-safety
38	Recalls, Market Withdrawals, & Safety Alerts	www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

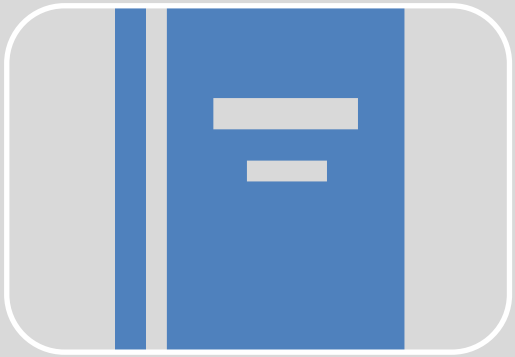
Topic	Resource	URL
MDRs	Overview of Medical Device Reporting	http://fda.yorkcast.com/webcast/Play/7885da0375b648bfb080f8c54d4c88561d
MDRs	Medical Device Reporting for Mandatory Reporters	http://fda.yorkcast.com/webcast/Play/de5daadc3c46467eb8a9b9f1ce9e156e1d
MDRs	Electronic Medical Device Reporting (eMDR)	http://fda.yorkcast.com/webcast/Play/409ff7c6e65b4ad1aaf69d73762caf2e1d
MDRs	Final Guidance on Medical Device Reporting for Manufacturers	www.youtube.com/watch_popup?v=Eo6uJjYKA5s
MDRs	Questions and Answers about eMDR - Electronic Medical Device Reporting – Guidance for Industry, User Facilities, and FDA Staff	www.fda.gov/media/76993/download
MDRs	Coding Resources for Medical Device Reports	www.fda.gov/medical-devices/mdr-adverse-event-codes/coding-resources-medical-device-reports

Resources and References

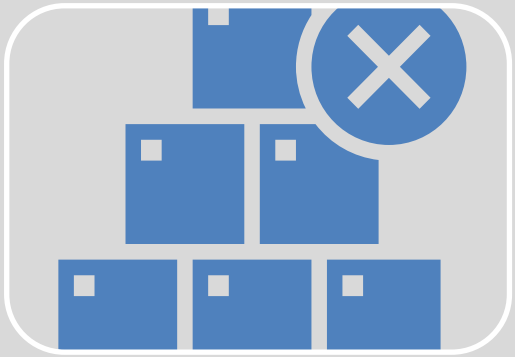
Topic	Resource	URL
Recalls	Distinguishing Medical Device Recalls from Medical Device Enhancements	www.youtube.com/watch_popup?v=ccgE5QD7Hcg
Recalls	Introduction to Medical Device Recalls: Industry Responsibilities	http://fda.yorkcast.com/webcast/Viewer/?peid=c830fc5a437d44b384fcefba1a59747c
Recalls	Recall Module 21 CFR Part 806: Medical Devices; Reports of Corrections and Removals	http://fda.yorkcast.com/webcast/Viewer/?peid=895f808c834f49bfbc230df241fe64501d
Recalls	Electronic Submission of 806 Reports of Corrections and Removals	www.fda.gov/media/105706/download
Recalls	Recall Communication: Medical Device Model Press Release	http://fda.yorkcast.com/webcast/Viewer/?peid=5cc9c724fd994989a32af7236c0a40711d
Recalls	Recall Communication: Medical Device Model Recall Notification Letter	http://fda.yorkcast.com/webcast/Viewer/?peid=c93236b6dd3d46468b9023bb0f6625381d
Recalls	Medical Device Recalls: Guidance for Industry	http://fda.yorkcast.com/webcast/Viewer/?peid=1b95461f64be40ecbe3415195cb394911d
Recalls	Recalls – 21 CFR 7, Subpart C	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7&showFR=1&subpartNode=21:1.0.1.1.6.3
Recalls	Medical Device Recall Authority – 21 CFR 810	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=810&showFR=1
QS Reg	Overview of the Quality System	http://fda.yorkcast.com/webcast/Play/4abbbeeb0f76423998cab8c782c3e4181d
QS Reg	Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions	www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp/quality-management-system-regulation-final-rule-amending-quality-system-regulation-frequently-asked

Summary

Phaseout Policy: Stage 1



MDR Requirements
(21 CFR pt. 803)



Corrections and Removals Reporting Requirements
(21 CFR pt. 806)

Complaint Files [Quality System Requirements]
(21 CFR 820.198)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Previously Submitted Questions

Thanks for Joining Today!

- **Presentation and Transcript will be made available**
  - CDRH Learn
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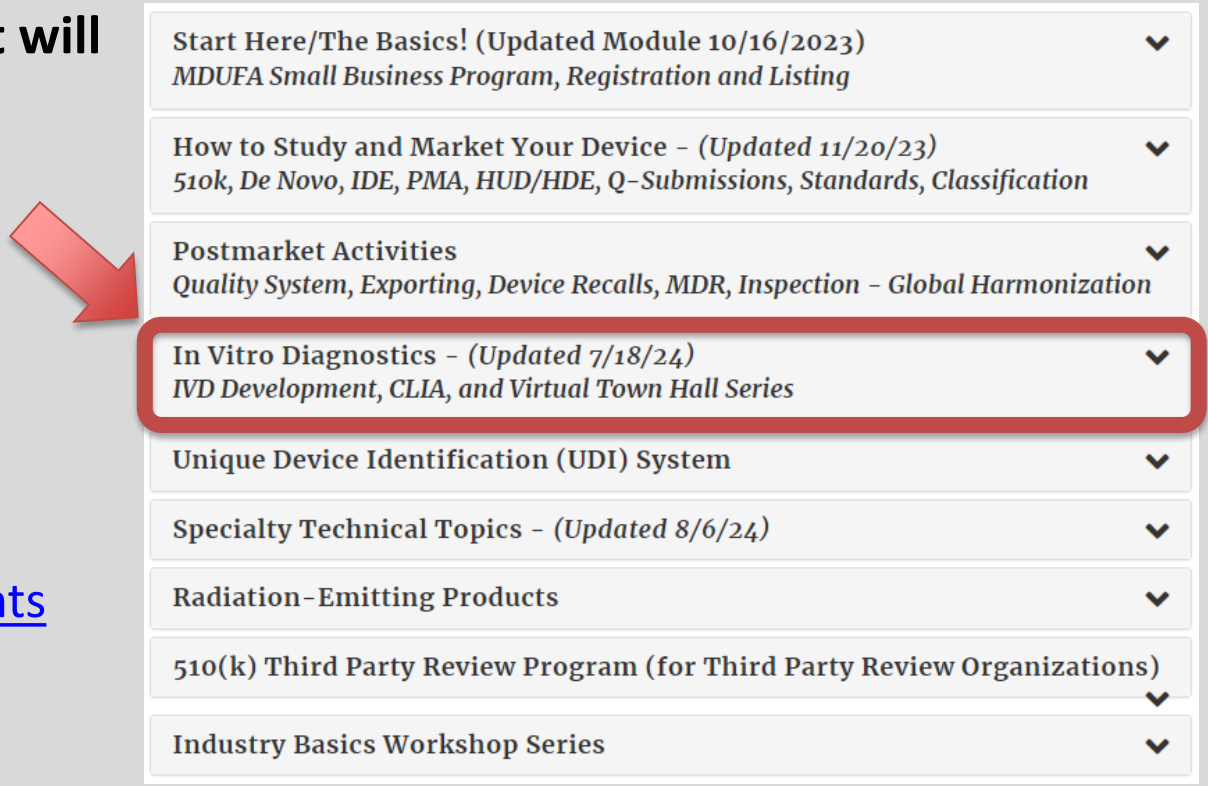
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHevents

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