Welcome to Today's Event

Thanks for joining us!

Today's Topic:

FDA's Quality Management System Regulation (QMSR): Medical Device Risk-Based Inspections

April 1, 2026

FDA's Quality Management System Regulation (QMSR): Medical Device Risk-Based Inspections

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Learning Objectives

- Identify Compliance Program updates related to the QMSR
- Describe medical device risk-based inspections
- Review inspection types and inspection models
- Explain after inspection strategy

Compliance Program Updates For QMSR

QMSR was effective on 2/2/2026

SHARE

FDA implements QMSR: Medical device inspections to be conducted under an updated process

On February 2, 2026, the FDA will begin implementing the Quality Management System Regulation (QMSR), which amends the Quality System Regulation (21 CFR Part 820). The FDA will discontinue use of the Quality System Inspection Technique (QSIT) for medical device inspections and will instead conduct inspections using the process described in the updated *Inspection of Medical Device Manufacturers Compliance Program (CP 7382.850)*. As of February 2, 2026, the FDA will no longer use *Inspection of Medical Device Manufacturers (CP 7382.845)* or *Medical Device PMA Preapproval and PMA Postmarket Inspections (CP 7383.001)*.

This action is part of implementing the amendments to 21 CFR Part 820, the Quality Management System Regulation. The action continues the FDA's efforts to align its regulatory framework with that used by other regulatory authorities to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients.

Learn More

Additional Resources:

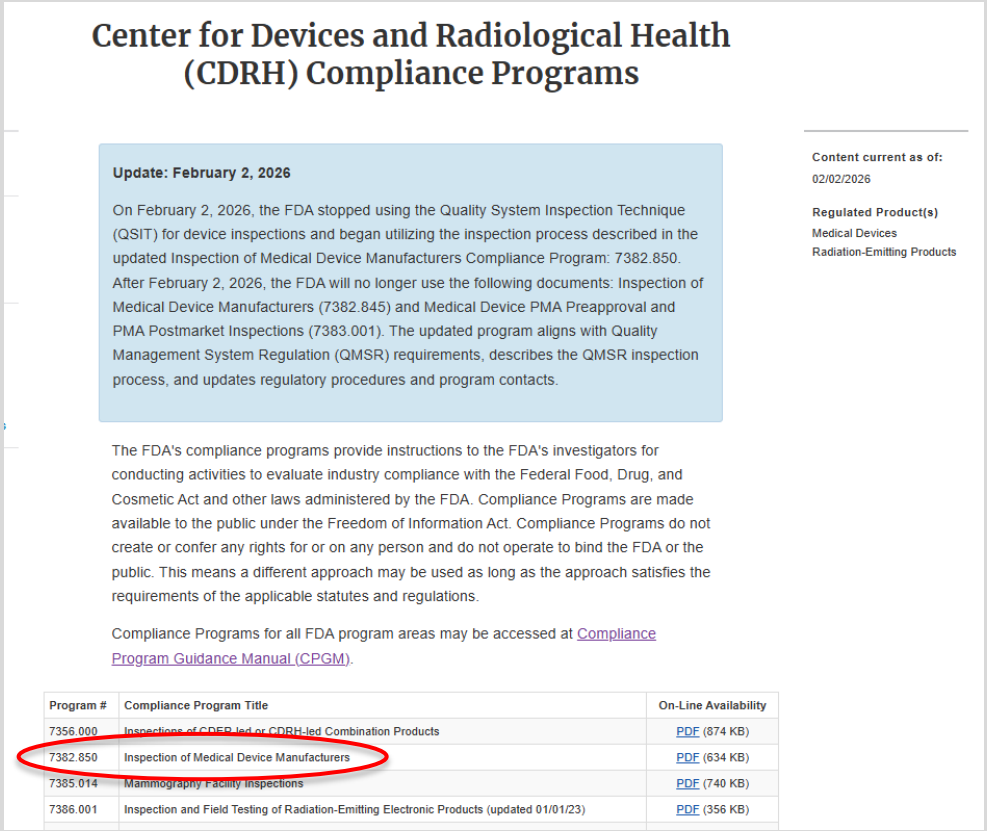
- Quality Management System Regulation – Frequently Asked Questions

Questions?

If you have questions, contact the Division of Industry and Consumer Education.

Compliance Program Update 7382.850

Includes QMSR aligned risk-based inspection process



Center for Devices and Radiological Health (CDRH) Compliance Programs

Update: February 2, 2026

On February 2, 2026, the FDA stopped using the Quality System Inspection Technique (QSIT) for device inspections and began utilizing the inspection process described in the updated Inspection of Medical Device Manufacturers Compliance Program: 7382.850. After February 2, 2026, the FDA will no longer use the following documents: Inspection of Medical Device Manufacturers (7382.845) and Medical Device PMA Preapproval and PMA Postmarket Inspections (7383.001). The updated program aligns with Quality Management System Regulation (QMSR) requirements, describes the QMSR inspection process, and updates regulatory procedures and program contacts.

Content current as of:
02/02/2026

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

The FDA's compliance programs provide instructions to the FDA's investigators for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by the FDA. Compliance Programs are made available to the public under the Freedom of Information Act. Compliance Programs do not create or confer any rights for or on any person and do not operate to bind the FDA or the public. This means a different approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations.

Compliance Programs for all FDA program areas may be accessed at Compliance Program Guidance Manual (CPGM).

Program #	Compliance Program Title	On-Line Availability
7356.000	Inspections of CDER-led or CDRH-led Combination Products	PDF (874 KB)
7382.850	Inspection of Medical Device Manufacturers	PDF (634 KB)
7385.014	Mammography Facility Inspections	PDF (740 KB)
7386.001	Inspection and Field Testing of Radiation-Emitting Electronic Products (updated 01/01/23)	PDF (356 KB)

Medical Device Risk-Based Inspections

Medical Device Risk-Based Inspections

The goal of FDA inspections of medical device manufacturers is to evaluate if the manufacturer's:

- Quality management system (QMS) meets FDA requirements and provides reasonable assurance that devices will be safe and effective
- Risk management and risk-based decision making are effectively used in the QMS

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part II

Medical Device Risk-Based Inspections

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Diagram 1

QMS Area Example: Management Oversight

Clauses refer to Clauses in ISO 13485:2016

Source: CP 7382.850 Inspection of Medical Device Manufacturers - Attachment A

Management Oversight QMS Area

Purpose:

To ensure top management:

- **Plans, establishes, and maintains an effective QMS that provides the necessary resources to design, manufacture, and distribute safe and effective medical devices.**
- **Uses risk management and risk-based decision making effectively in the QMS.**

QMS Area	Element	Requirements
	Quality Management System	Clauses 4.1.1, 4.1.2, 4.1.3, 4.1.4
	Risk-based Approach	Clause 4.1.2 b)
	QMS Software Validation	Clause 4.1.6
	Quality Manual	Clause 4.2.2
	Medical Device File	Clause 4.2.3
	Control of Documents and Records	21 CFR 820.35, 21 CFR 820.45, and Clauses 4.2.1, 4.2.4, 4.2.5
	Management Commitment	Clause 5.1
	Customer Focus	Clause 5.2
	Quality Policy, Quality Objectives, Quality Management System Planning	Clauses 5.3, 5.4.1, 5.4.2
	Responsibility, Authority, and Communication	Clauses 5.5.1, 5.5.2, 5.5.3
	Management Review	Clauses 5.6.1, 5.6.2, 5.6.3
	Provision of Resources	Clause 6.1
	Human Resources	Clause 6.2
	Planning of Product Realization	Clause 7.1

OAFR Example: Medical Device Reporting

OAFR	Purpose	Element	Requirements
 Medical Device Reporting	To ensure that device related deaths, serious injuries, and malfunctions have been identified, investigated, reported, and documented in a timely manner.	Medical Device Reporting	21 CFR 803, 21 CFR 820.10(b)(3)

OAFR: Other Applicable FDA Requirements

Source: CP 7382.850 Inspection of Medical Device Manufacturers - Attachment A

Medical Device Risk-Based Inspections

During a risk-based inspection, investigators:

- Use critical thinking and consider risk
- Become familiar with the manufacturer's roles, products, processes
- Identify product risks that could adversely impact patients and/or users and associated risk controls
- Review manufacturer's risk management documentation
- Evaluate requirements in selected elements within QMS Areas and OAFRs
- Determine if applicable requirements are met

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III

Medical Device Risk-Based Inspection Types and Inspection Models

Risk-Based Inspection Types

Inspection Type	Situation	Inspection Model
Non-baseline surveillance	• Previous FDA device inspection or MDSAP audit with final classification of NAI or VAI • Not currently enrolled in MDSAP	1
Baseline surveillance	• No FDA device inspection or MDSAP audit history • Risk factors indicate a need for evaluation • Not currently enrolled in MDSAP	2
Compliance follow-up	Previous FDA device inspection or MDSAP audit resulted in regulatory action, includes monitoring of post-injunction activities	1
For-cause	Signal, issue, or complaint	1
Specific Product Risk Assignment (SPRA)	Specific product risk identified	1
PMA preapproval	PMA application	2
PMA postmarket	Post PMA approval	1

Risk-based inspection types and associated inspection models

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 3

Inspection Model 1

For non-baseline surveillance, compliance follow-up, for-cause, specific product risk and PMA postmarket inspection types

Identify product risks that could adversely impact patients and/or users and evaluate, at minimum:

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 1

QMS Area: Change Control

Select at least one element

QMS Area: Design and Development

Select at least one element

QMS Area: Management Oversight

Select at least one element

QMS Area: Measurement, Analysis, and Improvement

Select at least one element

QMS Area: Outsourcing and Purchasing

Select at least one element

QMS Area: Production and Service Provision

Select at least one element

Inspection Model 1

For non-baseline surveillance, compliance follow-up, for-cause, specific product risk and PMA postmarket inspection types

OAFR: Medical Device Reporting

Select at least one element

OAFR: Reports of Corrections and Removals

Select at least one element

OAFR: Medical Device Tracking Requirements

Select at least one element

OAFR: Unique Device Identification

Select at least one element

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 1

Inspection Model 1

For non-baseline surveillance, compliance follow-up, for-cause, specific product risk and PMA postmarket inspection types

General Items:

- Registration and Listing
- Marketing Authorizations
- Previous 483/compliance issues
- Other areas as defined in assignment

Notes:

- Attachment A contains tables of QMS Areas, OAFRs, Elements, and Requirements.
- If MDSAP firm, discuss with supervisor before inspection

*If inspection reveals objectionable conditions or information cannot be adequately assessed through review of minimum requirements, consider selecting additional elements, as applicable.

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 1

Inspection Model 2

Baseline surveillance and PMA preapproval inspection types

Identify product risks that could adversely impact patients and/or users and evaluate, at minimum:

QMS Area: Change Control

Element: Product and Process Changes

QMS Area: Design and Development

Element: Design and Development Inputs

Element: Design and Development Outputs

Element: Design and Development Review

Element: Design and Development Verification

Element: Design and Development Validation

Element: Design and Development Software Validation

Element: Design and Development Transfer

QMS Area: Management Oversight

Element: Management Review

Element: Medical Device File

Element: Planning of Product Realization

QMS Area: Measurement, Analysis, and Improvement

Element: Analysis of Data

Element: Control of Nonconforming Product

Element: Complaint Handling

Element: Feedback

Element: Internal Audits

Element: Corrective Action

Element: Preventive Action

QMS Area: Production and Service Provision

Element: Validation of Processes for Production and Service Provision

Element: Control of Production and Service Provision

Element: Identification and Traceability

Element: Sterile Medical Devices and Validation Processes for Sterilization and Sterile Barrier Systems

QMS Area: Outsourcing and Purchasing

Element: Outsourcing

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 2

Inspection Model 2

Baseline surveillance and PMA preapproval inspection types

OAFR: Medical Device Reporting

Select at least one element

OAFR: Reports of Corrections and Removals

Select at least one element

OAFR: Medical Device Tracking Requirements

Select at least one element

OAFR: Unique Device Identification

Select at least one element

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 1

Inspection Model 2

Baseline surveillance and PMA preapproval inspection types

General Items:

- Registration and Listing
- Marketing Authorizations
- Previous 483/compliance issues
- Other areas as defined in assignment

Notes:

- Attachment A contains tables of QMS Areas, OAFRs, Elements, and Requirements.
- If MDSAP firm, discuss with supervisor before inspection.

*If inspection reveals objectionable conditions or information cannot be adequately assessed through review of minimum requirements, consider selecting additional elements, as applicable.

Source: CP 7382.850 Inspection of Medical Device Manufacturers Part III, Figure 2

After Inspection Strategy

After Inspection Strategy

- Determine:
  - Overall inspectional findings
    - Situation I
    - Situation II
  - Inspection classification
    - No Action Indicated (NAI)
    - Voluntary Action Indicated (VAI)
    - Official Action Indicated (OAI)
  - Appropriate regulatory action

Situation 1 Examples

Examples of situations that may result in FDA action following an FDA medical device risk-based inspection:

- Failure to establish, implement, and/or maintain one or more processes for risk management in product realization.

- Information gathered through the feedback process and/or postmarket surveillance is not used as potential input(s) into risk management for monitoring and maintaining the product realization or improvement processes.

Note: Additional examples in CP 7382.850 Part V Regulatory/Administrative Strategy

Situation 2 Examples

Examples of less significant deviations that may have minimal or no public health impact:

- The inspection documents QMSR deficiencies of a quantity and/or type to conclude that there is low probability that nonconforming product and/or defective devices will be produced

Inspection Classification

- No Action Indicated (NAI)
  - No objectionable conditions or practices observed
- Voluntary Action Indicated (VAI)
  - Objectionable conditions were observed, but do not meet the threshold for regulatory action
- Official Action Indicated (OAI)
  - Objectionable conditions were observed, and regulatory action is recommended

Examples of Regulatory Actions

- Advisory Actions
  - Untitled Letter
  - Warning Letter
- Regulatory Meeting
- Administrative Actions
  - Civil Money Penalty
  - 518 (e) Recall Authority
- Judicial Actions
  - Seizure
  - Injunction
  - Prosecution

Resources

Slide Number	Cited Resource	URL
4	Center for Devices and Radiological Health (CDRH) Compliance Programs	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/center-devices-and-radiological-health-cdrh-compliance-programs
4	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-a

Summary

- Beginning on February 2, 2026 and after:
  - FDA is no longer using the Quality System Inspection Technique (QSIT) for device inspections
  - FDA follows the updated compliance program 7382.850, for inspections of medical device manufacturers
  - Compliance Programs 7382.845 and 7383.001 are no longer in use


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Additional Panelists

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Panel Discussion

Your Call To Action

- Implement the QMSR and ensure you are meeting the requirements

- Review the updated Inspection of Medical Device Manufacturers Compliance Program, 7382.850, for information on the medical device risk-based inspection process and regulatory strategy

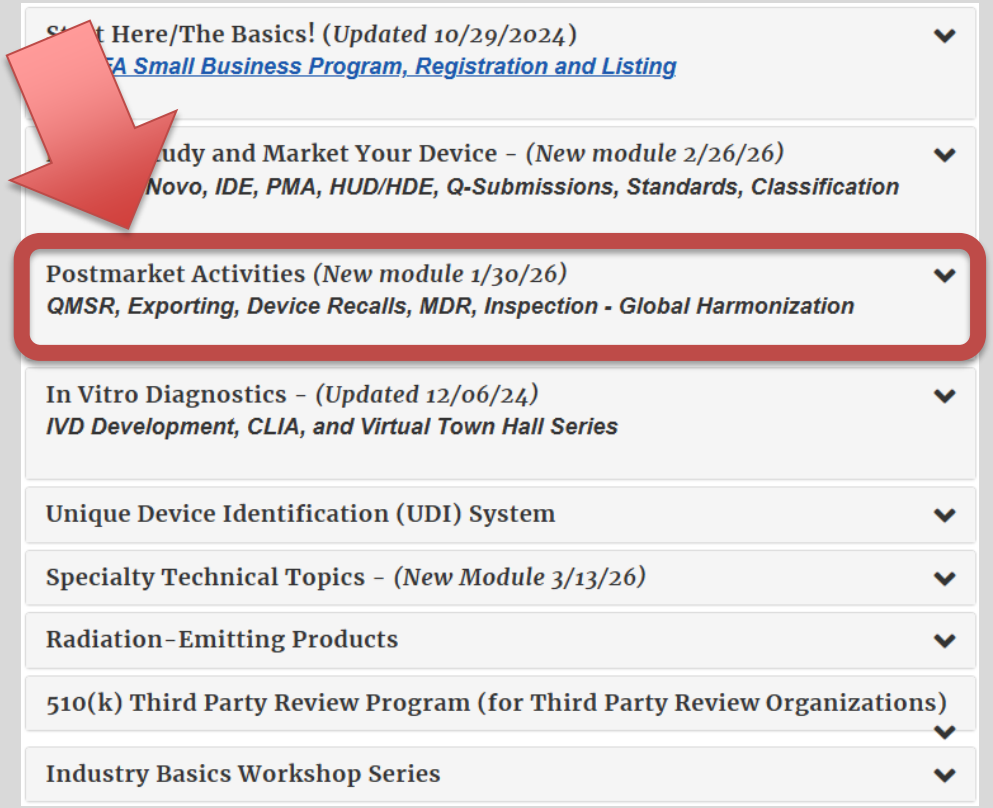
  Center for Devices and Radiological Health (CDRH) Compliance Programs | FDA

- Review the QMSR Frequently Asked Questions (FAQs)

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

Thanks for Joining Today!

- **Presentation, Slides and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Specific questions about the final rule**
  - Email: QMSR-Rule@fda.hhs.gov
- **General Medical Device question**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHEvents

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