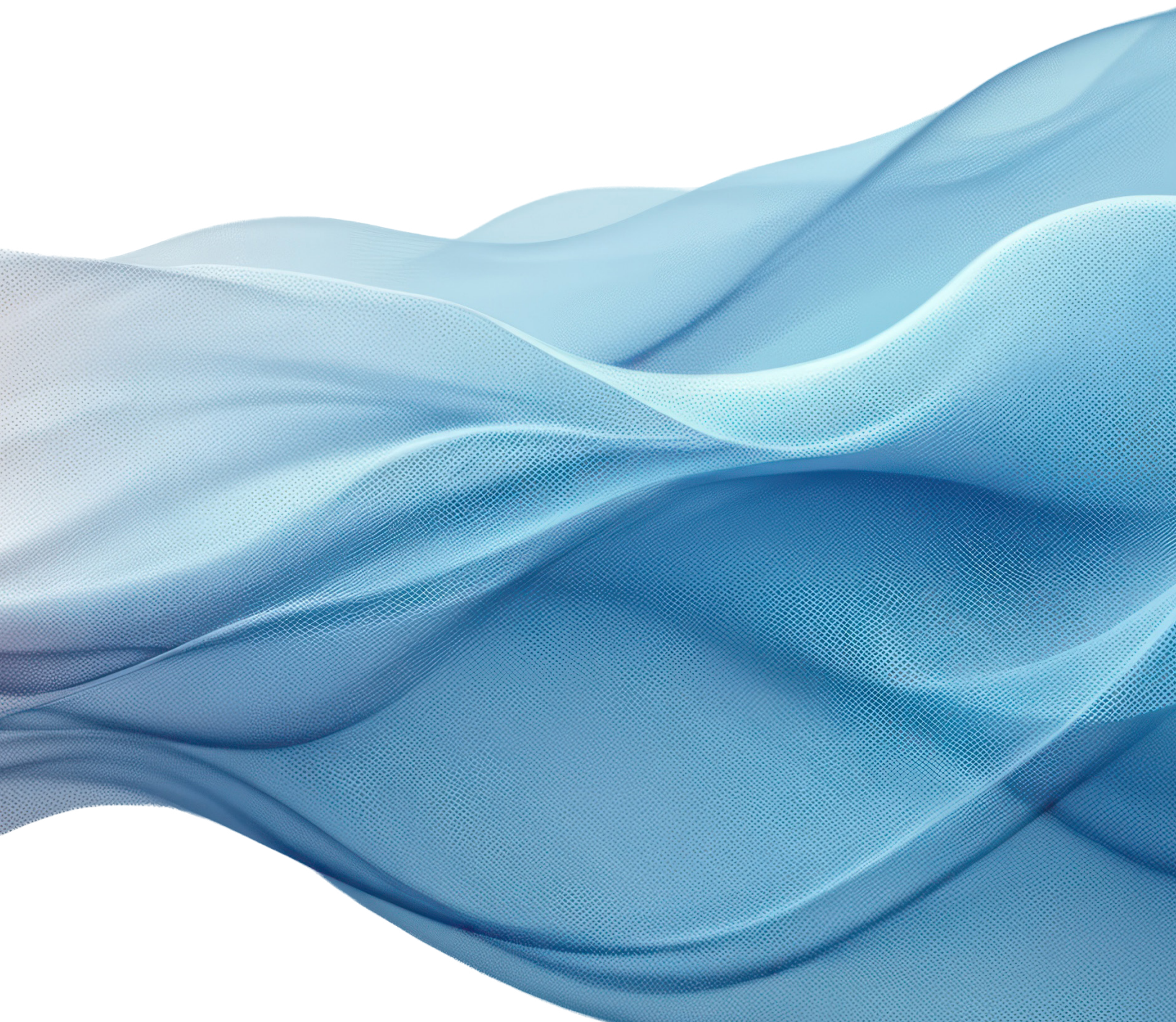
QualityHub Brief

INTERPRETING FDA'S QMSR COMPLIANCE PROGRAM

FDA Inspection Types & Corresponding Models



About This QualityHub Brief

The US Food and Drug Administration (FDA) has transitioned to the Quality Management System Regulation, or QMSR, and medical device companies are working to understand how this shift affects inspection practices. "Interpreting FDA's QMSR Compliance Program: FDA Inspection Types & Corresponding Models" provides a clear overview of how FDA inspections are structured under the updated framework. It outlines the different inspection types and explains the compliance models investigators may apply and helps in connecting regulatory terminology to real-world inspection activity. This QualityHub Brief supports regulatory, quality, and leadership teams in building a general understanding of what to expect when FDA shows up for an inspection and how approaches may vary depending on the situation.

ACRONYM GUIDE

MDR: Medical Device Reporting

MDSAP: Medical Device Single Audit Program

NAI: No Action Indicated

OAFR: Other Applicable FDA Requirements

PMA: Pre-Market Approval

QMS: Quality Management System

QMSR: Quality Management System Regulation

RRA: Remote Regulatory Assessment

UDI: Unique Device Identification

VAI: Voluntary Action Indicated

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FDA Inspection Types & When They're Used

INTERPRETING FDA'S QMSR COMPLIANCE

Non-Baseline Surveillance

- Used when a company's most recent FDA inspection or MDSAP audit result is NAI or VAI
- Focus on understanding of product risk through the evaluation of at least one element of each QMS area and OAFR
- Not used for manufacturers actively participating in MDSAP

Compliance Follow-Up

- Used to verify actions taken due to regulatory action
- Focus on risks documented in prior action, previous inspections, company commitment, and progress on corrections
- May include MDSAP-participating manufacturers

For-Cause

- Used in response to information that raises questions, concerns, or problems
- May address a variety of signals from a variety of sources, including inspections, corrections/removals/recalls/repairs/market withdrawals, MDRs, UDI, suspicion of fraud, RRA follow-up, MDSAP reviews, issues at a related facility (e.g., contract manufacturer or sterilizer), sample analysis, or other regulatory agency notification

Specific Product Risk Assessment

- Used to address specific risks associated with one or more product types or operations
- Addresses risks identified in the assignment
- May include MDSAP-participating manufacturers

PMA Post-Market

- Used for subject device to confirm commitments made at the time of FDA's approval decision are complete or underway, according to plan
- Focus on change control to evaluate newly marketed device performance risks identified based on available post-market information
- OAFRs must be reviewed because they might not have been covered during PMA pre-approval inspection

Baseline Surveillance

- Used for manufacturers with no history of FDA inspection or MDSAP audit, or if risk factors indicate need
- Focus on understanding of product risk through evaluation of several elements of each QMS area and all OAFRs
- Not used for manufacturers actively participating in MDSAP

PMA Pre-Approval

- Used for subject device to evaluate compliance with the QMSR regulation and associated requirements
- Focus on findings from review of PMA manufacturing section, implementation of required process validation, design and development, and sterilization (if applicable)
- OAFRs excluded for products not on the market in the US

Source: FDA Compliance Program Manual (CPM7382.850)

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FDA Inspection Types & Corresponding Models

MODEL 1

Non-Baseline Surveillance

Compliance Follow-Up

For-Cause

Specific Product Risk Assessment

PMA Post-Market

At least one element from each subsystem:

- **Change Control**
- **Design & Development**
- **Management Oversight**
- **Measurement, Analysis & Improvement**
- **Production & Service Provision**
- **Outsourcing & Purchasing**
- **OAFRs & General Items**

During a Model 1 Inspection, FDA Investigators Review:

At least one element within each QMS area, selected at the investigator's discretion
- If objectionable conditions or information cannot be reviewed through minimum elements, additional elements may be covered

At least one Other Applicable FDA Requirement (number of OAFRs covered depends on inspection type):
- MDR
- Reports of Corrections and Removals
- Medical Device Tracking
- UDI

General Items:
- Registration and Listing
- Marketing authorization
- Follow-up on previous FDA-483 inspectional observations or compliance issues
- Instructions accompanying the assignment

Note: If a manufacturer is actively participating in MDSAP, surveillance inspections will not be conducted, although other inspection types may be performed.

Source: FDA Compliance Program Manual (CPM7382.850)

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FDA Inspection Types & Corresponding Models

MODEL 2

Baseline Surveillance

PMA Pre-Approval

Multiple elements from each subsystem:

- **Change Control**
- **Design & Development**
- **Management Oversight**
- **Measurement, Analysis & Improvement**
- **Production & Service Provision**
- **Outsourcing & Purchasing**
- **OAFR & General Items**

Change Control: Product and Process Changes

Design & Development: Design and Development Inputs, Outputs, Review, Verification, Validation, Software Validation, Transfer

Management Oversight: Management Review, Medical Device File, Planning of Product Realization

Measurement, Analysis & Improvement: Analysis of Data, Control of Nonconforming Product, Complaint Handling, Feedback, Internal Audits, Corrective Action, Preventive Action

Production & Service Provision:

- Validation of Processes for Production and Service Provision, Control of Production and Service Provision, Identification and Traceability
- For sterile products: Sterile Medical Device and Validation of Processes for Sterilization and Sterile Barrier Systems (if applicable)

Outsourcing & Purchasing: Outsourcing

OAFR & General Items:

- OAFRs include MDR, Reports of Corrections and Removals, Medical Device Tracking Requirements, and UDI
- General issues include Registration and Listing, Marketing Authorizations, Previous FDA-483 and compliance findings and other areas that may be identified in the investigator assignment

Source: FDA Compliance Program Manual (CPM7382.850)