

OCTOBER SESSION · QMSR REMEDIATION

When FDA Enforces ISO 13485

What changes in risk management files and processes, read from the QMSR-cited warning letters

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12:00 ET · Live webinar

TODAY'S SPEAKER

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Quality engineering and remediation SME. A career spent rebuilding risk management and design history files for device and combination-product manufacturers.

Recent work: risk management and design control remediation programs through the QSR to QMSR transition.



Risk Management

Design Controls

Combination Products

SESSION OUTLINE

Agenda

1.	Framing	What changed on 2 February 2026
2.	The enforcement record	The QMSR-cited letters and the clause most of them cite
3.	Enforcement vs. assessment	Eight differences from a notified-body audit
4.	Changing the risk file	Gap lists by starting point, and the ninety-day list
5.	Q&A	Questions from the room

FRAMING

What You Will Leave With

- 1** The mechanism that makes risk management mandatory under the QMSR, and why it is not ISO 14971
- 2** Why risk management is a lifecycle obligation rather than a design deliverable
- 3** Four things FDA says a risk management procedure must define
- 4** What sits inside FDA inspection scope that was never on a certificate's scope
- 5** A ranked ninety-day remediation list, with enforcement-grounded items separated from judgement

Risk Management Is an Objective, Not a Document

The goal of FDA inspections of medical device manufacturers is to evaluate if the manufacturer’s ... risk management and risk-based decision making are effectively used in the QMS.

FDA Compliance Program 7382.850 · Part II, Objectives

Not whether you have a risk file, whether risk drove the decision.

Five of nine

OAI examples in Part V are risk-management failures

Three of six

QMS Areas name risk in their stated purpose

Clause 7.1

sits in Management Oversight, beside the risk-based approach

Risk Does Not Live in Design Controls



Risk management must be incorporated throughout product realization.

FDA Compliance Program 7382.850 · Part I, Phase 2, footnoted to ISO 13485 Clause 7.1

Clauses 7.3.1 to 7.3.10

filed under the Design and Development QMS Area

Clause 7.1

filed under Management Oversight, the only QMS Area it appears in

My reading: if this were a design-controls story, 7.3 would lead. It does not.



PART ONE

The Enforcement Record

The QMSR-cited letters, and the clause cited most often across them

THE ENFORCEMENT RECORD

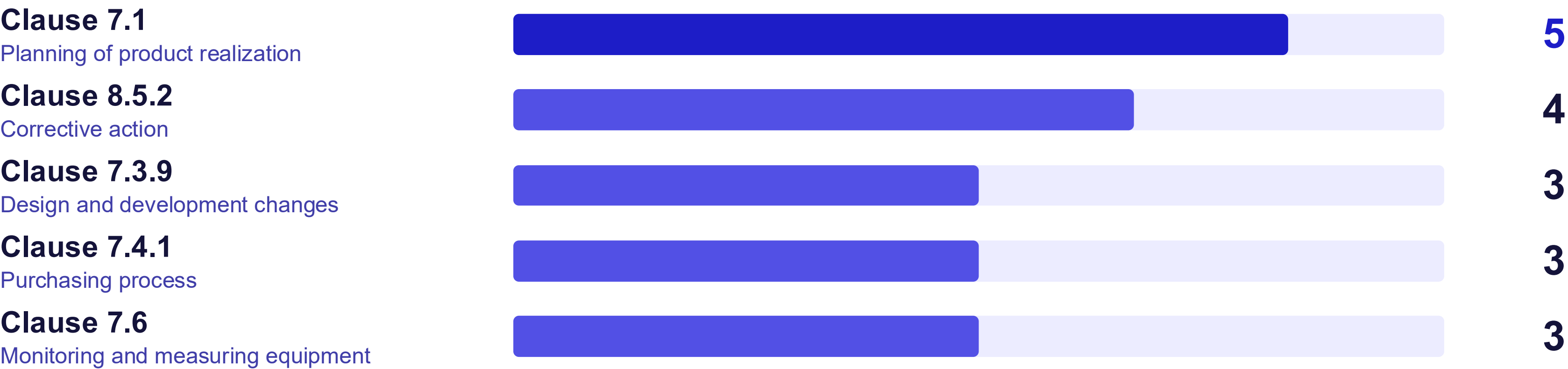
5 of 6

**Warning letters citing ISO 13485 since 2 Feb 2026
cite Clause 7.1**

The Exception Is the One Letter Without 7.1

Only O.N. Diagnostics, cited for corrective action (8.5.2), skips 7.1. 3B Medical mentions ISO 13485 only when summarising the firm's own response, so it is not counted.

Risk Management Leads, Corrective Action Follows



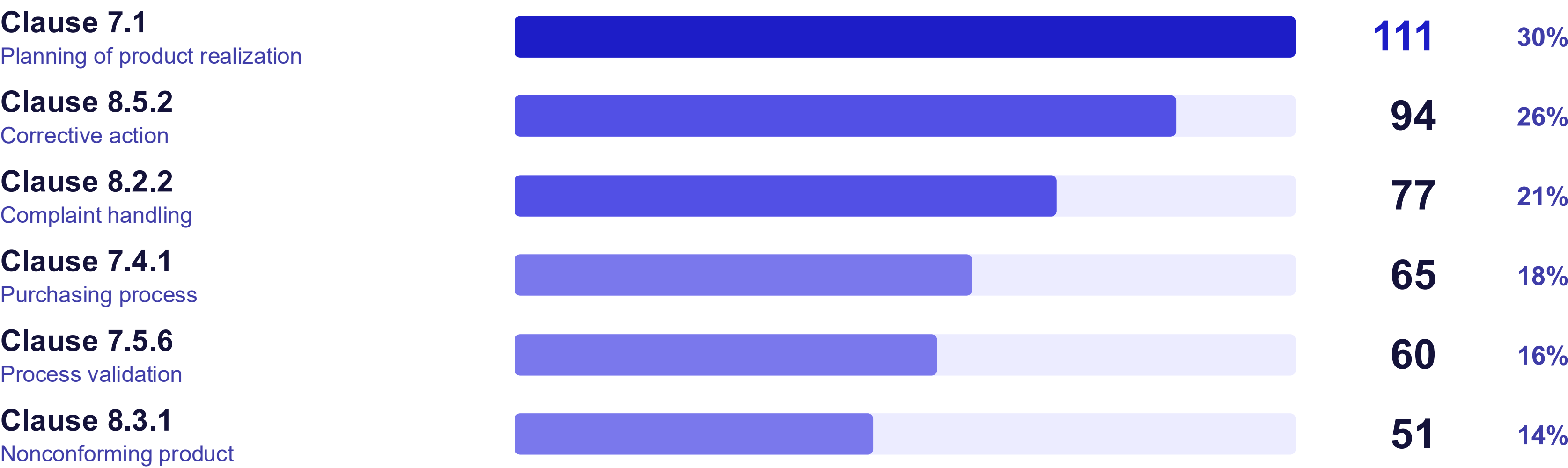
CITED ONCE OR TWICE



Bar length is share of the 6 letters citing ISO 13485. One letter can cite several clauses.

The Same Clause Leads Upstream, in Form 483s

365 device Form 483s since 2 Feb 2026 · 335 cite ISO 13485 · share of all 365 citing each clause



Distinct 483s citing each clause. 72 ISO 13485 clauses cited in total; top six shown, sub-clauses rolled up to parent.

Device Inspection Outcomes Since 2 Feb 2026

580 device inspections · 426 classified · deduplicated by inspection



NAI
171

No action indicated · 40% of classified

VAI
251

Voluntary action indicated · 59%

OAI
4

Official action indicated · 0.9%

PENDING
154

Not yet classified

Where Risk and Design Gaps Showed Up in the Field

FIRM · DATE	ACTION	RISK OR DESIGN CAUSE
Fresenius Medical Care 3 Jun 2026	Form 483 Class II recall	Assigned zero probability to reported events, deaths included, because harm was not confirmed. UF pump alarms not verified under clinical use.
Koven Technologies 21 Jul 2026	Warning letter Recall	No documented risk management process. Fetal-use hazards not evaluated.
Bear-Ent, LLC 26 Feb 2026	Form 483	No risk management plan, assessment or report. Cleaning process not validated.
MPS Pharma & Medical 13 Feb 2026	Form 483	Sterilization hazards missed. No design history file for an acquired legacy device.



Your firm maintains risk analysis reports for each of its products; however, these reports have not been updated since their initial creation.

FDA Warning Letter · Nipro Renal Solutions USA

24 Jul 2026 · ISO 13485 Clause 7.1 · while a Class I recall was ongoing

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PART TWO

Enforcement vs. Assessment

Why the same standard reads differently when FDA holds it

Eight Differences From a Notified-Body Audit

	NOTIFIED BODY	FDA UNDER QMSR
Consequence	Certificate at risk	Device adulterated, 501(h)
Certificate	The deliverable	No exemption, no credit
Scope	Certificate scope	Part 820 plus the standard
Records access	Agreed in contract	Audit records no longer shielded
Record selection	Sampled by plan	Chosen by the investigator
Depth	Was the process followed	Was the conclusion right
Who decides	The audit report	Compliance, on more than the 483
Access itself	Contractual	Delay or denial adulterates, 501(j)

Differences one to six rest on the letters. Seven rests on FDA's compliance program, eight on FD&C 501(j).

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PART THREE

Changing the Risk File

What remediation looks like, by starting point

The Ninety-Day List

Grounded in enforcement

FDA

1 Keep Risk Files Current

Name the triggers that force a revisit, the owner and the timeframe. A blank is not evidence.

Nipro · ISO 13485 Cl. 7.1

2 Ensure Alignment With Labeling

Intended use, populations, hazards and harms in the labelling must all appear in the analysis.

Koven · ISO 13485 Cl. 7.1

3 Do Not Bypass When Estimation Is Hard

Difficulty is not an exemption. The plan must carry criteria for accepting unestimable risk.

Fresenius 483 · ISO 14971 Cl. 4.4(d), 5.5

Practitioner judgement

Inference

4 Competence in the Loop

Clinical owns severity and harm causality. Engineering owns hazard, failure mode and occurrence.

ISO 14971 Cl. 4.3 · ISO/TC 210 guide

5 Risk-Based Decision Making

Apply effort in proportion to the risk. Uncertainty does not justify discounting a severe hazard.

A stated FDA inspection objective · CP 7382.850

6 Lifecycle Risk Management Verification

Before an audit, prove the loop on each highest-risk device and exercise every trigger.

Does the process actually run where it matters most

CLOSE

FDA is not asking whether you have risk management. It is asking whether you used it.

A handful of letters

is not a trend

Eight months

is not a track record

Not yet tested

in an enforcement action or a court

Questions

Drop them in the Q&A panel.

SPEAKER

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