THE MOST EXPENSIVE ASSUMPTION IN MEDTECH

ISO 13485 Is Not Enough

Your certificate says you built a quality system. An inspection asks whether it works. Those are different questions.

If your company is ISO 13485 certified and you assume that makes you inspection-ready, this guide is about the gap between the two — and how to close it before an investigator finds it for you.

ISO 13485 · 21 CFR 820 / QMSR · EU MDR 2017/745 · CDSCO MDR 2017

12-MINUTE READ · 12-POINT SELF-SCORECARD ·

US · UK · IRELAND · INDIA · 200+ ENGINEERS

WHAT AN INSPECTION ACTUALLY LOOKS LIKE

MONDAY, 9:15 AM

The FDA investigator signs in at reception. Behind the desk, the ISO 13485 certificate hangs in a frame.

Everything looks ready. The procedures exist. The records exist. The team has done this before.

Three days later, the company has eight observations.

Nothing was fake. Nothing was missing. Every system named in the 483 was certified, documented and audited.

The systems simply did not connect.

Why this happens to good companies

AN AUDITOR ASKS

"Do you have a procedure for this?"

Conformity. Sampled. Announced. Scoped in advance.

AN INVESTIGATOR ASKS

"Show me the record where you followed it — and the one where you didn't."

Evidence. Chosen by them. Traced across systems until something breaks.

> Every year, ISO-certified manufacturers discover the same painful thing: **passing the audit did not prepare them for the inspection.**

THE CHAIN INVESTIGATORS WALK

Nothing here is broken. The joins are.

An investigator does not audit systems one at a time. They pick one complaint and follow it until the trail stops. Certification proves each box exists. Inspection tests the arrows between them.

Complaint → **CAPA** → **MDR** → **483** → **Warning Letter** → **Consent Decree**

Every arrow is a decision that has to be recorded. A complaint that should have become a CAPA. A CAPA that should have been checked for effectiveness. An event that should have been filed within 30 days. Miss one arrow and the chain keeps moving — in the wrong direction.

THE UNCOMFORTABLE DATA

Your certificate made you easier to inspect, not harder.

~90%

of device observations now cite **ISO 13485 clauses directly.**

~30%

of citations are **management oversight** — the largest single category.

A certified quality system is a well-documented one — which means an investigator can point at the exact clause you signed up to and did not fully meet.

And this is how the three days actually run

DAY 1

Opening meeting

Scope set. They ask for your quality manual, org chart and complaint log.

DAY 2

The trace

One complaint is picked and followed across every system until the trail stops.

DAY 3

Form 483 issued

Observations read back to you at the closing meeting.

15 DAYS

Your response

Fix the systemic cause, not the record they happened to pull.

45-90 DAYS

Classification

NAI, VAI or OAI. The last one is where warning letters live.

▷ WATCH · 3-MINUTE EXPLANATION

Why certified companies still get cited

THE SEVEN · WHERE OBSERVATIONS LAND

Seven places investigators still find observations inside ISO-certified companies.

Read each one and ask the honest question: **could we produce that record this afternoon?**

1 Labeling & packaging controls

HIGH · 820.45

ISO 13485 folds labeling into general production controls. QMSR expects specific inspection, reconciliation and control — and labeling errors remain a leading cause of recalls.

OH NO "We have a labeling procedure" is not the same as "here is the reconciliation record for this batch."

2 MDR reporting

CRITICAL · 21 CFR 803

This sits entirely outside ISO 13485. Evaluating every complaint for reportability and filing within 30 days is a US regulation, not a standard clause.

OH NO Most certified firms have no defensible reportability-decision trail. The decision was made — it was just never written down.

3 Unique Device Identification

HIGH · 21 CFR 830

Also outside ISO 13485. UDI on the label and in the GUDID database is a US regulatory obligation your certificate never tested.

OH NO Your GUDID record was correct the day you filed it. The question is whether it survived three years of artwork revisions.

4 US record constructs (DHF / DMR / DHR)

MEDIUM · 820.30 / .180

ISO 13485 frames records differently. Investigators still expect to trace a Design History File, Device Master Record and Device History Records in the US sense.

OH NO Certified teams usually have the content. What they lack is the construct an investigator asks for by name.

THE SEVEN · RISK MAP

5 Management responsibility & review

CRITICAL 820.20

QMSR inspection puts management oversight under heavy scrutiny — now one of the largest citation categories. **A review that drove no decisions is a finding. The slide deck is not the evidence; the closed actions are.**

6 Complaint → CAPA → MDR linkage

CRITICAL 820.198 / .100 / 803

The certificate proves each system exists. Inspection tests whether they talk to each other. **This is the one that produces the eight-observation inspection. Nothing is missing. Nothing connects.**

7 Servicing & installation records

MEDIUM 820.200

For devices requiring servicing, QMSR expects specific servicing records analysed as a quality signal. **ISO 13485 covers this lightly, so certified firms under-document it — and never notice until asked.**

Your risk at a glance

Fix downward from red — not from number one.

1	2	3	4	5	6	7
Labeling & packaging	MDR reporting	UDI	US record constructs	Management review	Complaint→CAPA→MDR	Servicing records
HIGH	CRIT	HIGH	MED	CRIT	CRIT	MED

ISO 13485 COVERS WELL	QMSR ADDS ON TOP	WHERE TEAMS GET CITED
Core QMS, design, production	US labeling control (820.45)	Label reconciliation missing
Risk management (ISO 14971)	MDR reporting (803)	No reportability decision trail
Document control	UDI (830)	UDI inconsistent with GUDID
CAPA as a process	CAPA effectiveness proven	Closed with no effectiveness check
Management review exists	Review drives real decisions	Review is a formality
Complaint handling exists	Systems linked end-to-end	Complaint never becomes a CAPA

THE ASSUMPTIONS · EXPENSIVE BELIEFS

Three assumptions that have cost manufacturers millions.

"We're ISO 13485 certified, so we're QMSR-ready."

No. QMSR adds US-specific requirements — labeling (820.45), MDR (803), UDI (830) — that certification never tested. The certificate is a floor, not a ceiling.

"QMSR is just a rename of QSR."

No. It made ISO 13485 the legal backbone and changed what investigators cite — now overwhelmingly ISO 13485 clauses, directly. It handed them a cleaner map to your own commitments.

"We have time."

No. It has been law since February 2026. Inspections already run under it. The next one will not wait for your remediation plan.

CERTIFIED, OR COMPLIANT?

Which one are you? Your inspector already knows.

Twelve questions. Answer them with your **actual records open** — not from memory, and not from what the procedure says should happen.

Every company that received a 483 last year believed it was ready the morning the investigator walked in.

THE 12-POINT SELF-SCORECARD

Answer with the record in front of you.

Records open. **Y = 2 · P = 1 · N = 0.** The GAP column maps each line to one of the seven gaps — a weak score points straight at what to fix first.

#	REQUIREMENT — ANSWER WITH THE RECORD IN FRONT OF YOU	GAP	Y · P · N
01	Every complaint has a recorded MDR reportability decision with a rationale.	2	Y P N
02	You could produce a filed-within-30-days MDR trail for any reportable event this year.	2	Y P N
03	Every CAPA closure has dated, objective effectiveness evidence attached.	6	Y P N
04	A trending complaint automatically becomes a CAPA, and you can show the linkage.	6	Y P N
05	Your labeling is inspected against a master and reconciled, with records.	1	Y P N
06	UDI on your labels matches your GUDID entries exactly, today.	3	Y P N
07	You can trace one product's DHF from user needs to V&V without a gap.	4	Y P N
08	Every active supplier has an evaluation record and a current re-evaluation.	–	Y P N
09	Your last management review produced recorded decisions tracked to closure.	5	Y P N
10	Quality objectives are measured, trended and acted on — not just stated.	5	Y P N
11	Design changes this year all went through controlled change with risk re-evaluation.	4	Y P N
12	If an investigator pulled any record at random, it would be complete and dated.	–	Y P N

Max 24 Total your twelve answers. The GAP column shows which of the seven gaps each line belongs to — so a weak score points straight at what to fix first.

YOUR BAND · READ IT HONESTLY

Total your score, then find your tier.

20–24
QMSR-READY

Your certificate and your reality match. Confirm with an independent pre-read and keep the linkages tight.

12–19
CERTIFIED, NOT COMPLIANT

The gap between your certificate and QMSR is real and typical. Close the US-specific items in priority order.

0–11
EXPOSED

A clean certificate is masking material gaps. Get outside eyes on the US-specific requirements this month.

THE BENCHMARK THAT ACTUALLY MATTERS

Nobody publishes an industry average. But the FDA publishes where it looks.

Across roughly **2,660 device 483 observations**, citations concentrate in a handful of systems. Compare your weakest scorecard lines against this ranking — if they overlap, that is your real exposure. Not a feeling: a probability.

10.5%	7.9%	4.3%	3.6%	3.5%
CAPA	Complaints	Suppliers	Nonconforming	Process val.
820.100 · Lines 03,04	820.198 · 01,02,04	820.50 · Line 08	820.90 · Line 12	820.75 · Line 11

Design controls is not at the top. The findings land on the systems that prove you react correctly when something goes wrong.

THE COST · WHAT IT COSTS TO BE WRONG

The scorecard takes ten minutes. Getting it wrong takes years.

$10m–$600m

The cost of a single recall event

Depending on scope and severity. Business disruption alone is close to half of it.

$2.5–5bn

Industry cost of non-routine quality events, yearly

Recalls, warning letters and consent decrees, with the warranties and lawsuits that follow.

1,059

Device recall events in 2024

The highest in four years. Class I recalls reached their highest level in 15 years.

2–5 yrs

Recovery time after a major recall

Long after remediation closes, the commercial effect is still being carried.

And the costs nobody puts in the model

Launch
A remediation plan competes with your roadmap. Your launch date moves; the competitor's does not.

Customers
Distributors and hospital groups ask for inspection history. A warning letter is public, and permanent.

Legal
A 483 that escalates brings counsel, consent decrees and personal accountability for named executives.

People
Your best quality engineers spend two quarters on remediation instead of the work you hired them for.

The cheapest inspection you will ever run is the one you run on yourself. Ten minutes, twelve questions — and you already have the records.

HeLiXA
Powered by SOLIDPRO

YOUR FREE NEXT STEP

INSPECTION READINESS REPORT

Get your Inspection Readiness Report.

Answer the twelve questions online and we return a personalised report: your score, your band, the gap behind every weak line, and a ranked list of what to fix first. **Free, no deck, no obligation.**

SCAN · GET YOUR REPORT

solidpro-es.com/readiness-report

Interactive scorecard · instant result · your records stay with you

Design & build
Device design, DHF, V&V, NPD sprints.

Quality & regulatory
eQMS, QMSR & MDR readiness, 483 remediation.

Cost & localize
VAVE cost-down, Make-in-India localization.

Prefer to talk? Book a StartSmart call.

Free · 60 minutes · no deck · a straight answer about whether we can help.

connect@solidpro-es.com · 044-6900 4500 · solidpro-es.com

Prepared by Helixa — the healthcare & life sciences engineering practice of SolidPro Engineering Services. Regulatory references are to 21 CFR Part 820 / QMSR, ISO 13485, EU MDR 2017/745 and 21 CFR 803/830 as current at time of writing. Practical guidance, not legal advice.