

IPA ADVANCED GMP WORKSHOP 2026

Regulatory Observation Trends

Recurring Quality-System Learnings

What USFDA, EMA, MHRA and CDSCO keep telling us — why the same findings return — and what leadership must do about it

USFDA

EMA

MHRA

CDSCO

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What we will cover today

01

The case for attention

Why recurring findings now matter more

Slide 3

04

Deep dive: why findings keep coming back

Evidence, the recurrence loop and fifteen root causes

Slides 10–12

02

What regulators are finding

USFDA · EMA · MHRA · CDSCO

Slides 4–8

05

Fixing the system and building capability

Process fixes, people and laboratory excellence

Slide 13

03

Cross-regulator synthesis

Eight themes common to all four

Slide 9

06

Measure, anticipate and act

Early-warning KPIs and horizon 2026–27

Slides 14–15

Closing: key takeaways, Q&A and references (slides 16–17)

Same findings, escalating consequences

303

USFDA drug & biologics
Warning Letters in FY2025 — up
59% from 190 in FY2024

4 years

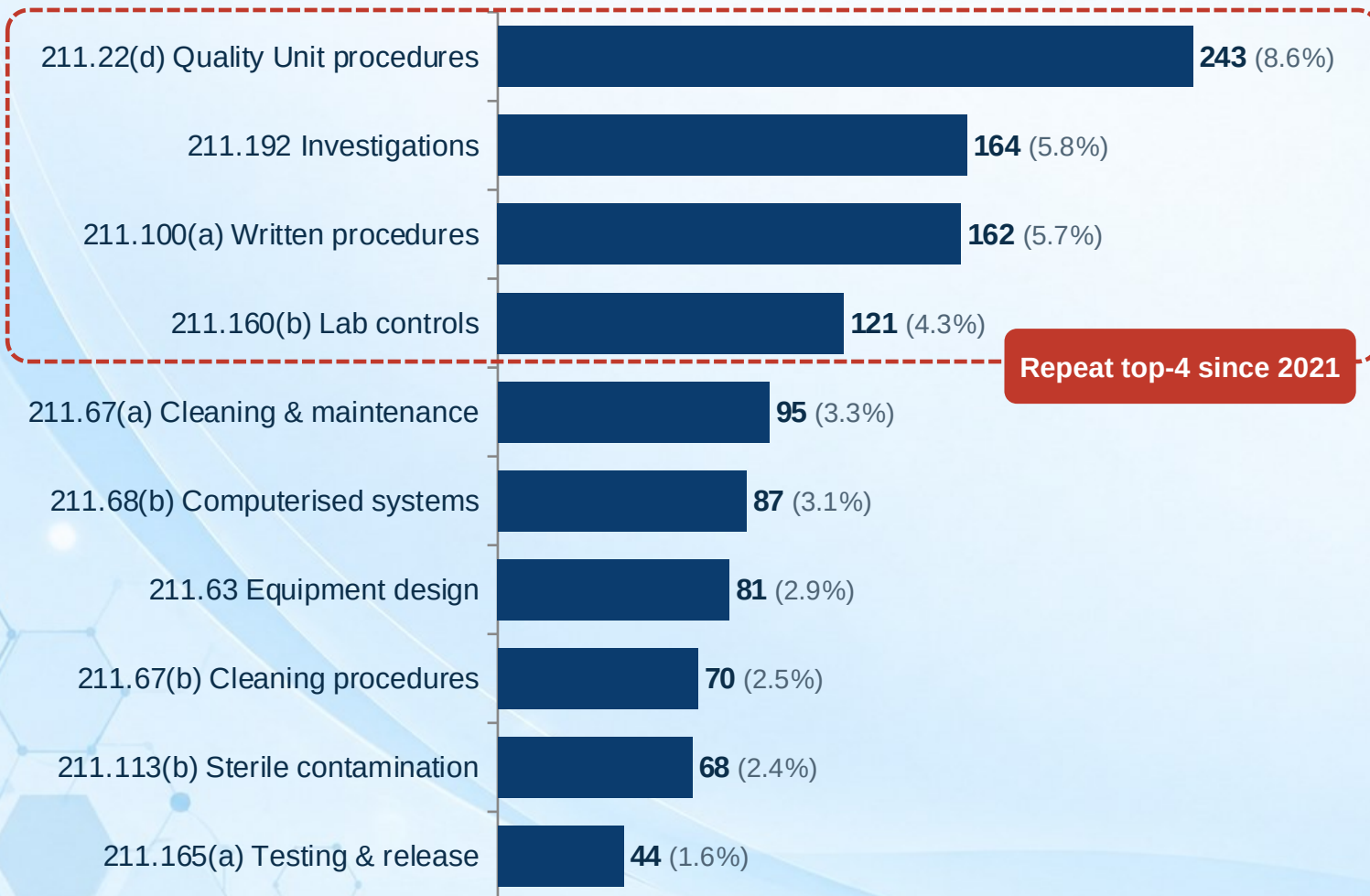
The same four 21 CFR 211
citations have topped USFDA
drug 483 rankings since 2021

1,879

Batches declared Not-of-
Standard-Quality by CDSCO in
2025 — more than double
2024's 877

Leadership message: Recurrence is a system signal, not bad luck — and the cost of ignoring is rising.

Quality Unit and investigations lead the top-10



2,837

drug citations across 316 unique provisions (system-generated 483s)

What the pattern says

- Quality Unit not acting as the governing authority
- Investigations superficial; scope too narrow
- Procedures exist but don't reflect practice
- Lab controls not scientifically sound

Data integrity dominates Warning Letters to Indian sites

~60%

of FDA Warning Letters to Indian sites cite data integrity (vs ~15% overall)

94 / 114

surprise inspections in India (2022–24) ended with a Form 483

5

Q1 2026 Warning Letters citing deliberate falsification — 4 of them in India

Conduct cited in 2026 Warning Letters

Observed behaviour	Site type
Destroyed / torn analytical records; unofficial diaries	Contract testing lab
Batch records completed retrospectively; originals destroyed	API manufacturer
Failing OOS results replaced without investigation	Contract testing lab
Recreated logbook presented to investigator	OTC manufacturer
Delayed or limited access to records during inspection	Multiple

Each of these is an integrity failure first — and a quality-culture failure underneath.

EU non-compliance: sterile assurance & PQS failures lead

14

EU GMP non-compliance statements tracked, Sep 2025 – Jul 2026

8 of 14

issued to sites in India (4) and China (4)

7 + 9

critical + major deficiencies at one Indian sterile unit (Mar 2026)

Next baseline: digital GMP is being rewritten

- Jul 2025** Drafts: Annex 11, Annex 22 (AI), Ch. 4
- Oct 2025** EC–PIC/S consultation closed
- 2026** Finalisation by EMA–PIC/S

Annex 11: 5 → 19 pages; IAM, audit trails, cyber security, supplier oversight

Annex 22: only static, deterministic AI in GMP-critical uses

Chapter 4: risk-based data governance for paper, electronic & hybrid records

Consequence: prohibition of supply to the EEA, and Member States advised not to approve new MAs naming the site until a new GMP certificate is issued.

Typical findings behind EU non-compliance statements



PQS not functioning: Weak deviation management, ineffective QRM, inadequate OOS investigations



Annex 1 aseptic practice: Smoke studies not matching operations; manual interventions in Grade A; media-fill gaps



Cleaning validation & CCIT: Rated critical; container-closure integrity issue left uncorrected for long



Records & transparency: Requested documents not provided promptly; authenticity of records questioned



Supplier qualification: Critical starting materials and primary packaging not adequately qualified

Data integrity is read as a proxy for quality culture

#1

Data integrity — most prevalent MHRA GMP deficiency category in the 2025–26 cycle, as it has been for much of the past decade.

Industry analysis; MHRA's last consolidated public deficiency dataset is for 2019.

Typical findings behind the headline



Shared log-ins on CDS, LIMS and EM systems



Audit trails disabled, mis-configured or not reviewed



Paper records completed retrospectively or corrected improperly



Raw electronic data overwritten or not retained

Sterile sites: revised Annex 1 is driving findings on the contamination control strategy — expected to be a living, site-wide document, not a one-time report.

From 'Is there an SOP?' to 'Show me it works'

Enforcement journey

- Dec 2022**
Nationwide risk-based inspections begin
- May 2025**
MSMEs file upgrade plans to seek extension
- 31 Dec 2025**
Extended compliance deadline ends
- Jan 2026**
MSME compliance inspections start

905+ units inspected · **694+ actions**
SPOs, suspensions, cancellations, WLs, SCNs

What inspectors now verify in operation



PQS

CAPA, change control & deviations run as one connected system



QRM

Documented risk assessments applied to real decisions



PQR

Periodic trending of batches, complaints & deviations



Qualification

Current, traceable IQ/OQ/PQ and validation status



Computerised records

Electronic record-keeping for drug product records



ALCOA+

Contemporaneous, attributable data — not reconstructed

State drug controllers now report inspection findings to the DCGI monthly

Eight themes recur across all four regulators

Recurring theme	USFDA	EMA	MHRA	CDSCO
Quality Unit / PQS oversight	High	High	High	High
Investigations, OOS & CAPA effectiveness	High	High	High	High
Data integrity & ALCOA+	High	High	High	High
Cleaning & contamination control	High	High	High	High
Laboratory controls	High	Medium	Medium	High
Computerised systems & audit trails	High	High	High	Medium
Written procedures vs actual practice	High	Medium	Medium	High
Contract lab / supplier oversight	High	Medium	Medium	Medium

Unresolved findings are the fastest route to escalation

26 of 44

FY2025 FDA drug Warning Letters analysed cited CAPA deficiencies (59%)

10+ years

CAPA has featured in FDA's top-10 inspection observations every year since 2015

50%+

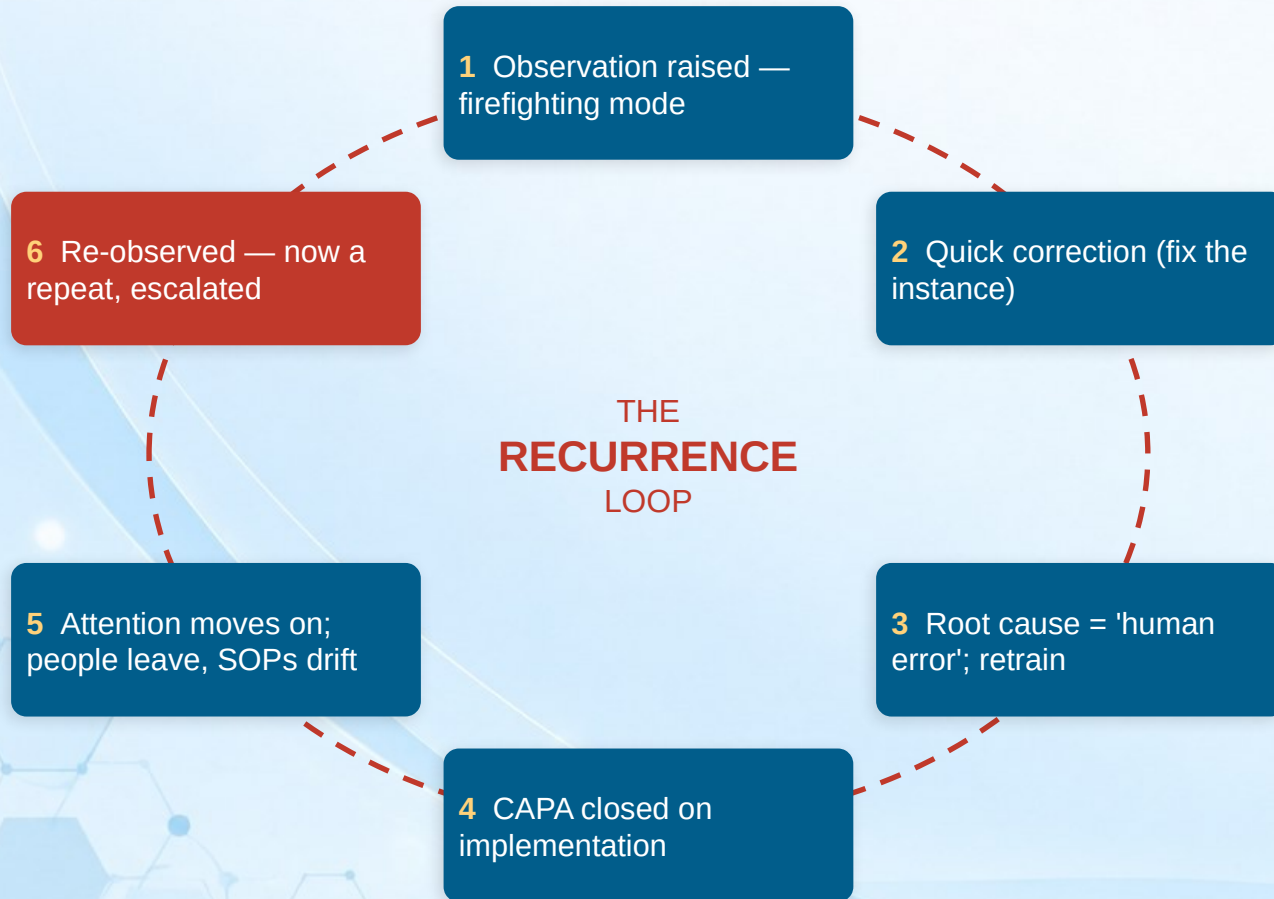
Warning Letter risk associated with a weak Form 483 response

Case in point: one contamination problem, 17 months, escalating action (USFDA, 2025–26)



Same pattern elsewhere in 2026: An API/finished-dose WL (Jan) cited inadequate corrective actions to a prior 483; a March WL found microbial deviations 'invalidated' without scientific justification.

How a closed observation quietly re-opens itself



What leaders can do to break the loop

At step 2

Assess impact across all batches, products & sites — not just the cited instance

At step 3

Reject 'human error' without a human-factors analysis of why the error was possible

At step 4

Close CAPA only on verified effectiveness, with pre-defined success criteria

At step 5

Succession plans & competency mapping so fixes survive attrition; re-audit at 6–12 months

Fifteen reasons the same findings keep coming back

Investigation	CAPA	System & governance	People & capability	Data integrity
01 'Human error' as default root cause	04 Closed on implementation, not effectiveness	07 Local fix; no horizontal deployment	10 Skill gaps; roles not competency-mapped	13 Audit-trail review a formality; shared log-ins
02 Scope limited to the cited batch / area	05 Retraining used as the default action	08 QU lacks authority, capacity or data	11 No succession — knowledge leaves with people	14 Hybrid paper—electronic records outside control
03 Lab errors & OOS invalidated without science	06 Unrealistic timelines; shortcuts under pressure	09 KPIs reward closure speed, not outcomes	12 Lab overloaded; poor planning, rushed analysis	15 Pressure to 'pass' — data altered, not investigated

Insight: most of these causes are decided above the QA department — they are leadership levers.

Recurrence stops when capability is built, not borrowed

People capability

-  **Hire for talent, not headcount**
Recruit investigation, data-integrity, CSV and analytical skills; strengthen QA/QC bench depth
-  **Competency mapping**
Role-wise skill matrix; qualify (not just train) before GMP-critical tasks
-  **Succession planning**
Ready successors for critical QA/QC roles; structured knowledge transfer
-  **Quality culture & speak-up**
Reward early reporting; no-blame investigations; QU decisions protected from production pressure

Laboratory excellence

-  **Appropriate lab planning**
Capacity-based scheduling and realistic analyst workload; avoid month-end release rush
-  **Lab error reduction programme**
Trend lab incidents by analyst, method & instrument; target right-first-time
-  **Error-proofing**
Robust methods, system-enforced calculations, validated templates instead of manual entry
-  **Analyst qualification & mentoring**
Practical demonstration, periodic re-qualification and buddy system for new analysts

Why it matters: lab controls (211.160) and investigations (211.192) are in USFDA's top four — capability gaps before procedure gaps.

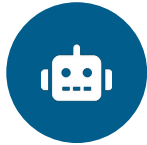
Nine early-warning indicators of a repeat finding

Indicator	What it reveals	Warning sign
Repeat-observation index	Do fixes last across audits & sites?	Any regulatory observation seen before
% deviations closed as 'human error'	Depth of root-cause analysis	High share without human-factors review
% CAPAs with verified effectiveness	Outcome vs paperwork closure	CAPAs closed on implementation only
Recurring deviations (same cause, 12 mo)	Systemic vs local fixing	Same cause appearing again
Horizontal deployment completion	Cross-site / cross-product learning	Fix applied only at the cited site
CAPA extensions & overdue ageing	Resourcing, planning & firefighting load	Repeated timeline extensions
Lab error rate & OOS invalidation rate	Lab planning and investigation rigour	Rising incidents; invalidation without cause
Competency coverage on critical tasks	Right person on the right task	Unqualified staff on GMP-critical work
Critical roles with a ready successor	Bench strength in QA / QC	Single-person dependency

Review quarterly in site and corporate management review — before an inspector reviews them for you.

Presenter recommendations; warning signs are qualitative — set site-specific thresholds. Aligned to ICH Q10 management review and 21 CFR 211.180(e).

Where the next observations will come from



AI in GMP records

FDA's Apr 2026 Purolea Warning Letter appears to be the first to expressly cite inappropriate AI use in CGMP documentation. GxP AI-use policies are now an inspection topic.



Quality of the 483 response

FDA's Mar 2026 draft guidance sets expectations for what a response should contain — and notes responses can inform later regulatory decisions.



Unannounced inspections as the norm

MHRA has expanded unannounced inspections and USFDA continues surprise visits — readiness has to be every-day, not event-driven.



Sponsor accountability for partners

Falsified data at contract labs and CROs puts sponsors' own release decisions and submissions at risk — oversight must test data, not paperwork.

KEY TAKEAWAY

Findings come back when we fix the observation instead of the system — stopping them is a leadership choice.

Same findings

4 regulators, 8 recurring themes

Effectiveness over closure

Fix the system, not the instance

Capability-led

People, lab planning & prevention over firefighting

Thank you | Questions & discussion

Sources used in this presentation

1. US FDA – Inspection Observations (FY2025); Warning Letters database; WL 320-26-105 (Jul 2026); Draft Guidance FDA-2025-D-1504 on Form 483 responses (Mar 2026)
2. GMP Insiders – FY2025 FDA Inspection Observations; VelSafe – FDA 483 & enforcement statistics (Jun 2026); IntuitionLabs – FDA 483/WL statistics (Aug 2026)
3. Policy Canary (Mar 2026); IGMPI (Mar 2026) – 2026 data-integrity Warning Letters
4. GMPify – CAPA systems: why they fail (Jul 2026); ECA Academy – OraLabs WL on RCA/CAPA (Mar 2026); Learn GMP – Jan 2026 483/WL summary; The FDA Group – Human error in CAPA
5. European Commission / PIC/S – Consultation on EU GMP Chapter 4, Annex 11 and new Annex 22 (Jul–Oct 2025); MFLRC (Jun 2026); EudraGMDP; EFPIA inspection survey (May 2026)
6. Quality & Vigilance – MHRA Inspection Findings: Top 15 Deficiencies 2025–2026 (Aug 2026); GOV.UK MHRA GMP deficiency data
7. CDSCO / Revised Schedule M – ValiCore (Jul 2026); Pharmabiz (Feb 2026)
8. ICH Q10 Pharmaceutical Quality System; 21 CFR 211.25 (personnel qualifications), 211.180(e) (annual product review)