iFeed | WEEKLY SIGNALS · W26 · 22 – 28 JUN 2026

Enforcement finds the gaps governance left open

CHMP moved to revoke a marketed product on trial data-integrity grounds, while FDA drug warning letters climbed 59% year on year.

Nine signals • traced to primary sources • selected by iFeed

1 CT Clinical trials 2026-06-26

CHMP recommends revocation of Tavneos (avacopan), EMA will act on historical GCP failures in pivotal trial data

CHMP recommended revoking Tavneos's EU marketing authorisation on 26 June 2026, a drug on the market since 2022, after finding the pivotal ADVOCATE trial was run in breach of Good Clinical Practice and that its data, in EMA's own words, "were found to be incorrect and misleading and could no longer be relied upon for demonstrating Tavneos' effectiveness."

WHY IT MATTERS

CHMP opened its review of Tavneos to assess new information questioning the data integrity of the pivotal ADVOCATE trial, not because of a new safety signal or a post-marketing failure. On 26 June 2026, EMA said the study data submitted with the original application "were found to be incorrect and misleading and could no longer be relied upon for demonstrating Tavneos' effectiveness."

WHAT TO CHECK

Pull your pivotal trial audit history this week. For every EU marketing authorisation, check whether the pivotal dataset carried unresolved GCP findings, monitoring deviations, or source data discrepancies, even ones closed out before approval. CHMP's Tavneos review was triggered by exactly that kind of retrospective question, not by a new safety signal.

Source · EMA, Tavneos EPAR ↗

2 QMS Quality 2026-06-01

QMSR inspection data, management oversight is 30% of FDA observations across 93 post-QMSR audits

FDA's device inspection manual changed on 2 February 2026 when Compliance Program 7382.850 took over from QSIT, inspectors now build the audit from a manufacturer's risk management and postmarket data rather than starting at CAPA, which means a complaint trend an inspector traces back can land on a risk decision your quality unit never formally signed off on.

WHY IT MATTERS

FDA's compliance program for QMSR inspections, CP 7382.850, replaced the QSIT framework on 2 February 2026 and directs investigators to build their inspection around a manufacturer's risk management documentation, reviewing complaints, corrections and removals, and postmarket surveillance data to decide which quality system areas to prioritize and how deeply to dig. Under the old QSIT approach, a solid CAPA system was usually enough to carry an audit. Under CP 7382.850, an inspector can trace a device recall or complaint pattern back to a risk decision that was never formally owned by management, a gap the old sequence didn't surface.

WHAT TO CHECK

Trace your own risk management file forward the way an inspector now will: from medical device reports, complaints, corrections and removals, and postmarket surveillance data through to CAPA and supplier quality records. If that chain has gaps, risk decisions that management never formally signed off on, or risk documentation that doesn't connect to an actual CAPA, close them before your next FDA visit, not during it.

Source · FDA, Device Quality System CP 7382.850 ↗

3 QMS Quality 2026-03-06

FDA 483 draft guidance (March 2026), CAPA effectiveness plan required before implementation, not at closure

FDA's 6 March 2026 draft guidance on Form 483 responses tells firms to determine "why the issues leading to the observation were not previously identified by the quality unit or corrected by the establishment's management before the FDA inspection", root cause analysis that stops at the floor-level error, without asking why the quality system didn't catch it first, no longer meets the bar FDA is describing.

WHY IT MATTERS

FDA's 6 March 2026 draft guidance says plainly that "an establishment should be aware of and minimize bias in risk evaluation and decision-making when determining root cause", a standard that rules out root cause analysis that stops at the first plausible operator error. That turns a 483 response into a partial audit of the quality unit itself, not just the manufacturing floor finding. Comments closed 8 May 2026.

WHAT TO CHECK

Rewrite your root cause analysis template to add two explicit prompts before the next 483 response goes out: what bias could have shaped this risk evaluation, and why didn't the quality unit catch this before FDA did. Comments on the draft closed 8 May 2026, but FDA is already applying this reasoning in live inspection findings, don't wait for final text to update the template.

Source · FDA, Draft Guidance: Responding to Form FDA 483 ↗

4 QMS Quality 2026-04-01

Veeva AI Agents for Quality live in validated GxP, platform validation is Veeva's scope, oversight SOP is yours

Veeva's AI Agents went live in Vault Quality applications in April 2026, running on Anthropic and Amazon models, Veeva holds the Computer System Validation documentation for the platform, but the SOP governing who reviews the AI's output and on what criteria is explicitly the customer's responsibility, and in any instance where that SOP hasn't gone through change control, it doesn't exist yet.

WHY IT MATTERS

21 CFR Part 11 and EU GMP Annex 11 require electronic records in GxP environments to be created under controlled, documented conditions. When an AI system drafts content and a human approves it, that approval is itself a GxP record, and if the review criteria, rejection threshold, and audit trail for the AI-assisted step aren't defined in a validated SOP, the record isn't fully controlled. An inspector will ask for that oversight SOP, not just Veeva's own validation documentation.

WHAT TO CHECK

Check your Vault configuration this week: is Veeva AI Agents for Quality switched on? If so, is there a validated SOP, through change control, not a side memo, that defines who reviews AI-generated content, what the rejection criteria are, and how a corrected record gets traced back to the original AI draft? If that SOP doesn't exist yet, pause AI-assisted record generation until it does.

Source · Veeva, Vault AI (AI Agents for Quality) ↗

5 QMS Quality 2026-05-25

EU CIR 2026/977 revises notified body conformity assessment under MDR/IVDR, three transition dates to map now

CIR 2026/977, in force since May 2026, sets fixed maximum timelines for notified bodies for the first time, a 120-day cap on QMS audits, 90 days for technical documentation review, 20 days to issue a certification decision, with the main requirements applying from 25 February 2027, so a certification programme that crosses that date needs its NB agreement checked now for which rules govern the remaining steps.

WHY IT MATTERS

CIR 2026/977 entered into force in May 2026 to fix what the Commission has described as inconsistent and divergent timelines and interpretations across the EU's notified body network. For a device manufacturer whose certification is expected to complete around the 25 February 2027 boundary, which set of rules and deadlines applies to the remaining steps is now something to confirm with the NB directly rather than assume.

WHAT TO CHECK

Map every active and pending notified body agreement against 25 February 2027, when CIR 2026/977's main requirements take effect. For each programme whose certification timeline runs past that date, get written confirmation from your NB of which procedural rules govern the remaining assessment steps, application review, QMS audit, and technical documentation timelines are all reset under the new regulation.

Source · health.ec.europa.eu ↗

6 QMS Quality 2026-02-12

EU PV Regulation 2025/1466 in force since February 2026, PV subcontractor contracts without three mandatory clauses are non-compliant now

EU 2025/1466 became fully applicable on 12 February 2026, and it's the first substantive rewrite of the EU pharmacovigilance legislative framework since the 2012 Pharmacovigilance Directive, any PV subcontractor agreement still missing MAH audit rights, NCA inspection rights, or written consent before further subcontracting is now out of step with a regulation in force, not a guidance document.

WHY IT MATTERS

If a PV vendor has further subcontracted signal detection, Individual Case Safety Report processing, or Pharmacovigilance System Master File maintenance to a third party without the MAH's written consent, that arrangement now breaches a regulation in force, not just GVP Module I guidance. Regulators can inspect subcontractors directly whether or not the contract says so, but a missing consent clause is still the kind of documentation gap an NCA inspection is built to find.

WHAT TO CHECK

Pull your PV subcontractor register. For every vendor contract, check for the three clauses now required under EU 2025/1466: MAH audit rights, NCA inspection rights, and written MAH consent before any further subcontracting. Contracts signed or last reviewed before the regulation's 12 February 2026 application date are the ones most likely to be missing at least one, the further-subcontracting consent requirement is new to the framework, not a restatement of prior guidance.

Source · EUR-Lex, Commission Implementing Regulation (EU) 2025/1466 ↗

7 CT Clinical trials 2026-06-26

CHMP rejects three orphan-designated therapies in June 2026 plenary, unmet need does not offset unconvincing benefit-risk

CHMP adopted negative opinions for three orphan-designated medicines in its 22-25 June 2026 plenary, a tumour-infiltrating lymphocyte therapy for melanoma, a pooled faecal microbiota product for graft-versus-host disease, and narsoplimab for transplant-associated thrombotic microangiopathy, and the common thread across three unrelated therapeutic areas is manufacturing and endpoint data that orphan status didn't rescue.

WHY IT MATTERS

The Advanced Therapy Medicinal Product field has operated on a working assumption that CHMP exercises flexibility on evidence certainty for serious unmet needs with no alternatives. Manufacturing heterogeneity, batch-to-batch variability inherent in autologous cell therapies or live microbiome products, is not something CHMP is discounting at the marketing authorisation stage. The same session's Daybu reversal is the counterpoint: following re-examination, CHMP granted trofinetide a marketing authorisation for Rett syndrome, restricted to patients aged five and older, a narrower label backed by refined data, not resubmission of the same package.

WHAT TO CHECK

When EMA publishes the European Public Assessment Reports for the three rejected medicines, map the specific rejection grounds, manufacturing consistency, endpoint variability, benefit-risk weighting, against your own ATMP development programme. Treat the Daybu re-examination outcome as a process precedent: if you have a negative CHMP opinion, re-examination with a refined indication and updated analysis is a viable path.

Source · EMA, CHMP June 2026 meeting highlights ↗

8 QMS Quality 2026-06-01

FDA drug Warning Letters up 59% in FY2025, June 2026 adds a finding where a QA employee directed undocumented EBR changes

FDA cited Intas Pharmaceuticals under 21 CFR 211.22 on 30 March 2026 because, in the letter's words, "your quality assurance employee instructed your software vendor to make changes to your electronic batch record which were not captured in the audit trail or managed through your quality system", one example being an employee ID quietly swapped in a "Dispensed by" field. That is not a manufacturing floor failure; it is the quality unit itself operating outside the controls it exists to enforce, in a year when FDA issued 303 drug warning letters, up 59% from 190 the year before.

WHY IT MATTERS

A March 2026 warning letter over Intas Pharmaceuticals' Dehradun, India facility shows what FDA's rising enforcement looks like at the record level. Most internal audit programmes are built to check the records QA oversees. This finding checks whether QA itself is operating inside the controls it's supposed to enforce, a different category of gap.

WHAT TO CHECK

Add two explicit scope items to your next internal audit cycle: quality unit independence (can QA leadership direct a vendor to change GxP records outside your change control system?), and EBR audit trail completeness (does vendor access to your EBR system require a change control record, and would that record capture every modification, including field-level ones like an operator ID substitution?). If your current audit programme cannot answer both questions, that is the gap the Intas letter describes.

Source · FDA, Warning Letters database ↗

9 BA Bioanalytical 2026-04-01

Ph. Eur. 5.1.10 revised, rFC formally accepted as endotoxin test alternative; EDQM comment deadline 30 June 2026

EDQM's Pharmeuropa 38.2 draft revises Ph. Eur. 5.1.10 to add recombinant Factor C as an accepted alternative alongside the existing Limulus Amebocyte Lysate test, not a replacement for it, and reinstates Section 11 to cover recombinant cascade reagent methods, the public consultation closes 30 June 2026, EDQM's last formal comment window before this becomes the compendial standard for rFC method validation.

WHY IT MATTERS

EDQM frames the revision as part of the 3Rs push to reduce animal-derived reagents in testing. That text will set the compendial standard for method validation, equivalence demonstration, and change control documentation for every lab using or transitioning to rFC. After 30 June, the next chance to shape the text through a formal comment cycle is years away.

WHAT TO CHECK

Pull the Pharmeuropa 38.2 draft of Chapter 5.1.10 from the EDQM website and compare it against your current rFC method SOP and change control documentation. EDQM's own summary of the revision: it "has been revised to add the method using recombinant factor C (rFC) and to clarify which specific provisions apply only when using amoebocyte lysate," and Section 11 "has been reinstated and now includes a new reference to the method using recombinant cascade reagents (rCRs)." Flag any gap between that text and your current validation approach before the 30 June 2026 comment deadline.

Source · edqm.eu ↗