THE ENFORCEMENT RECORD

FDA findings tell you what went wrong.

We examine why the decisions failed to hold up.

Learn from actual FDA enforcement cases. Understand the evidence investigators questioned, the decisions behind the findings, and what your own Quality team should examine.

Issue 1 · Sample briefing · November 17, 2026

FICTIONAL DECISION · BR-042 · ILLUSTRATIVE ONLY

Release authorized

Finished-product tests	**Passed**
Environmental monitoring	**Acceptable**
Quality authorization	**Signed**

UNANSWERED QUESTION

Did the evidence adequately address the unresolved airflow discrepancy?

FDA ENFORCEMENT · USV PRIVATE LIMITED

The tests passed. FDA still challenged whether the process was under control.

A warning letter to USV Private Limited raises a fundamental Quality question: when do acceptable test results fail to establish that a manufacturing process is adequately designed and controlled?

FDA warning letter · November 2, 2026 · Reference 320-27-17 · Inspection April 7–17, 2026 · Daman, India · Read the FDA letter ↗

THE EXECUTIVE ASSESSMENT *COMPLIANCEWORXS ANALYSIS*

The central issue was whether passing results adequately addressed documented aseptic-process deficiencies, not simply whether the firm had acceptable test outcomes.

In FDA's words, "such inherent flaws cannot be validated and necessitate redesign." The firm's conclusion that the process was in a state of control rested on outcome results that did not address the design problem. That is a management question about evidence and decisions, not only a manufacturing one.

WHAT FDA FOUND

Unidirectional airflow was not shown over the ISO 5 filling line. Operators breached first air during interventions, and on another line a conveyor blocked airflow to open bottles.

WHY IT MATTERS

Favorable results did not resolve FDA's concern about process design. In FDA's words, such inherent flaws "cannot be validated and necessitate redesign."

THE DECISION EXPOSED

Whether passing results justified concluding the process was in control, and so supporting release.

WHAT YOUR TEAM SHOULD EXAMINE

Which process-control conclusions are supported by direct qualification evidence, and which rest mainly on acceptable test results?

What FDA documented *FROM THE ORIGINAL LETTER*

What FDA observed directly

Evidence about the process itself

AIRFLOW

Smoke studies on the ISO 5 vial filling line did not show unidirectional airflow; air swirled and moved upward. FDA saw significant turbulence in the airflow videos, yet the firm concluded airflow was adequate.

OPERATOR INTERVENTIONS

Operators breached first air by extending their forearms over sterile equipment. Material flow from ISO 7 to ISO 5 was inadequately controlled.

EQUIPMENT POSITION

On another filling line, a conveyor physically blocked ISO 5 airflow from reaching open sterile bottles in transit. Critical areas for aseptic connections and transfers could not assure ISO 5 conditions.

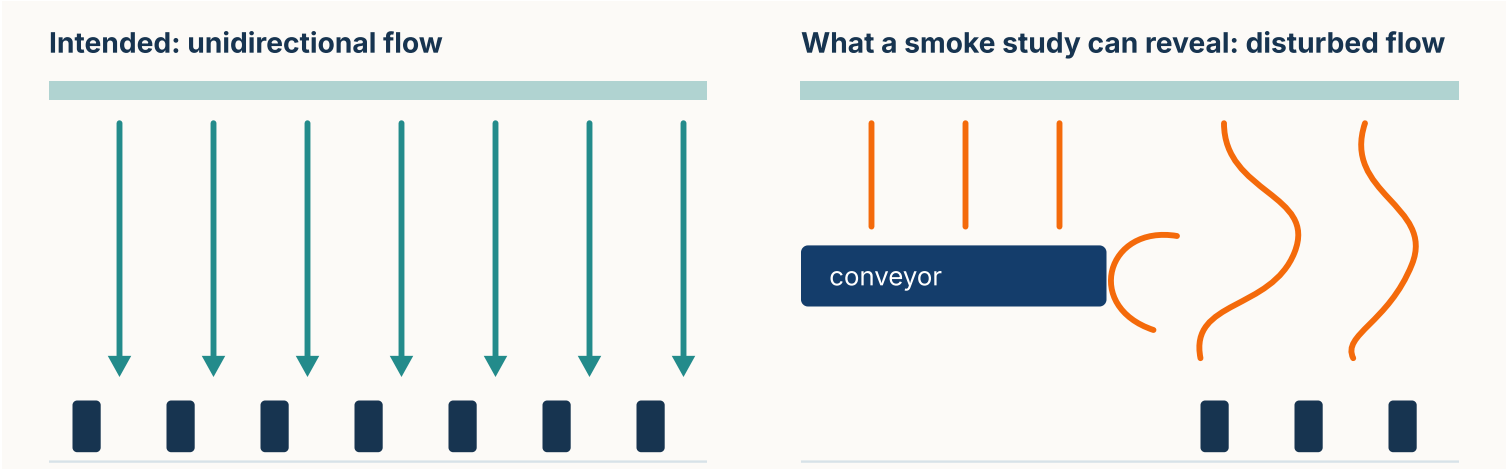
vs.

What the firm relied on

Outcome results and an assessment built on them

- A retrospective risk assessment concluding the process was in a state of control
- Compliant sterility and bacterial endotoxin results for the vial filling line
- Passing media fills for other lines
- Compliant environmental monitoring and “no growth” monitoring

FDA: “your risk assessment relies on proxy indicators such as sterility results, media fill pass rates, and environmental monitoring data without systematically addressing deficiencies in the design and control of your operation.”



Illustrative schematic of the airflow concept. It is not from the FDA letter and does not depict USV's equipment.

AIRFLOW AND UNIDIRECTIONAL PROTECTION

Smoke studies on the ISO 5 vial filling line "did not exhibit unidirectional airflow throughout the ISO 5 area." Air was observed to swirl and move upward, and the studies did not adequately evaluate airflow at the ISO 5 to ISO 7 transition interfaces. FDA also states that significant turbulence was visible in the vial filling line's airflow videos, yet the firm concluded airflow was adequate.

OPERATOR INTERVENTIONS AND FIRST AIR

FDA observed poor aseptic technique during interventions on the filling lines. Operators breached first air by extending their forearms over sterile equipment, and there was inadequate control of material flow from ISO 7 to ISO 5 areas.

EQUIPMENT POSITION AND CRITICAL AREAS

On another filling line, a conveyor system physically blocked continuous ISO 5 unidirectional airflow from reaching open sterile bottles during transport to the filling station. Critical areas used for aseptic connections, sterile component unwrapping and material transfers were insufficient to assure ISO 5 conditions.

WHAT THE FIRM RELIED ON

The firm’s retrospective risk assessment concluded the process was in a state of control. It cited “no growth” monitoring, compliant environmental monitoring for one filling line, compliant sterility and bacterial endotoxin results for the vial filling line, and passing media fills for other lines.

FDA’S ASSESSMENT OF THAT RELIANCE

FDA called the response inadequate: the operations “have fundamental flaws in design leading to unidirectional airflow deficiencies, poor ergonomics, and deficient aseptic practices.” In FDA’s words, “your risk assessment relies on proxy indicators such as sterility results, media fill pass rates, and environmental monitoring data without systematically addressing deficiencies in the design and control of your operation.” FDA described the firm’s remediations as “minor and narrow in scope,” and states the firm committed to suspend production on one line and later told FDA it would discontinue commercial manufacturing from that line for the U.S. market.

Why the response mattered *COMPLIANCEWORXS ANALYSIS*

Two kinds of evidence

Some evidence observes the process itself: smoke studies, the way operators actually intervene, where equipment sits relative to open product. Other evidence samples the outcome: a sterility test on a sample of units, endotoxin results, media fills, environmental monitoring. Both matter. They answer different questions.

Where the letter draws the line

The letter draws its line at what outcome evidence can show. Where direct observation had documented turbulence, upward-moving air and a conveyor blocking airflow, favourable outcome results could not resolve the design question. The firm’s own airflow videos showed turbulence, and its conclusion was that airflow was adequate.

What the letter does not say

The letter does not say passing tests are meaningless. It says they were being asked to carry a conclusion they could not carry. For a Quality team, the useful question is where, in its own records, an outcome result is standing in for evidence about design or control.

What another Quality team should examine

COMPLIANCEWORXS ANALYSIS

1 **Process evidence**

What direct evidence shows how air moves over open product and how operators actually intervene, and who reviewed it?

Where to look. Airflow visualization studies and their video, intervention observations, and the conclusions drawn from each. Check whether the written conclusion agrees with what the footage shows.

2 Qualification

Do our qualification records challenge the known vulnerabilities, such as interventions, transition interfaces and conveyors, or mainly document that the process passed?

Where to look. The worst-case conditions each study used, how they were chosen, and whether any known weakness was left outside the study design.

3 Decision rationale

When a risk assessment concluded the process was in control, which evidence did it weigh, and which contradicting evidence did it address?

Where to look. Whether the assessment begins from the design hazards or from the passing results; which alternatives (redesign, interim controls, restricted release) were considered, and why they were set aside.

4 Quality oversight

How does the quality unit exercise authority over aseptic operations, and what shows it did so before release and continued manufacturing?

Where to look. The frequency and depth of quality oversight of aseptic processing, the authority to stop production, and the review of each batch and its related investigations before disposition. FDA asked USV to address each.

TAKE THIS TO YOUR TEAM

Questions for your next Quality management meeting

1

Where do we rely on acceptable test outcomes as evidence that a manufacturing process remains in control?

2

Do our qualification records directly address known vulnerabilities, or primarily document passing outcomes?

3

When contradictory evidence emerges, can we trace the investigation, risk assessment, disposition decision, and authorization?

A design flaw is a different kind of evidence problem

Validation presupposes a design capable of control. FDA's statement that inherent flaws "cannot be validated" places the problem upstream of any result: if the design lets air swirl over open product or a conveyor interrupt unidirectional flow, a favourable result on a sample does not show that every unit was protected. Outcome results describe what was tested, not how the untested units were protected. (ComplianceWorxs analysis.)

Direct observation versus lagging indicators

Smoke studies are direct evidence about the process. Sterility, endotoxin, media fill and monitoring results lag behind it and can be favourable while the design remains flawed.

The letter’s most instructive detail is a conclusion that contradicted the firm’s own direct evidence: turbulence in the airflow videos, with a finding that airflow was adequate. The review question for any Quality team is whether conclusions are reconciled with the direct evidence they cite.

What FDA asked for shows what it treats as adequate evidence

FDA requested smoke studies conducted under dynamic conditions, with emphasis on the impact of aseptic interventions and the interaction with the surrounding cleanroom, using neutrally buoyant media, after remediation. It also requested the location of each air return and a comprehensive, independent risk assessment of human interactions, equipment suitability, air quality, facility layout, and personnel and material flow. Read as a list, it describes the evidence that would have spoken to the design.

Operating conditions

The letter ties the airflow concern to how the line is actually operated: interventions, material transfers between ISO 7 and ISO 5, and aseptic connections. Evidence gathered under idealised or static conditions does not describe those. A record of continued manufacturing is only as strong as the conditions the underlying evidence represents. (ComplianceWorxs analysis.)

The rationale for continued manufacturing and release

FDA states the firm’s retrospective risk assessment concluded the process was in a state of control. Any decision to keep manufacturing and releasing from that operation while the design concerns were open depended, in practice, on that conclusion. The record question is whether the reasoning connecting the design concerns to those decisions was written down at the time, by someone with the authority to stop production. (ComplianceWorxs analysis; the letter does not describe the firm’s release decisions beyond the particulate finding.)

What a defensible record would need to show

Not that the product was unsafe, and not that passing results are unimportant. A defensible record would show the design evidence reviewed, how the contradicting direct evidence was addressed, the residual risk accepted, and who accepted it under what authority, before the decision was made. (ComplianceWorxs analysis, not an FDA statement.)

Limits. The letter is FDA's account at the time of issuance. It does not describe USV's current status or remediation, and it does not report a contaminated batch; FDA's concern is the design and control of the process. Some passages are redacted in the public letter and are not reconstructed here.

Source: **FDA warning letter 320-27-17 to USV Private Limited ↗**

Working through a release decision? Batch Release Authorization Record · $75 →

FROM ENFORCEMENT FINDING TO YOUR QUALITY SYSTEM

How could the same reasoning weakness appear in your organization?

> FICTIONAL DECISION REVIEW / BR-042
> A fictional scenario. It is not an FDA finding and not a real case.

A fictional sterile injectable manufacturer completed a batch. Release testing passed. Environmental monitoring was acceptable. An airflow-study discrepancy near the filling operation remained unresolved at the time Quality authorized release.

Batch release record

BR-042

FICTIONAL RECORD

PRODUCT

Sterile injectable (fictional)

RELEASE TESTING

Passed

ENVIRONMENTAL MONITORING

Acceptable

AIRFLOW-STUDY DISCREPANCY

Unresolved at authorization

APPROVAL RATIONALE

All release criteria were met. No evidence of contamination was detected. Batch release approved.

QUALITY AUTHORIZATION

Signed

Choose a part of the analysis. The matching line of the record is highlighted.

Evidence

THE QUESTION TO EXAMINE

What information actually supported the decision?

WHAT THE FICTIONAL RECORD ESTABLISHES

Release testing passed. Environmental monitoring was acceptable. The approval rationale states that all release criteria were met and that no evidence of contamination was detected.

WHAT IT DOES NOT ESTABLISH

What the airflow-study discrepancy was, where it was observed, or whether it was assessed against this batch’s operations. The rationale does not mention it.

WHAT STRONGER EVIDENCE OR REASONING WOULD REQUIRE

The airflow study itself, the location and operating conditions of the discrepancy, and a statement of how it bears on this batch.

Judgment

THE QUESTION TO EXAMINE

Why was that information considered sufficient?

WHAT THE FICTIONAL RECORD ESTABLISHES

A conclusion that criteria were met and no contamination was detected.

WHAT IT DOES NOT ESTABLISH

Why favourable results were considered enough to resolve an open process concern, or whether alternative explanations for the discrepancy were weighed.

WHAT STRONGER EVIDENCE OR REASONING WOULD REQUIRE

Reasoning that addresses the contradicting evidence directly, explains what the results could and could not answer about it, and records the alternatives considered: further investigation, a hold, or restricted release.

Risk

THE QUESTION TO EXAMINE

What uncertainty remained, and how was it evaluated?

WHAT THE FICTIONAL RECORD ESTABLISHES

Nothing. The rationale does not mention remaining uncertainty.

WHAT IT DOES NOT ESTABLISH

That the discrepancy was risk-assessed, what residual risk existed, or who judged it acceptable.

WHAT STRONGER EVIDENCE OR REASONING WOULD REQUIRE

A documented risk evaluation tied to the discrepancy, with the residual risk, any conditions on release, and the basis for accepting it.

Authorization

THE QUESTION TO EXAMINE

Who accepted the decision, and on what documented basis?

WHAT THE FICTIONAL RECORD ESTABLISHES

Quality authorization is signed.

WHAT IT DOES NOT ESTABLISH

That the signer saw the airflow discrepancy, the authority under which release was approved with it open, or whether anyone else reviewed it.

WHAT STRONGER EVIDENCE OR REASONING WOULD REQUIRE

The named authority, the date, the evidence reviewed at the time, and a record that the unresolved item was visible to the person who authorized release.

Passing test results do not substitute for resolving contradictory evidence.

The point is not that the fictional batch should have been rejected. It is whether the authorization was scientifically justified, adequately documented, and consistent with applicable requirements.

ALSO IN THIS ISSUE

Different findings. The same need for defensible decisions.

INVESTIGATION ADEQUACY, STERILITY-TEST INVALIDATION AND RELEASE AUTHORIZATION

Baxter International Inc.

FDA warning letter · September 29, 2026 (posted October 20) · Reference 320-26-132

WHAT FDA DOCUMENTED

FDA states a 2025 cefazolin sterility failure was invalidated as a “no-test” without adequate scientific justification, and the lot was released in July 2025.

THE DECISION OR RESPONSIBILITY EXPOSED

Whether an invalidated result, and a complaint closed without field action, could support release.

THE QUESTION FOR YOUR OWN ORGANIZATION

For any critical result we have invalidated: who decided it was invalid, on what basis, and what did release then rely on?

Read the FDA letter ↗

FDA describes a 2025 cefazolin sterility failure whose root cause the firm assigned to a non-integral test container. Records had shown container integrity verified; after turbidity was observed, the investigation said it had not been, classified the result a “no-test,” and, without a Phase II investigation, concluded there was no risk. FDA states the result was invalidated “without adequate scientific justification,” and the lot was released in July 2025.

FDA also describes a returned cefazolin sample that confirmed foreign particulate consistent with cardboard. The investigation concluded field action was not warranted; FDA states the firm agreed to a voluntary recall of lot LD175708 on July 17, 2026, only after the Agency contacted it. The letter also cites containment monitoring, aseptic process and visual inspection deficiencies, and says FDA discussed similar violations at the facility in January 2025.

ComplianceWorxs analysis: the decisions exposed are closing a sterility investigation as a no-test, releasing the lot, and concluding a confirmed complaint did not warrant field action.

Limits. FDA's account at the time of issuance; not Baxter's current status. Passages are redacted in the public letter.

OOS Investigation Case File · $149 →

SUPPLIER QUALIFICATION, MANUFACTURING RESPONSIBILITY AND CHANGE AUTHORIZATION

Nanjing Hanxin Pharmaceutical Technology Co. Ltd.

FDA warning letter · November 3, 2026 · Reference 320-27-19 · Records review under section 704(a)(4)

WHAT FDA DOCUMENTED

FDA found the quality unit failed to adequately qualify suppliers of critical raw materials for an API. After November 2025, production of one API had moved to a subsidiary.

THE DECISION OR RESPONSIBILITY EXPOSED

Whether supplier qualification and the production move rested on evidence.

THE QUESTION FOR YOUR OWN ORGANIZATION

For each critical starting material: what evidence qualified the supplier, and who approved the change when supply moved?

Read the FDA letter ↗

FDA's letter follows a review of records the firm submitted, not an inspection. FDA found the quality unit failed to adequately qualify suppliers of critical raw materials for an active pharmaceutical ingredient, after production of one API was moved to a subsidiary following November 2025.

FDA states it is concerned that naming the firm rather than the actual manufacturer "may have been an attempt to circumvent safeguards," and that all drugs the firm offers for import have been on Import Alert 66-40 since June 22, 2026.

ComplianceWorxs analysis: the decisions exposed are the qualification of a supplier for a critical starting material and the production move around it. FDA's letter cites supplier qualification and quality unit responsibility; it does not cite a change-control record, and we analyze the move as a change decision.

Limits. FDA's account at the time of issuance. Passages are redacted in the public letter.

Change Control Approval Case File · $149 →

MANUFACTURING-RECORD AVAILABILITY, TRACEABILITY AND QUALITY OVERSIGHT

Chongqing Qiancan Technology Co., Ltd.

FDA warning letter · October 29, 2026 (posted November 10) · Reference 320-27-14 · Records review under section 704(a)(4)

WHAT FDA DOCUMENTED

FDA requested records on June 17, 2026. The firm refused, deregistered on June 29 and re-registered on July 13. The records were never provided.

THE DECISION OR RESPONSIBILITY EXPOSED

Whether the firm could produce the record when asked.

THE QUESTION FOR YOUR OWN ORGANIZATION

If FDA requested the records behind a U.S.-bound lot tomorrow, who would assemble them, and what would they show?

Read the FDA letter ↗

FDA requested manufacturing records under section 704(a)(4) on June 17, 2026. The firm refused to provide them, deregistered and discontinued its drug listing on June 29, and re-registered on July 13. The records were never provided, although its APIs had been imported into the United States and were still within expiry.

FDA states it has “no indication of the level of quality assurance” for the drugs listed as made at the facility, and that refusing access to records is a prohibited act under section 301(e) of the FD&C Act.

ComplianceWorxs analysis: the responsibility exposed is the ability to produce, on request, the records behind a product shipped to the United States. The letter describes a refusal, not a decision made inside a quality system.

Limits. FDA’s account at the time of issuance. It describes a refusal to provide records, not a finding about the firm’s manufacturing.

No ComplianceWorxs product is attached to this item. The letter describes a refusal, not a decision.

TAKE THE ANALYSIS INTO YOUR ORGANIZATION

Give your team something to work with.

The Quality Decision Review is a working guide built on the issues in the USV analysis. It helps a Quality team examine its own decisions in a structured internal discussion.

- Evidence to examine
- Process-control assessment questions
- Qualification and investigation considerations
- Unresolved-risk review prompts
- A fictional authorization example
- A management discussion guide
- A discussion worksheet, with a completed fictional example
- Source references and limitations

Quality Decision Review

PDF · Free · No email required

Download the guide ↓

Read it online →

A discussion resource. It does not determine whether your organization is compliant, and its fictional applications are marked as fictional.

Each week, The Enforcement Record reads the newest FDA enforcement the way a Quality leader reads it: not as a list of violations, but as a test of one decision. What happened. What the FDA source says. The decision it tested. What the record failed to show.

What FDA documented. Taken from the original warning letter, in the letter's own terms. Quotation marks mark FDA's exact words.

ComplianceWorxs analysis. Our reading of the decision the letter tests. It is not an FDA statement and not a finding about any company's current operations.

Questions for your own team. What to check in your own records. Nothing here describes your organization.

All four sources are FDA warning letters, not Form 483s. A Form 483 lists an investigator's observations at the close of an inspection, and FDA states it is not a final agency determination. A warning letter is FDA's later written notice of significant violations, often after reviewing the firm's response to the 483.

Related: FY2025 Form 483 citations, ranked from FDA's own data · the ComplianceWorxs 2026 FDA Enforcement Intelligence Report · this issue as a PDF

COMPLIANCEWORXS ENFORCEMENT INTELLIGENCE

One enforcement case is valuable. Recognizing patterns across cases is more valuable.

Give your Quality team a consistent way to examine what FDA is finding, understand why the underlying decisions were challenged, and identify questions worth investigating within your own organization.

ComplianceWorxs translates actual FDA enforcement findings into intelligence that helps Quality professionals examine the reasoning behind their own decisions: the

finding, the evidence at issue, the decision exposed, the management implication, and a practical review for your organization.

Subscribers would receive continuing intelligence they can apply to their Quality oversight, week after week, not simply more articles.

WEEKLY · PROPOSED

The Enforcement Record

Complete analysis of selected actual FDA enforcement findings.

- Source-supported regulatory findings
- The decision each finding exposes
- Evidentiary weaknesses
- Quality-management implications
- Practical review questions

HOW YOUR TEAM USES IT

Bring one case to your Quality meeting and examine a decision of your own against it.

MONTHLY · PROPOSED

Enforcement Intelligence Review

A synthesis across the month’s cases.

- Recurring enforcement themes
- Patterns across cases
- Implications for Quality leadership
- Areas that warrant examination within Quality systems

HOW YOUR TEAM USES IT

Brief leadership on the patterns, and on where your own systems deserve a closer look.

TEAM APPLICATION · PROPOSED

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HOW YOUR TEAM USES IT

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