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U.S. Quality Intelligence Brief

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Independent analysis of consequential U.S. pharmaceutical and medical-device quality developments, with practical implications for investigations, CAPA, remediation, and product disposition.

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This edition examines three developments involving sterile-product quality, with a common lesson: quality decisions must account for the full body of available evidence.

FDA's September 22 warning letter to Fresenius Kabi illustrates why passing finished-product tests cannot erase adverse evidence from complaints, in-process bioburden, media fills, or observed aseptic practices. Two additional developments reinforce related lessons about injectable-material suitability and the responsibilities of companies using contract manufacturers.

1. Fresenius Kabi: Passing Release Tests Did Not Justify Release

What changed

In its September 22, 2026, warning letter, FDA described significant deficiencies at Fresenius Kabi's sterile-injectable facility at **2085 North Hawthorne Avenue, Melrose Park, Illinois**, following an inspection conducted from January 27 through February 18, 2026.

The findings concerned investigations, aseptic processing, media fills, visual inspection, contamination control, and batch disposition.

Among the findings:

- The company released famotidine injection batches despite in-process bioburden action-limit failures, relying on passing finished-product sterility and endotoxin results. Subsequent retain testing during investigations of adverse-event complaints—including apparent pyrogenic reactions—identified an endotoxin failure. Three batches were ultimately recalled.
- Media-fill failures in 2024 and 2025 were attributed to deficient operator technique, but the investigations did not adequately examine why the aseptic-observer program had failed to detect the practices during commercial operations.

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- The company placed certain commercial batches on hold but did not take comparable action for liquid products made on other limited-barrier lines that shared implicated operators.
- Beginning in May 2022, the company documented at least nine incidents of extrinsic contamination during visible particulate inspection, including free-floating hair in direct contact with the drug product. Associated commercial batches were released without timely, sufficiently comprehensive investigations.
- Media fills did not adequately represent maximum intervention counts or worst-case operations. FDA also identified inadequate documentation of routine interventions—a concern previously raised during the 2022 inspection.
- The visual-inspection program classified all non-glass particles, including hair, as “major,” failing to recognize biological contamination as a critical defect. Visible glass particles were not consistently detected.

FDA requested independent assessments of the investigation and CAPA systems, together with a retrospective review of critical investigations from the preceding three years. It also requested broad assessments of contamination control, environmental monitoring, media fills, supplier quality, and quality-unit oversight.

Notably, FDA requested an updated plan to expedite an existing transfer of manufacturing away from deficient aseptic filling lines while maintaining drug availability, including arrangements for backup contract manufacturing.

[Read the Fresenius Kabi warning letter](#)

Why it matters

This is a strong enforcement example of **overreliance on passing finished-product tests**.

Sterility and endotoxin testing evaluate samples from a batch. Passing results do not negate adverse evidence generated elsewhere in the manufacturing and quality systems.

When complaints, in-process bioburden, environmental monitoring, media fills, or direct observations indicate a potential loss of control, the quality unit must assess the significance and scope of that evidence. Passing release results alone cannot establish that the affected batch—or related batches—was unaffected.

The letter also illustrates why “operator error” is rarely an adequate root cause by itself. If trained observers repeatedly failed to identify poor aseptic practices, the investigation

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must examine more than the conduct of an individual operator. Depending on the evidence, potential systemic contributors to evaluate include:

- Supervision and production oversight
- Operator and observer qualification
- Production pressure and staffing
- Line design and ergonomics
- Intervention frequency and complexity
- Whether the observation program reliably detects the behaviors it is intended to control

These are investigation considerations, not a claim that FDA established each as a cause in this case.

FDA's request for expedited production-transfer planning also carries a practical message: procedural revisions, retraining, and enhanced monitoring may be insufficient when underlying equipment or facility design cannot support robust aseptic control. Transfer plans likewise do not eliminate the need for effective controls while existing lines remain in operation.

Carry forward

Review batch-disposition decisions in which an adverse upstream signal was discounted because finished-product testing passed.

A useful challenge question is:

What evidence did the quality unit discount because the final tests passed—and was that scientifically justified?

For organizations operating legacy aseptic lines, remediation should distinguish between:

- Immediate containment and interim controls
- Improvements that can be achieved procedurally
- Equipment or facility modifications
- Operations that must ultimately be transferred or discontinued

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2. Greenwich Rx: Another Injectable-Glutathione Endotoxin Recall

What changed

On October 1, 2026, Greenwich Rx announced a voluntary nationwide recall of ten lots of compounded glutathione, 200 mg/mL, in 10 mL multidose vials because of potentially elevated endotoxin levels.

The 503A compounding pharmacy distributed the product to patients nationwide between June 26 and September 21, 2026.

The preparation was intended for subcutaneous injection. However, the company reported two cases involving patients who received emergency-department care following intravenous administration of a glutathione product that was not formulated for IV use.

The company's recall announcement, posted by FDA, identified potential consequences of elevated endotoxin exposure including fever, hypotension, inflammatory reactions, anaphylactic shock, and death. The announcement reports adverse events; it does not establish the cause of each patient's reaction.

[Read the Greenwich Rx recall announcement](#)

The recall follows FDA's August 27 advisory concerning injectable products compounded from glutathione labeled for dietary-supplement use. FDA reported at least 30 patients who experienced adverse events after receiving intravenous compounded glutathione, alone or in combination with other ingredients.

FDA emphasized that compounders must establish ingredient suitability for the intended route of administration and should not rely on testing alone to ensure product quality.

The Greenwich recall announcement does not identify the supplier or source of its glutathione. A direct connection to the material identified in FDA's earlier investigation therefore should not be assumed.

[Read FDA's compounded-glutathione advisory](#)

Why it matters

Taken together, these reports warrant attention to a broader set of quality risks:

- Raw-material suitability
- Supplier qualification
- Upstream-manufacturer traceability

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- Endotoxin controls
- Route of administration
- Assessment of all products and batches potentially affected by the same API lot

A certificate of analysis establishing identity, assay, or purity does not by itself demonstrate that an ingredient was manufactured, packaged, stored, and controlled under conditions appropriate for parenteral use.

The reported intravenous administration also matters. From an investigation and risk-management perspective, assessments should consider documented actual use, including use through a route other than the one intended. This does not establish that Greenwich knew of such use before the reported events or that its product was suitable for intravenous administration.

Carry forward

When an incoming material is implicated, construct the exposure map by **material lot**, not merely by finished-product lot.

As applicable, the assessment should identify:

- Every preparation and strength containing the material
- Every affected batch and dispensing date
- Patients, prescribers, and administering clinics associated with affected preparations
- Intended routes of administration and documented or reasonably foreseeable alternative use
- Remaining raw material, stock solutions, and partially used containers
- Other products potentially affected through shared materials, equipment, or processes

For injectable products, supplier qualification should establish suitability for the intended route—not solely compliance with identity, assay, or purity specifications.

3. Neogen and Sciarra Aeromed: Sterile-Product Responsibility Cannot Be Outsourced

What changed

On September 29, FDA announced warning letters dated September 23 to Neogen Corporation and its contract manufacturer, Sciarra Aeromed, following fungal contamination of Neogen Vet HYCOAT, a hyaluronate sodium product labeled as sterile.

FDA linked the product to serious joint infections in nearly 100 horses and reported that at least 20 horses were euthanized after unsuccessful treatment.

FDA testing identified several fungal organisms, including *Purpureocillium lilacinum*, which the agency described as particularly resistant to antifungal drugs. Although marketed as a topical wound-management product, HYCOAT was also commonly used as an injection into equine joints.

FDA emphasized that contamination presented serious risks even when the product was used topically as labeled. The concern was therefore not limited to off-label injection.

Manufacturing findings included:

- No use of a sporicidal agent in the relevant cleanroom areas
- No cleaning validation or written cleaning procedure
- Missing viable-air and personnel monitoring during production
- No static or dynamic smoke studies
- Deficient gowning practices, including exposed skin
- Media fills that did not adequately represent worst-case production
- Apparent water damage, residues, poor facility maintenance, and gaps permitting potential pest ingress

FDA also faulted Neogen's oversight of its contract manufacturer. The agency emphasized that distributing the product under Neogen's label carried responsibility for ensuring that it was not adulterated or misbranded before introduction into interstate commerce.

[Read FDA's summary of the Neogen and Sciarra Aeromed enforcement actions](#)

[Read the Neogen warning letter](#)

[Read the Sciarra Aeromed warning letter](#)

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Why it matters

Although this is a veterinary case, the quality-system lessons are relevant to human pharmaceuticals and medical devices. The specific regulatory requirements differ by product category.

A quality agreement, supplier questionnaire, or document-only audit cannot substitute for a meaningful assessment of:

- The physical condition of the manufacturing facility
- Actual aseptic practices
- Contamination-control measures
- Environmental-monitoring performance
- Validation evidence
- Complaint and adverse-event information
- The way the product is used in the field

The case also demonstrates why risk assessments should account for known real-world use. FDA specifically discussed common joint-injection use in its findings. At the same time, the product's labeled topical use already required effective contamination controls.

For product owners, the practical question is whether supplier oversight provides reliable evidence of manufacturing capability and continuing control—not simply whether an agreement or audit report exists.

Carry forward

For sterile contract manufacturing, confirm that supplier oversight evaluates, as applicable:

- Facility condition and cleanroom suitability
- Dynamic smoke studies and intervention design
- Environmental and personnel monitoring
- Cleaning validation and demonstrated disinfection effectiveness, including sporicidal treatment
- Worst-case media-fill design

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- Complaint and adverse-event sharing
- Information about actual field use, including known off-label use
- Escalation responsibilities
- Batch-disposition authority
- Contractual rights and mechanisms for investigating concerns and requiring corrective action

The central question is not whether the contract manufacturer has written procedures. It is whether the product owner has sufficient evidence that those procedures are scientifically sound, consistently executed, and effective.

The Week in Context

This edition focuses on three developments illustrating contamination control, investigation scope, and manufacturing oversight. It is a selective analysis rather than an exhaustive inventory of the week's regulatory actions or recalls.

Across these cases, the common lesson is clear:

Quality decisions must consider the totality of the evidence. Passing release tests, contractual separation, or nominal labeling cannot justify disregarding credible indications of process failure or product risk.

For quality leaders, that means ensuring investigations extend far enough to identify affected products, challenge unsupported assumptions, and distinguish procedural weaknesses from fundamental limitations in materials, equipment, facilities, or oversight.

Worth Reading

1. [Fresenius Kabi warning letter](#)
A detailed case study in investigations, aseptic processing, batch disposition, CAPA, visual inspection, and remediation of legacy manufacturing lines.
2. [FDA's Neogen and Sciarra Aeromed enforcement summary](#)
An illustration of the consequences of inadequate sterile-manufacturing controls and weak contract-manufacturer oversight.
3. [Neogen warning letter](#) and [Sciarra Aeromed warning letter](#)
Best read together to compare the responsibilities of the product owner with those of the contract manufacturer.

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4. Greenwich Rx recall announcement and FDA's compounded-glutathione advisory

Source material for raw-material suitability, material-lot investigation scope, supplier qualification, and route-of-administration risk.

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