

HAMILTON QUALITY LLC

U.S. Quality Intelligence Brief

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This Week: Microbiological Data, Sterile Manufacturing, and Investigation Evidence

FDA's October 13 postings included five drug-CGMP warning letters and one warning letter addressing Good Laboratory Practice for nonclinical studies. The letters were issued between September 14 and October 6; their posting dates should not be confused with the dates of the underlying inspections or findings.

This edition examines those letters alongside a Par Health injectable-drug recall and an FDA early alert concerning an Edwards Lifesciences delivery system.

The practical question connecting these developments is whether the available evidence supports a quality decision—from the original laboratory observation through investigation, product-impact assessment, and final disposition.

Editorial note: This brief summarizes the cited public records. Warning-letter summaries describe FDA's stated findings as of the letter date; subsequent responses or corrective actions may have changed the status of the matters discussed. "Why it matters" and "Carry forward" present Hamilton Quality's analysis and recommendations, rather than additional findings about the named organizations.

1. Silgan: FDA Questions Averaging of Microbiological OOS Results

What changed

FDA's October 5 warning letter to Silgan Dispensing Systems addresses its Silgan Unicep Packaging facility in Spokane, Washington.

FDA stated that the firm invalidated individual out-of-specification microbiological results by averaging sample results to obtain a passing result, then revised its sampling plan to permit averaging. The agency considered that approach inconsistent with USP <61> and inadequate for detecting nonuniform contamination. According to the letter, the affected components were released and used in manufacturing.

The letter also describes a customer recall involving potential fungal contamination and subsequent OOS results that FDA considered evidence of an ineffective corrective action.

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FDA acknowledged commitments to prohibit averaging and conduct a retrospective review, but found the proposed review too narrowly limited to documented OOS events.

[Read the FDA warning letter to Silgan Dispensing Systems](#)

Why it matters

An overall passing result may not adequately represent the significance of an individual failure. The appropriateness of averaging depends on the method, sample design, and scientific justification; averaging independent sample results should not be confused with calculating a result from method-defined replicates.

Carry forward

Retrospective reviews should examine invalidated results, repeat testing, changes to acceptance practices, and related disposition decisions. Define how the review will identify questionable passing conclusions as well as recorded failures.

2. Eurofins: FDA Cites Incomplete Microbiological Records and Customer-Impact Assessment

What changed

FDA's October 6 letter concerns Eurofins SF Analytical Laboratories' contract laboratory in Horsham, Pennsylvania.

FDA described omitted results assessed as too numerous to count, reported results from cracked or desiccated media, and a colony observed on a plate recorded as zero colony-forming units. The letter also describes damaged plates discarded without secondary review.

According to FDA, the firm's response acknowledged inconsistent reporting practices dating to February 2025 and proposed procedural changes, training, and audits. FDA found that the response did not adequately address whether customers had received incomplete or potentially inaccurate data or certificates of analysis.

The agency requested independent assessments, stronger sample controls, secondary verification, and time-stamped photographs of plates when read. The photographic controls are a request in this particular letter, not a newly announced universal requirement.

[Read the FDA warning letter to Eurofins SF Analytical Laboratories](#)

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Why it matters

A laboratory report is only as dependable as the underlying observations and records. Correcting future reporting practices does not, by itself, establish the reliability of historical results.

Carry forward

Contract-laboratory oversight should address raw-data access, anomalous media, sample retention, secondary review, and timely customer notification. When historical reliability is uncertain, establish how affected results, products, and decisions will be identified and assessed.

3. Hanlim Pharm: FDA Identifies Aseptic-Process Design and Control Deficiencies

What changed

FDA's October 2 letter describes findings at Hanlim Pharm's Yongin facility in South Korea.

The agency reported interruptions to first-air protection, a visibly stained gown in a Grade A area, inadequate airflow studies, and equipment-design concerns. FDA stated that airflow patterns permitted lower-quality air to enter the aseptic-processing line when portions of the barrier were opened.

The letter also addresses disinfection in place of sterilization of certain critical contact surfaces, environmental-monitoring deficiencies, and inadequate visual-inspection controls.

FDA acknowledged commitments to redesign equipment, decommission certain lines, improve training, and suspend or cease specified production. It nevertheless found the response insufficient and requested broader assessments, remediation, and qualification of the revised operations.

[Read the FDA warning letter to Hanlim Pharm](#)

Why it matters

Training and facility design address different parts of contamination control. Operators need both appropriate skills and equipment that permits reliable execution of aseptic practices.

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Carry forward

Evaluate airflow, ergonomics, interventions, equipment suitability, and monitoring together. Qualification should challenge the remediated process under representative operating conditions. Effectiveness checks should demonstrate sustained control during routine production, beyond completion of training or installation activities.

4. SCA Pharmaceuticals: FDA Addresses Evidence Retention and Batch-Impact Assessments

What changed

FDA's September 14 letter concerns SCA Pharmaceuticals' Little Rock, Arkansas outsourcing facility.

FDA stated that the firm retained still images, rather than the complete production video reviewed during a contamination investigation. The letter describes recordings being overwritten after a retention period; it does not establish that footage was deleted to obstruct an investigation.

FDA also questioned whether released portions of affected batches had been adequately assessed for the same sanitization deficiencies associated with rejected portions. Additional findings addressed particle classification and investigation thresholds.

The agency acknowledged that some corrective actions appeared adequate, while finding others deficient or insufficiently supported.

[Read the FDA warning letter to SCA Pharmaceuticals](#)

Why it matters

Still images may omit sequence, duration, movement, or interventions necessary to evaluate an investigation's conclusions. Likewise, rejecting part of a batch does not establish that the remainder was unaffected.

Carry forward

Protect video and other transient records when they become investigation evidence. Document the basis for separating affected and unaffected product. Particle classification and escalation should reflect the nature of the material and its potential product contact, alongside defect frequency.

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5. Jiangmen Shuizirun: FDA Questions Sterile Labeling and Lot Identification

What changed

FDA's September 23 letter addresses Jiangmen Shuizirun Sanitary Articles' manufacturing facility in China.

FDA stated that certain OTC products were labeled sterile despite not being sterilized or subjected to sterility testing at release. The letter also describes inadequate component testing and supplier-test verification.

FDA reported that products with different active ingredients, routes of administration, use instructions, and manufacturing dates shared a batch number.

The letter acknowledges proposed raw-material testing changes but finds them insufficiently specified. It also states that, as of the letter date, neither the firm nor its U.S. agent had responded to FDA's February recall-related outreach. FDA recommended removal of affected, unexpired products labeled sterile from the U.S. market.

[Read the FDA warning letter to Jiangmen Shuizirun](#)

Why it matters

Labeling claims need supporting manufacturing and release controls. Product identification must also permit reconstruction of the relevant manufacturing, testing, and distribution history.

Carry forward

Verify that specifications and process controls support each product claim. Challenge traceability using actual records: can the organization distinguish affected products and production periods, identify recipients, and reconcile quantities during a recall assessment?

6. Par Health: Argatroban Recall Highlights Particulate Investigation Scope

What changed

Par Health announced a voluntary recall of 22 lots of Argatroban Injection on October 13; FDA posted the announcement on October 14.

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The company reported particulate matter detected in certain lots, including cellulose, polystyrene, polyethylene terephthalate, stopper material, and possibly stainless steel. The announcement does not establish that every recalled lot contained every listed material.

The notice describes potentially life-threatening consequences from administration of affected product. Par reported no related adverse events as of the announcement.

For context, FDA had posted a separate Par recall of two Brevital Sodium lots on October 9 because of cellulose particles. That posting falls in the preceding reporting week.

[Read the Argatroban recall announcement](#)

[Read the Brevital Sodium recall announcement](#)

Why it matters

Different particle materials can require different investigative approaches. The public announcements do not establish a common cause, manufacturing line, or facility for the two recalls.

Carry forward

For comparable investigations, reconcile particle identification with components, equipment, filtration, cleaning materials, maintenance, and inspection history. Evaluate shared systems where evidence supports doing so, and document both the rationale for expanding the assessment and the basis for excluding unrelated products.

7. Edwards Lifesciences: FDA Early Alert Addresses Four Delivery-System Lots

What changed

FDA's October 15 early alert concerns four lots of Edwards Lifesciences Commander M delivery systems used with the SAPIEN M3 transcatheter mitral-valve replacement system.

According to the alert, Edwards received three reports of balloons bursting during inflation. As of October 5, the company had reported one death and one serious injury associated with the issue. These reported associations should not be presented as an independent determination of causation.

FDA described potential embolism and difficulty retrieving the device, possibly requiring additional intervention. Edwards instructed customers to remove and return affected units.

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The alert identifies four affected lots and states that other lot numbers can continue to be used.

FDA indicated that its review was continuing.

[Read the FDA early alert concerning the Edwards Commander M delivery system](#)

Why it matters

Complaint counts need context. Severity, patient vulnerability, and the feasibility of recovering from a device failure can justify urgent action even when the reported number of events is small.

Carry forward

Escalation criteria should address credible harm and available interventions. Distinguish reported event counts from incidence rates, which require an appropriate denominator, and distinguish reported associations from established causation.

8. Lovelace Biomedical: FDA Questions Reconciliation of Study Reports to Raw Data

What changed

FDA's October 6 letter to Lovelace Biomedical Research Institute addresses Good Laboratory Practice requirements for nonclinical studies.

FDA stated that final study reports omitted clinical observations and dosing-related information present in the raw data. The agency acknowledged revised reports and corrective-action commitments, but found that dosing issues remained incompletely addressed and that the response lacked sufficient detail on procedures, training, and audits.

FDA also acknowledged that the finding as described in the warning letter had not been included on the Form FDA 483. The correspondence should therefore not be characterized as a failure to answer that exact inspectional observation.

[Read the FDA warning letter to Lovelace Biomedical Research Institute](#)

Why it matters

This is a GLP matter, distinct from the CGMP manufacturing letters discussed above. The broader quality lesson is that a report can be internally consistent while failing to represent its underlying records adequately.

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Carry forward

QA review should test traceability from source records to final conclusions. When a report is corrected, verify both the completeness of the amendment and the effectiveness of changes intended to prevent recurrence.

The Week in Context

This edition focuses on selected enforcement and safety developments; it is not an exhaustive inventory of regulatory activity.

Hamilton Quality's interpretation is that these cases offer useful prompts for reviewing how quality systems preserve evidence and support decisions:

- Can reviewers reconstruct the original observations behind a reported result?
- Does an investigation's scope include potentially affected product beyond the initially identified failure?
- Are transient electronic records preserved when they support quality decisions?
- Do corrective actions address process design and oversight as well as personnel performance?
- Can product-impact assessments be followed from the identified hazard through batch disposition and customer action?

These questions are useful beyond the specific facilities and products discussed. They provide a practical way to examine whether a completed investigation or CAPA has produced adequate evidence of control.

Worth Reading

- [Silgan warning letter](#): OOS evaluation and retrospective review.
- [Eurofins warning letter](#): Microbiological records and customer-impact assessment.
- [Hanlim warning letter](#): Aseptic-process design and remediation.
- [SCA Pharmaceuticals warning letter](#): Investigation evidence and batch-impact assessment.
- [Lovelace warning letter](#): Reconciliation of final reports to raw data.
- [FDA warning-letter index](#): Original correspondence and available updates.

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

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