HAMILTON QUALITY LLC

U.S. Quality Intelligence Brief — Week Ended September 20, 2026

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

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The week was moderately active but highly concentrated. FDA's Warning Letter to Bausch + Lomb is the clear headline and belongs in any current reference file addressing contamination investigations, adverse trending and sterile-product disposition.

A newly classified BD Alaris recall also provides an unusually concrete lesson in complete-system validation: equipment that meets nominal performance expectations may still produce unacceptable results when used with specific accessories under foreseeable clinical conditions.

1. Bausch + Lomb: FDA connects environmental trends, complaint isolates and batch-release decisions

What changed

FDA posted a Warning Letter to Bausch & Lomb following its March 2026 inspection of the company's sterile-drug manufacturing facility at 8500 Hidden River Parkway in Tampa, Florida.

FDA cited deficiencies involving the company's environmental- and personnel-monitoring programs, contamination investigations, aseptic-process design and process simulations.

The agency described environmental recoveries between 2023 and 2025 that included water-associated gram-negative organisms and other potentially objectionable microorganisms. Deficiencies included:

- Inadequate environmental-monitoring sampling locations and procedures.
- Inadequate selection and use of microbiological growth media.
- Insufficient organism identification and adverse-trend investigation.
- Inadequate investigation of recurring ISO 5 excursions.
- Continued manufacturing without sufficient CAPA for persistent contamination signals.
- Barrier, restricted-access barrier system and ergonomic design weaknesses.

- Smoke studies that did not adequately demonstrate unidirectional-airflow protection during setup and interventions.
- Aseptic practices that included reaching over exposed containers and returning bottles associated with questionable interventions to the production line.
- Media fills that were not sufficiently representative of commercial-batch size, duration and operational risk.

FDA also noted that *Pseudomonas aeruginosa* and *Aspergillus brasiliensis* recovered from the manufacturing facility were the same species identified in several consumer-complaint samples. A July 2025 process simulation produced two contaminated units.

Why it matters

The company cited environmental-monitoring results, passing finished-product sterility tests and complaint rates as evidence supporting continued product release. FDA rejected reliance on those factors as sufficient justification.

The Warning Letter emphasizes that a finished-product sterility test is only one element of the overall contamination-control system. A passing result cannot independently overcome adverse evidence involving facility conditions, environmental trends, process simulations, interventions, aseptic behavior and complaint samples.

The enforcement significance extends beyond individual environmental excursions. FDA connected organisms, locations, water-related signals, process conditions and customer complaints into a larger contamination pattern.

FDA requested retrospective investigation of every potentially contaminated or out-of-limit batch, including batches associated with results that were subsequently invalidated. The agency also requested retain-sample testing of within-expiry products.

Carry forward

Sterile-product investigations should include a contamination relationship map that evaluates:

- Organism identity and relatedness.
- Recovery location and classification.
- Date and manufacturing campaign.
- Personnel and interventions.

- Water-system and utility data.
- Cleaning and disinfection activities.
- Process-simulation performance.
- Complaint isolates and returned samples.
- Potentially affected batches and distributed-product risk.

Invalidating an individual environmental result does not erase it from the historical trend or eliminate its relevance to product-impact assessment.

Batch disposition should integrate the totality of contamination-control evidence. "The batch passed sterility" is not, by itself, a scientifically adequate release rationale when other parts of the control system indicate a credible contamination risk.

2. BD Alaris: published specifications did not fully represent pump-and-set performance

What changed

FDA classified the correction involving approximately 94 million BD Alaris pump infusion sets as a Class I recall.

The correction concerns the performance of the BD Alaris Pump Module Model 8100 when used with certain compatible infusion sets. Under some conditions—particularly low flow rates and low bolus volumes—the complete pump-and-set system can perform worse than previously disclosed.

Potential consequences include:

- Under-infusion or over-infusion.
- Inaccurate delivery of small bolus volumes.
- Delayed detection and alarming for upstream occlusions.
- Delayed or incorrect administration of critical medications.

FDA's detailed performance communication illustrates the magnitude of some differences. Under specified configurations and operating conditions, a programmed loading bolus of less than 1 mL could vary by approximately –15% to +102%.

For certain sets operated below 1 mL per hour, upstream occlusion-alarm time could extend from the previously disclosed 2 hours and 22 minutes to approximately 3 hours and 44 minutes.

Performance was influenced by the configuration of the complete system, including filters, back-check valves, Y-sites and other infusion-set components. Some affected sets are being discontinued, and customers were advised to prioritize available alternatives for neonatal, pediatric and critical-care applications.

Why it matters

This is not simply a disposable-component issue or a pump-performance issue considered in isolation.

The marketed and clinically used system consists of the pump, tubing set, filters, valves, connectors, programming parameters, medication characteristics and intended clinical conditions. Validation and risk analysis must represent that complete system.

A pump may meet its nominal specification while a marketed pump-and-set combination performs outside previously disclosed expectations under foreseeable operating conditions.

The case also raises design-transfer and change-control questions. Performance claims should be supported by testing of representative finished configurations, including worst-case low-flow and small-bolus applications—not primarily by nominal pump behavior or a limited set of accessories.

Carry forward

Device validation should establish worst-case performance across:

- Compatible disposable and accessory configurations.
- Minimum and maximum flow rates.
- Small bolus volumes.
- Clinically significant medications.
- Neonatal, pediatric and critical-care applications.
- Filter, valve and Y-site combinations.
- Occlusion-detection and alarm-response times.

- Reasonably foreseeable user workflows.

"The pump met specification" is not a complete conclusion if the marketed pump-and-set system does not perform as represented.

3. FDA finalizes guidance for buffy-coat blood systems

What changed

FDA finalized its guidance, Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.

The guidance applies to manufacturers developing systems used to produce blood and blood components for transfusion through the buffy-coat method. Covered systems include:

- Blood-collection bags.
- Anticoagulant and additive solutions.
- Processing and storage containers.
- Empty bags used for platelet pooling.
- Associated system configurations included in regulatory submissions.

The final version provides recommendations regarding system development, validation and submissions to FDA. Changes from the 2024 draft include clarification concerning overnight ambient-temperature hold periods, additive solutions that are not currently approved and the transition toward systems that do not contain diethylhexyl phthalate, or DEHP.

The guidance is principally directed to system manufacturers. Blood establishments implementing the buffy-coat method must use appropriately approved or cleared systems and may need to submit biologics-license-application supplements before implementation.

Why it matters

The guidance is narrow in application, but it reinforces an important change-control principle for blood-system and combination-product operations.

A change involving bag material, additive solution, processing hold time or component configuration may simultaneously affect:

- Device design and biocompatibility.
- Blood-component quality.
- Process validation.
- Storage conditions and shelf life.
- Regulatory submissions and establishment licensure.

Such changes should not be managed as isolated supplier substitutions or routine component replacements.

Carry forward

Change assessments involving blood-collection and processing systems should document the complete regulatory and quality impact across the device, the manufacturing process and the resulting blood component.

The relevant question is not simply whether a replacement component meets its own specification. The firm must determine whether the complete system remains suitable for its intended use and whether regulatory approval or notification is required before implementation.

4. Impella correction illustrates risk-based field-action planning

What changed

FDA classified a correction involving approximately 4,100 Automated Impella Controllers as Class I.

The controllers may experience purge-cassette recognition problems associated with a component in the purge-pressure-sensor assembly. Failure to recognize or maintain the purge system correctly can interrupt appropriate operation of the Impella circulatory-support system.

The manufacturer is replacing affected components through a phased service program. Pending service, customers may continue using the controllers under specified precautions, including ensuring that an appropriate backup controller is available.

Why it matters

A Class I recall classification does not invariably require the immediate removal of every affected device from clinical service.

Impella systems provide critical circulatory support. Removing all affected controllers simultaneously could itself create patient risk by reducing the availability of necessary equipment. The field-action strategy must therefore balance the risk presented by the defect against the clinical consequences of removing devices from service.

That risk-benefit decision becomes part of the corrective action and must be supported by effective interim controls.

Carry forward

A phased device correction should include:

- A documented health-hazard and continuity-of-care assessment.
- Clear instructions for identifying affected equipment.
- Availability of backup controllers or alternative therapy.
- Service prioritization based on clinical risk and utilization.
- Traceable scheduling and completion of each correction.
- Reconciliation of all affected serial numbers.
- Escalation requirements for alarms, failures or new complaints.
- Effectiveness monitoring throughout the correction program.

Completion should be measured against the full affected population, not merely the number of service work orders closed.

Worth reading

1. **Bausch & Lomb Warning Letter** — The week's most valuable document for contamination investigations, environmental trending, aseptic-process control, batch disposition and systemic CAPA.
2. **FDA's detailed BD Alaris performance communication** — An unusually useful case study in worst-case testing and validation of the complete marketed system.
3. **BD Alaris recall record** — Useful for understanding the affected configurations, field-action scope and recall classification.
4. **Buffy-coat system guidance** — Important for manufacturers and establishments working with blood bags, processing systems, additive solutions or related combination products.

5. **Automated Impella Controller recall record** — A concise example of phased correction under continuity-of-care constraints.

Closing observation

No consequential new pharmaceutical or medical-device quality consent decree, significant newly released Form FDA 483 or OOS/OOT-specific FDA guidance was identified during the period.

FDA also issued draft guidance concerning an electronic submission template for premarket approval applications. That document primarily addresses submission format and mechanics rather than establishing a significant new manufacturing-quality expectation.

The week's strongest signal came from the Bausch & Lomb and BD actions. Both demonstrate the limitations of evaluating one favorable result in isolation.

A passing sterility test cannot independently overcome a failing contamination-control system. Likewise, acceptable nominal pump performance cannot establish the suitability of every marketed pump-and-set configuration. In both pharmaceutical and device quality systems, disposition and risk decisions must account for the performance of the complete system under representative conditions.

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