HAMILTON QUALITY LLC

**U.S. Quality Intelligence Brief — Week Ended September 27, 2026**

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

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This was not a quiet week for pharmaceutical and medical-device quality. The strongest developments involved retrospective OOS review, visible particulate investigations, packaging-control recurrence, sterile compounding and the effectiveness of device CAPA systems.

Several of the week's enforcement actions also reinforce a common regulatory expectation: rejecting a batch, recalling a product or opening a CAPA does not complete an investigation. Firms must determine what happened, establish the affected population, evaluate distributed-product risk and demonstrate that their corrective actions address the underlying system.

**1. FDA defines the expected scope of an OOS reinvestigation**

**What changed**

FDA posted a Warning Letter to kdc/one Chatsworth, an OTC-drug contract manufacturer, citing inadequate stability investigations, unsupported specifications, deficient distributed-product risk assessments and CAPA plans without clear timelines.

Among the findings, the company had not adequately investigated out-of-specification viscosity results involving distributed products. FDA stated that the company's response did not include:

- An adequate risk assessment for previously distributed products with OOS results.
- A CAPA plan with clear implementation timelines.
- Documented scientific justification for the applicable specifications.
- An updated investigation procedure supported by training records.

FDA also raised concerns about contaminant testing and a Canadian recall involving products with the same formulation, packaging and labeling used for the U.S. market. The company had not adequately determined whether affected lots had entered U.S. distribution or assessed the resulting risk to U.S. products.

**Why it matters**

FDA requested an independent retrospective review of all invalidated in-process, release and stability OOS results involving marketed products that remain within expiry.

The requested review effectively establishes a two-stage decision model. First, the reviewer must determine whether laboratory error was conclusively established. If it was, the firm must consider whether other methods or results were vulnerable to the same laboratory failure.

If laboratory error was not conclusively demonstrated, FDA expects a full production investigation. That review should include batch records, manufacturing steps, equipment and facilities, raw materials, process capability, deviation history, complaints, previous batch failures and other potential manufacturing causes.

An invalidated OOS result is therefore not safely removed from further consideration merely because the original laboratory investigation assigned error.

**Carry forward**

Retrospective OOS reviews should be designed around an explicit decision tree:

1. Was laboratory error scientifically and conclusively demonstrated?
2. If so, what other methods, analysts, instruments or results could be affected?
3. If not, was a complete manufacturing investigation performed?
4. Were recurrence, distributed-product risk and potentially related batches evaluated?
5. Did the resulting CAPA address the demonstrated or most credible systemic cause?

This is the week's most useful enforcement document for organizations planning OOS reinvestigations or remediating an investigation backlog.

**2. Par recalls two injectable lots for particulate matter**

**What changed**

Par Health recalled two lots of Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 400 mcg/100 mL, to the hospital level. The affected lots are 87558 and 88802.

The recall was initiated after particulate matter was identified as cellulose or stopper material. Par reported no associated adverse events as of the announcement date.

The recall is particularly noteworthy when read alongside FDA's April 2026 Warning Letter to Par Health and Endo USA. That letter addressed the Rochester facility's visible-particulate inspection program, particulate investigations and retrospective assessment methodology.

The recall announcement does not identify the facility that manufactured the affected dexmedetomidine lots. The available public information therefore does not establish that the recall arose from the Rochester facility or from the conditions described in the earlier Warning Letter.

**Why it matters**

Identification of the observed material as cellulose or stopper material presents several possible investigative paths. The result may indicate more than one particle source, uncertainty within the analytical identification or a common upstream event capable of producing multiple materials.

The investigation should not be forced prematurely into a single assignable cause. Appropriate scope would include:

- Confidence and limitations associated with particle identification.
- Stopper damage, closure preparation and equipment interaction.
- Potential cellulosic sources within components, filtration, cleaning or the manufacturing environment.
- Complaint, reject and visual-inspection history.
- Container-closure and handling operations.
- Other batches exposed to the same components, equipment, personnel or process conditions.
- Whether previous particulate CAPAs anticipated either observed particle type.

**Carry forward**

Particle identification is an input to root-cause analysis, not the conclusion. The investigation must connect the analytical result to a credible generation mechanism and then use that mechanism to establish defensible horizontal and vertical bounding.

**3. Another potassium-chloride overwrap event raises a CAPA-recurrence question**

**What changed**

Otsuka ICU Medical recalled one lot of 0.9% Sodium Chloride Injection after a customer found a highly concentrated 10 mEq potassium-chloride bag inside an overwrap labeled as 0.9% sodium chloride.

The affected lot was manufactured on November 13, 2025, and distributed in the United States between December 30, 2025, and June 22, 2026. The error could result in severe hyperkalemia, neuromuscular effects, arrhythmia, cardiac arrest or death.

The event follows a different October 2025 recall in which 20 mEq potassium-chloride bags had overwraps identifying them as 10 mEq potassium chloride.

**Why it matters**

The two recalls involve different product discrepancies. Publicly available information does not establish a common root cause. Nevertheless, both involve a failure to maintain the correct relationship between a flexible container and its overwrap.

That common escape pathway justifies a formal recurrence assessment covering:

- Packaging-line clearance and component segregation.
- Overwrap issuance and reconciliation.
- Vision-system or barcode-control coverage.
- Manual inspection and challenge-set design.
- Reject handling and reintroduction controls.
- Batch-record reconciliation.
- The effectiveness of CAPA implemented after previous overwrap events.

A recurrence review should compare failed controls and escape pathways—not merely determine whether the exact incorrect labels were identical.

**Carry forward**

A different defect description does not automatically establish a new and unrelated problem. CAPA effectiveness should be assessed against the control system the CAPA was intended to strengthen.

**4. Empower Pharmacy: product status determines the applicable quality regime**

**What changed**

FDA issued a Warning Letter to Empower Clinic Services, doing business as Empower Pharmacy, following inspection of its Houston facility.

FDA concluded that certain high-volume compounded semaglutide and tirzepatide combinations appeared to be essentially copies of commercially available approved products. The agency stated that the production volumes suggested the differences between the compounded and approved products were pretextual.

FDA therefore concluded that the affected products did not qualify for the exemptions available under section 503A of the Federal Food, Drug, and Cosmetic Act. The letter also cited sterile products prepared under insanitary conditions and deficiencies involving microbial control and aseptic-process simulation.

**Why it matters**

The applicable quality requirements cannot be determined solely by identifying an operation as a pharmacy or compounder. Product-specific activities must first satisfy the statutory conditions supporting the claimed exemption.

When a product falls outside section 503A, it may become subject to requirements that include FDA approval, adequate directions for use and compliance with current good manufacturing practice.

Quality-system assessment must therefore begin with an accurate regulatory classification of the products and activities being evaluated.

**Carry forward**

Compounding audits and change-control evaluations should include product-by-product verification of:

- The statutory basis for compounding.
- The existence and adequacy of patient-specific prescriptions.
- Whether a product is essentially a copy of an approved drug.
- The clinical justification for formulation differences.
- The manufacturing scale and ordering patterns.
- The quality requirements applicable when an exemption is unavailable.

Adding an ingredient does not, by itself, establish a clinically meaningful difference.

**5. Disposition does not replace investigation**

**What changed**

FDA's Warning Letter to NexCell Scientific addressed an umbilical-cord-blood-derived cellular product manufactured for allogeneic use.

FDA found that the company lacked validated manufacturing and aseptic processes. Finished-product testing was limited, and multiple lots had failed sterility testing between August 2023 and June 2025.

Although the failing lots were discarded, the company had not performed investigations to determine root cause or assess whether other lots were affected. FDA also found that one employee was responsible for both manufacturing and quality-unit activities, with no independent quality unit in place.

**Why it matters**

Rejecting or destroying a failed lot is a disposition decision. It does not satisfy the separate obligation to investigate the failure, assess recurrence and determine whether other production was exposed to the same condition.

This distinction becomes particularly important for sterility failures because contamination may reflect a shared weakness in aseptic technique, environmental control, cleaning and disinfection, personnel practices or process design.

**Carry forward**

Every batch failure requires two related but distinct decisions:

- What should happen to the affected batch?
- What does the failure reveal about other batches and the manufacturing system?

Completing the first does not eliminate the second.

**6. Device CAPAs cannot depend on the same deficient CAPA procedure**

**What changed**

FDA's Warning Letter to Lion Street Medical, doing business as Pensar Medical, addressed negative-pressure wound-therapy systems.

FDA cited deficiencies involving Medical Device Reporting and reports of corrections and removals. The agency also found that certain firmware or software changes took effect at

specified serial-number thresholds without adequate batch or other records confirming implementation.

In response to the inspection, the company opened seven CAPAs. FDA observed, however, that all seven continued to be managed under the same underdefined CAPA procedure identified as deficient during the inspection.

**Why it matters**

Opening additional CAPAs does not correct a deficient CAPA system. If the governing procedure does not adequately require investigation, root-cause analysis, implementation evidence, verification or validation, effectiveness assessment and management oversight, every new CAPA inherits the same structural weakness.

Similarly, approval of an engineering change does not establish that the change reached every affected device. Implementation must be supported by serial-number-level or otherwise appropriately granular reconciliation.

**Carry forward**

When the CAPA system itself is deficient, remediation should proceed in the correct order:

1. Correct the governing procedure and decision framework.
2. Establish appropriate review and approval authority.
3. Train and qualify responsible personnel.
4. Reassess CAPAs processed under the deficient system.
5. Verify implementation and effectiveness using objective evidence.

**Worth reading**

1. **kdc/one Chatsworth Warning Letter** — The week's strongest document for OOS reinvestigation, distributed-product risk, specifications, CAPA timelines and retrospective-review scope.
2. **Par recall and April Warning Letter** — A useful paired reading for particulate investigations and remediation, subject to the manufacturing-site limitation discussed above.
3. **Empower Pharmacy Warning Letter** — A significant intersection of regulatory status, sterile controls and quality-system applicability.

4. **Current ICU Medical recall and 2025 overwrap recall** — A strong case study for recurrence assessment and CAPA effectiveness.
5. **Pensar Medical Warning Letter** — Useful for device CAPA architecture, software-change traceability, MDR and field corrections.
6. **NexCell Scientific Warning Letter** — A concise example of why rejection or destruction cannot replace investigation and product-impact assessment.

**Closing observation**

FDA issued no consequential new OOS/OOT guidance, major quality-related Department of Justice consent decree or newly released Form FDA 483 warranting separate treatment during the period.

The week's central quality signal came instead from enforcement and recall activity: an investigation is not complete until the organization has established a scientifically credible cause or evaluated the absence of one, bounded the potentially affected population, assessed distributed-product risk and demonstrated that corrective action addresses the responsible system.

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