

PHARMTECH.AI BY ALIGNED EXECUTIVE SOLUTIONS, INC. · TURN FDA ENFORCEMENT INTO PREVENTION

## The Prevention Brief — FDA edition · Week of June 15–19, 2026

32 letters newly posted June 16, 2026 · 3 Critical manufacturer/device letters · 1 food (FSVP) · most of the rest a GLP-1 telehealth misbranding sweep

### THIS WEEK'S READ

Of 32 letters this week, **only four deserve a manufacturer's attention** — the other 28 are mostly a **GLP-1 telehealth misbranding sweep** you can skip unless you compound or market GLP-1s. The four share one theme: *FDA is going after what you didn't verify yourself*. **Sante** took suppliers' COAs on faith and never qualified its water. **Pharmathen** couldn't prove its aseptic process actually holds sterility. **ZOLL** let complaint codes keep real device failures out of CAPA. **M G R Produce** had no program to verify its foreign suppliers. **Your one move this week:** pick the one that looks most like your plant, and go prove on the floor it can't happen to you.

**Say this at your tier board:** "Pull our last 3 high-risk incoming-material lots and show me our *own* identity test for each — not just the supplier's COA."

**Severity key:** Critical = sterility / data-integrity / quality-unit failure, active import alert, or direct patient-safety risk · High = serious CGMP/QSR gaps, contained scope · Moderate/Low = procedural or labeling.

### BY SECTOR — WHAT TO DO THIS WEEK

**Drug:** Three letters worth your time (below). The honest one-action: don't accept high-risk components on supplier paperwork alone, prove your aseptic processes are validated, and make sure no complaint-coding rule can hide a problem.

**Food:** One letter — [M G R Produce](#) (an importer, FSVP). If you import any food or ingredient: do you have a **written Foreign Supplier Verification Program**, a current hazard analysis, and documented proof you verified each foreign supplier? If any of those is "no," that's this week's gap. (See the food self-check below.) **Domestic manufacturer, not an importer?** The same "verify your suppliers" logic lives in your Preventive Controls plan under FSMA (21 CFR 117) — written food-safety plan, hazard analysis, and supplier verification for your own ingredients.

**Cosmetic:** No cosmetic letters this week — but the week's theme carries over: under **MoCRA**, the same "don't trust suppliers blindly" lesson applies to your ingredient/supplier documentation and safety substantiation.

## YOUR 60-SECOND SELF-CHECK — ARE YOU AT RISK THIS WEEK?

Do only the box for your sector. Each item you can't confidently check is a potential gap — the matching letter is detailed below.

### ARE YOU AT RISK? — DRUG — INCOMING COMPONENTS & WATER (SANTE)

Check what you can confidently confirm today. Each box you leave blank is a gap.

- Do you accept any high-risk incoming component on supplier COA alone, without your own per-lot identity test to the USP monograph?
- Do you use process/purified water as a drug component without a qualified, routinely monitored water system?
- Can your quality unit show current process validation, validated methods, and a stability program for every marketed product?

**Your score — gaps: \_\_\_\_ of 3 (0–1 defensible · 2 audit this quarter · 3+ act now). A self-check, not a substitute for your own gap assessment.**

### ARE YOU AT RISK? — STERILE DRUG — ASEPTIC ASSURANCE (PHARMATHEN)

Check what you can confidently confirm today. Each box you leave blank is a gap.

- Do your smoke (airflow-visualization) studies show real worst-case interventions, not idealized conditions?
- Are all aseptic and sterilization processes validated, with current media fills covering your actual line activities?
- Does your environmental monitoring trend toward action before a batch is at risk, not after?

**Your score — gaps: \_\_\_\_ of 3 (0–1 defensible · 2 audit this quarter · 3+ act now). A self-check, not a substitute for your own gap assessment.**

### ARE YOU AT RISK? — MEDICAL DEVICE — COMPLAINTS & CAPA (ZOLL)

Check what you can confidently confirm today. Each box you leave blank is a gap.

- Could any complaint-coding category ('No Fault Found', 'User Error') keep a real field failure below your CAPA escalation threshold?
- Do you re-open or re-trend a closed CAPA when new complaints of the same type arrive?
- Are your MDR / adverse-event clocks tracked so nothing exceeds the deadline (30 days — or 5 days when remedial action is needed)?

**Your score — gaps: \_\_\_\_ of 3 (0–1 defensible · 2 audit this quarter · 3+ act now). A self-check, not a substitute for your own gap assessment.**

### ARE YOU AT RISK? — FOOD — FSVP / IMPORTED (M G R PRODUCE)

Check what you can confidently confirm today. Each box you leave blank is a gap.

- Do you have a written FSVP for each food or ingredient you import?
- Is your hazard analysis for each imported food current and documented?
- Can you show documented proof you verified each foreign supplier (audit, COA, or sampling)?

**Your score — gaps: \_\_\_\_ of 3 (0–1 defensible · 2 audit this quarter · 3+ act now). A self-check, not a substitute for your own gap assessment.**

CRITICAL · DRUG

OTC drug · contract / private-label

## Sante Manufacturing Inc.

Aylmer, ON · WL 320-26-94 · Issued: June 5, 2026 · Posted by FDA: June 16, 2026 · [Read the FDA letter →](#)

**In plain terms: they trusted supplier paperwork instead of testing incoming materials, and couldn't prove their water and processes were validated.**

Three CGMP violations: (1) failed to identity-test high-risk incoming components and relied on supplier COAs without validating them ([21 CFR 211.84\(d\)\(1\)/\(2\)](#)); (2) process/purified water used as a drug component without a qualified, monitored water system, plus inadequate process validation (CFR subparts per the letter); (3) quality-unit failure — no stability program, unvalidated methods ([211.22 / 211.166\(a\) / 211.160\(b\)](#)). FDA recommends an independent CGMP consultant + six-system audit. Import Alert 66-40 active.

### PHARMTECH.AI INTERPRETATION — NOT STATED BY FDA

FDA **redacted** the component and contaminant names. The "high-risk component / lethal poisoning worldwide" language is *consistent with several adulteration scenarios* (e.g. glycol-excipient contamination, among others) — **we are not asserting which one**; confirm against the letter.

### SUPPLY-CHAIN RISK IF NO ACTION IS TAKEN — PHARMTECH.AI INTERPRETATION

Sante is already on **FDA Import Alert 66-40**, so its drug shipments can be detained at the U.S. border without physical exam until it clears. If you source product that traces to this firm without a qualified second source, that detention **could** interrupt your supply — and qualifying an alternate typically takes months. Sante is a **contract / private-label OTC manufacturer** (per public sources), so this can ripple to the brands and retailers it fills for — your product may trace here even if Sante isn't on the label.

**What good looks like:** per-lot identity testing to the USP monograph before use; a qualified, monitored water system with action limits; current validation, validated methods, and stability for every product.

**CRITICAL · DRUG (STERILE)**

**Sterile drug · CDMO · often sole-sourced**

## Pharmathen International S.A.

Marousi / Sapes, Greece · WL 320-26-80 · **Issued: May 27, 2026** · Posted by FDA: June 16, 2026 · inspection Nov 10–21, 2025 · [Read the FDA letter →](#)

**In plain terms: a sterile-drug maker couldn't prove its aseptic (contamination-controlled) process actually keeps product sterile.**

FDA cited failure to follow procedures to prevent microbiological contamination of products purporting to be sterile, including validation of aseptic and sterilization processes ([21 CFR 211.113\(b\)](#)) — the airflow-visualization (smoke) studies were deficient. Products are deemed **adulterated** under FD&C Act 501(a)(2)(B). A sterility-assurance failure is top-tier because it goes straight to patient safety.

### **SUPPLY-CHAIN RISK IF NO ACTION IS TAKEN — PHARMTECH.AI INTERPRETATION**

A sterility-assurance gap at a sterile-injectable site is a fast path to a voluntary or FDA-driven production hold. Because injectables are often sole-sourced, a stop-ship here **could** expose a downstream product to shortage and push buyers to qualify a second source they **may** not unwind later. Pharmathen is a **CDMO that manufactures for many pharma companies** (per public sources), so this can ripple across multiple brands — your supplier's supplier may be here. Public reporting (*not the FDA letter*) also ties this sterile site to a product on the **ASHP shortage list** — verify against the current FDA/ASHP shortage lists.

**What good looks like:** smoke studies that film real worst-case interventions; current media fills covering actual line activities; environmental monitoring that trends to action before release.

**CRITICAL · DEVICE**

Medical device · critical care

## ZOLL Medical Corporation

Chelmsford, MA · Issued: April 30, 2026 · Newly public this week (posted June 16) · inspection Feb 27–Apr 15, 2025 · [Read the FDA letter →](#)

**In plain terms: complaints on life-saving devices were coded in ways that kept real failures from being counted and escalated.**

Per the FDA letter: a **systemic complaint-handling and CAPA failure** on life-sustaining devices. On the 731-Series MRI ventilator (CAPA CA-90), FDA found **27 complaints documented vs. 50 the investigator identified** (2016–2024), with complaints coded "No Fault Found," "User Error," and "No Product Returned." On the AccuVent sensor, FDA noted **at least 28 complaints** (Jan 2022–Feb 2025), 15 of them about the device "not reading or not accurately reading." One MDR was filed **~264 days** after ZOLL became aware. FDA called the responses "not adequate" and cited multiple Quality System (21 CFR 820) violations plus a medical-device reporting (21 CFR 803) violation. (*Issued April 30; only became public June 16 — newly posted, not new enforcement.*)

### PHARMTECH.AI INTERPRETATION — NOT STATED BY FDA

Per FDA records, the 731-Series was also subject to a Class I recall (confirm against the FDA recall database). In our reading, the coding pattern had the *effect* of keeping field failures below escalation/CAPA thresholds — we are characterizing the pattern, **not** quoting FDA on intent. Confirm specifics against the letter.

### SUPPLY-CHAIN RISK IF NO ACTION IS TAKEN — PHARMTECH.AI INTERPRETATION

Unresolved CAPA and complaint-handling findings on life-sustaining devices **can** escalate to further field actions, recalls, or shipment holds. Hospitals and distributors that depend on these devices **could** face constrained availability and a scramble to qualify alternates.

**What good looks like:** every complaint code mapped to a CAPA-eligibility decision; complaints reconciled to the risk file; MDR clocks started at awareness and met every time.

HIGH · FOOD

Food — imported produce

## M G R Produce LLC

Houston, TX · Issued: June 2, 2026 · Posted by FDA: June 16, 2026 · Office of Inspections & Investigations · [Read the FDA letter](#)

⇒

**In plain terms: an importer didn't have the required program to verify the foreign suppliers it buys produce from.**

An FSVP (Foreign Supplier Verification Program) letter to a produce importer. FSVP requires importers to develop, maintain, and follow a program that verifies each foreign supplier controls food-safety hazards ([21 CFR part 1, subpart L](#)).

### SUPPLY-CHAIN RISK IF NO ACTION IS TAKEN — PHARMTECH.AI INTERPRETATION

FSVP failures expose imported product to detention or refusal at the border. If you rely on imported ingredients without verified suppliers, shipments **could** be held or refused — interrupting your inputs until verification is in place.

**What good looks like:** a written FSVP per imported item, a current hazard analysis, and documented evidence you verified each foreign supplier.

HIGH · DRUG SWEEP

## GLP-1 telehealth/compounding misbranding sweep

Issued: early–mid June 2026 (most June 8; e.g. [altRx](#)) · Posted by FDA: June 16, 2026

A large group of near-identical letters: false manufacturer identity (**201.1(h)(2); 502(a)**) + fake "clinically proven / FDA-approved" claims (**502(bb)**) for compounded semaglutide/tirzepatide on websites. **Relevant to telehealth/compounding marketers; a real manufacturer can largely ignore it.** All members are linked in the full list below.

## HOW TO RUN A GEMBA WALK — A SIMPLE GUIDE

**"Gemba" means "the real place" — where the work actually happens (the line, the lab, the receiving dock).**

A Gemba walk is simple: go there, watch the real work, and ask questions. Most problems hide in the gap between what the written procedure says and what people really do. You only see that gap by going and looking.

### FIVE STEPS

- **Go to the spot.** See the work in person — not from a report or your office.
- **Watch first.** Spend a few minutes watching before you say anything.
- **Ask, don't tell.** Use open questions like "Show me..." or "What happens when...". Stay curious, not blaming.
- **Follow one thing all the way.** Pick a single lot, batch, or complaint and trace it from start to finish.
- **Write down the gap.** Fix the cause, not the person. Come back later to check it stuck.

Three rules: do it often (not once a year), respect the people doing the work, and look for the broken system — never someone to blame.

## PREVENTIVE GEMBA WALKS (TOP 3)

- **Receiving dock + QC bench** (~45 min · you + incoming-QC lead) — verify per-lot identity testing on every high-risk incoming component (not COA reliance). *Food version: trace one imported ingredient back to its FSVP supplier-verification record.*
- **Aseptic line + release desk** (~60 min · you + micro/QA lead) — watch a real smoke study / media-fill, and confirm the quality unit can show current validation before release.
- **Complaint-coding audit** (~30 min · you + complaints/CAPA owner) — confirm no coding rule ("No Fault Found," etc.) can suppress a CAPA or MDR escalation.

### TEAM QUESTION CHECKLIST — WHO ASKS, WHO ANSWERS

Plain questions tied to this week's letters. Use the rows that fit your plant.

| Ask this on the floor  | Who asks                     | Who answers  |
|--|------------------------------|--|
| "Show me the last 3 high-risk material lots — where's <i>our own</i> identity test for each?"  | QA Incoming Mgr              | Receiving / Incoming-QC Supervisor                         |
| "When did we last re-qualify this supplier's COA reliability?"   | Supplier Quality Lead        | Supplier Quality / QA (Procurement informed, not deciding) |
| "Show me today's water test vs. limits — what halts production if it fails?"   | QC Manager                   | Water-System Operator (QA holds the stop authority)        |
| "Walk me through our last smoke study — did it copy real worst-case line activity?"  | Head of Quality / Micro Lead | Aseptic Production Supervisor                              |
| "Which marketed products are shipping without completed process validation (PPQ)?"   | QA Validation Lead           | Validation Engineer  |
| "Show me how a complaint gets coded — could any code keep it out of CAPA?"   | QA / Complaints Mgr          | QA / CAPA owner (independent of the coder)                 |
| "Show me our MDR clock for the last reportable event — when did it start, did we meet the deadline (30 days, or 5 days if remedial action)?" | RA / Vigilance Lead          | Complaint / Vigilance Specialist                           |
| "Show me the last event we decided was NOT reportable — who decided, and on what basis?"   | RA / Vigilance Lead          | QA / Reportability decision-maker (independent)            |
| "Show me the FSVP and supplier verification for one imported item."  | Food Safety / QA Lead        | Purchasing / Supplier-Verification Owner                   |

### DECISION TREE — WHAT TO DO WITH WHAT YOU FIND

#### After you ask the question — what did you hear?

##### ✓ Clear evidence — you're covered

Document the evidence. Re-check after any process or supplier change. No further action.

##### ✗ Unclear or "no" — a potential gap

Go to the next step.

#### Could product safety or already-shipped product be affected?

**YES** — Contain now: quarantine / stop-use. **If product already shipped, assess recall / field action and reporting obligations (e.g. MDR, field alert).** Then open a CAPA.

**NO** — Open a CAPA with a named owner and a due date.

**Then, for any gap:** Gemba-walk the root cause (fix the cause, not the person) → confirm root cause before declaring the fix effective → verify effectiveness over a defined, risk-based interval (e.g. +90 days or N production cycles) → if it comes back, re-open the CAPA.

### KPI ESSENTIALS — THE METRICS THAT PREVENT THIS

Track from your system of record. **Leading** = warns you before the gap occurs; **Lagging** = confirms after. The value is watching the **gaming vector** — the way a number can look green while the risk is live. Lock the denominator so it can't be gamed by reclassifying items out.

| Metric (denominator locked)   | Type    | Target    | Watch for (don't game it)                                     |
|---|---------|-----------|---|
| % of high-risk incoming lots with an in-house identity test before use  | Leading | 100%      | Composite sampling across drums hiding a bad lot              |
| % of suppliers of high-risk components (shipped last 12 mo) with current COA-reliability validation           | Leading | 100%      | Marking a lapsed supplier "inactive" to leave the denominator |
| % of aseptic processes & smoke studies validated and current  | Leading | 100%      | Studies run under idealized, not real, interventions          |
| % of all marketed products with completed process validation (PPQ)  | Leading | 100%      | "In progress" PPQ while product still ships                   |
| Complaints re-coded to a non-escalating category without a documented basis                                   | Lagging | 0         | "No Fault Found" used to dodge CAPA thresholds                |
| % of closed CAPAs passing an effectiveness check (risk-based interval)  | Lagging | 100%      | Closure with no recurrence check at all                       |
| Median time from <b>awareness</b> to MDR filing (vs. the 30-day limit; 5 days if remedial action is required) | Lagging | < 30 days | Clock started at "confirmation" instead of awareness          |

**ALL 32 LETTERS POSTED JUNE 16, 2026 — CLICK ANY TO READ THE FDA LETTER**

- [Altru Telehealth, LLC dba Altru Telehealth](#)
- [Amie Health, Inc. dba Amie](#)
- [Clover Meds LLC dba Clover Meds](#)
- [D&H Medical Services](#)
- [Eden Health International Inc. dba Eden](#)
- [Ezra Holdco LLC dba Ezra](#)
- [FITISH](#)
- [FitRX, LLC dba AM RX](#)
- [Glow Medispa, LLC dba Mint Med](#)
- [HydraMed IV LLC dba HydraMed](#)
- [InvaDerm, Inc.](#)
- [Joi and Blokes dba Joi + Blokes](#)
- [M G R Produce LLC \(Food — detailed above\)](#)
- [Maximus Health, Inc. dba Maximus](#)
- [Medica Weight Loss](#)
- [Momentum Health 360 dba Momentum Health](#)
- [NativeMed LLC dba NativeMed](#)
- [Nexlife Inc. dba Nexlife](#)
- [Nexus Health Solutions LLC dba Harper Meds](#)
- [Nova Vascular LLC dba NOVARX](#)
- [OrderlyMeds LLC dba OrderlyMeds](#)
- [Pharmathen International S.A. \(Critical — detailed above\)](#)
- [Public Health Solution LLC dba DrMedHealth](#)
- [Ready Med](#)
- [Roen Health, Inc. dba RoenRx](#)
- [Sante Manufacturing Inc. \(Critical — detailed above\)](#)
- [SL Follen Company](#)
- [ThriveLab Co. dba ThriveLab](#)
- [Trinity HealthCare Supply, LLC dba altRx](#)
- [VivioMD Group LLC dba VivioMD](#)
- [YS Group Inc.](#)
- [ZOLL Medical Corporation \(Critical — detailed above\)](#)

Detailed above: the 3 Critical manufacturer/device letters and the food letter. The remaining 28 are mostly the GLP-1 telehealth sweep plus a few other drug letters — all linked here for the full record.

## ACRONYMS

|                     |  |              |   |
|---------------------|--|--------------|---|
| <b>CGMP</b>         | Current Good Manufacturing Practice    | <b>CAPA</b>  | Corrective and Preventive Action                                    |
| <b>CFR</b>          | Code of Federal Regulations            | <b>COA</b>   | Certificate of Analysis   |
| <b>QSR</b>          | Quality System Regulation (21 CFR 820) | <b>MDR</b>   | Medical Device Reporting (21 CFR 803)                               |
| <b>FSVP</b>         | Foreign Supplier Verification Program  | <b>MoCRA</b> | Modernization of Cosmetics Regulation Act                           |
| <b>PPQ</b>          | Process Performance Qualification      | <b>QU</b>    | Quality Unit  |
| <b>USP</b>          | United States Pharmacopeia             | <b>GLP-1</b> | Glucagon-Like Peptide-1 (e.g. semaglutide)                          |
| <b>WL</b>           | Warning Letter                         | <b>FEI</b>   | FDA Establishment Identifier  |
| <b>FD&amp;C Act</b> | Federal Food, Drug, and Cosmetic Act   | <b>FSMA</b>  | FDA Food Safety Modernization Act (Preventive Controls, 21 CFR 117) |

### You just spotted your own gaps. Let's close them.

The findings in this brief — incoming-material testing, aseptic assurance, complaint handling, supplier verification — are the same gaps that become 483s and warning letters. PharmTech.AI helps Quality and Operations teams get ahead of them, pairing hands-on Gemba reviews with **custom, human-in-the-loop AI** that flags your exposure before an inspector does — your team stays in control of every decision.

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The cases above are drawn from public FDA records and shared for educational purposes.

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