COVINGTON

Quarterly Medical Device Warning Letters Update: October – December 2025 and 2025 Annual Summary

February 19, 2026

Medical Devices and Diagnostics

This client alert summarizes trends and otherwise notable allegations in publicly available FDA warning letters relating to medical devices. This alert summarizes trends in the warning letters issued in the fourth quarter of 2025 (October through December), as well as trends in the warning letters issued in the 2025 calendar year.[1]

October – December 2025

As of February 19, 2026, twenty warning letters issued in the fourth quarter of 2025 alleging violations of the Food, Drug, and Cosmetic Act (FDCA) related to medical devices were posted by FDA.[2] Key trends and otherwise notable allegations in these warning letters include:

1. **Most Commonly Cited Violations**: In connection with a group of warning letters sent to manufacturers and distributors of breast binders, FDA issued ten letters alleging manufacturers failed to register and list their devices. Beyond these letters, alleged violations of the Quality System Regulation (QSR) continued to be most common, with seven of the twenty letters including such allegations. The most commonly alleged QSR violations continue to relate to corrective and preventive action (CAPA) under 21 CFR 820.100, design controls under 21 CFR 820.30, and complaint files under 21 CFR 820.198, each alleged in four letters—making these three QSR requirements the most frequently cited alleged violations for at least the last two years. In one of the letters this

[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #717941 (Oct. 2, 2025), CMS #716715 (Oct. 3, 2025), CMS #718112 (Oct. 28, 2025), CMS #718762 (Nov. 11, 2025), CMS #718444 (Dec. 9, 2025), CMS #708579 (Dec. 11, 2025), CMS #720852 (Dec. 16, 2025), CMS #720843 (Dec. 16, 2025), CMS #720839 (Dec. 16, 2025), CMS #720850 (Dec. 16, 2025), CMS #720842 (Dec. 16, 2025), CMS #720822 (Dec. 16, 2025), CMS #720838 (Dec. 16, 2025), CMS #720849 (Dec. 16, 2025), CMS #720840 (Dec. 16, 2025), CMS #720845 (Dec. 16, 2025), CMS #720847 (Dec. 16, 2025), CMS #720846 (Dec. 16, 2025), CMS #720661 (Dec. 17, 2025), and CMS #720826 (Dec. 22, 2025). Late posted letters will be addressed in a future client alert.

quarter, FDA specifically cited a company's failure to review and evaluate complaints received on eCommerce sites and via international country officials.

2. **Breast Binders**: FDA issued twelve warning letters to manufacturers and distributors of breast binders that FDA alleged are misbranded because the manufacturers did not comply with registration and listing requirements. All of the letters allege that the companies made claims about the breast binders relating to "gender dysphoria," "dysphoria," and/or use after surgery to keep swelling down. FDA sent ten letters to manufacturers, alleging the breast binders were misbranded because the companies failed to comply with registration and listing requirements, as well as two letters to distributors who introduced these allegedly misbranded devices into interstate commerce.
3. **Continued Data Integrity Concerns**: As mentioned in our prior alerts (here, here, and here), FDA has continued to focus on third-party non-clinical testing laboratories that allegedly failed to comply with Good Laboratory Practice (GLP) requirements. This quarter, FDA issued a warning letter to a non-clinical laboratory in India, citing "serious" GLP violations and "systemic failures" in oversight that FDA concluded raise concerns about the quality and integrity of safety data produced at the facility. As in prior quarters, FDA requested a detailed accounting of all non-clinical laboratory studies involving FDA-regulated devices conducted over the preceding five years by the company.
4. **Lead Test False Results:** FDA issued two warning letters this quarter citing concerns that certain devices could contribute to false lead test results. In a warning letter to ASP Global, LLC dba Anatomy Supply Partners, LLC ("ASP Global"), FDA alleged the company's Safe-T-Fill Micro Capillary Collection System Devices—which can be used with Magellan LeadCare systems—are adulterated and misbranded because, among other things, the company failed to implement adequate purchasing controls to ensure design control, and failed to report to FDA that the company sent a customer letter following FDA's Safety Alert related to the company's devices. The warning letter states that ASP Global decided to remove these products from U.S. commercial distribution due to the significant GMP violations documented in FDA's May 2025 warning letter to Kabe Labortechnik GmbH pertaining to the same devices. FDA also issued a warning letter to Meridian Bioscience, Inc. ("Meridian"), the manufacturer of Magellan LeadCare systems, alleging QSR violations and failure to report MDRs and corrections and removals. FDA requested Meridian submit annual certifications of an expert audit of its manufacturing and quality assurance systems, including a certification by the CEO that he or she reviewed the expert's report and that the company had initiated or completed all corrections called for in the report.

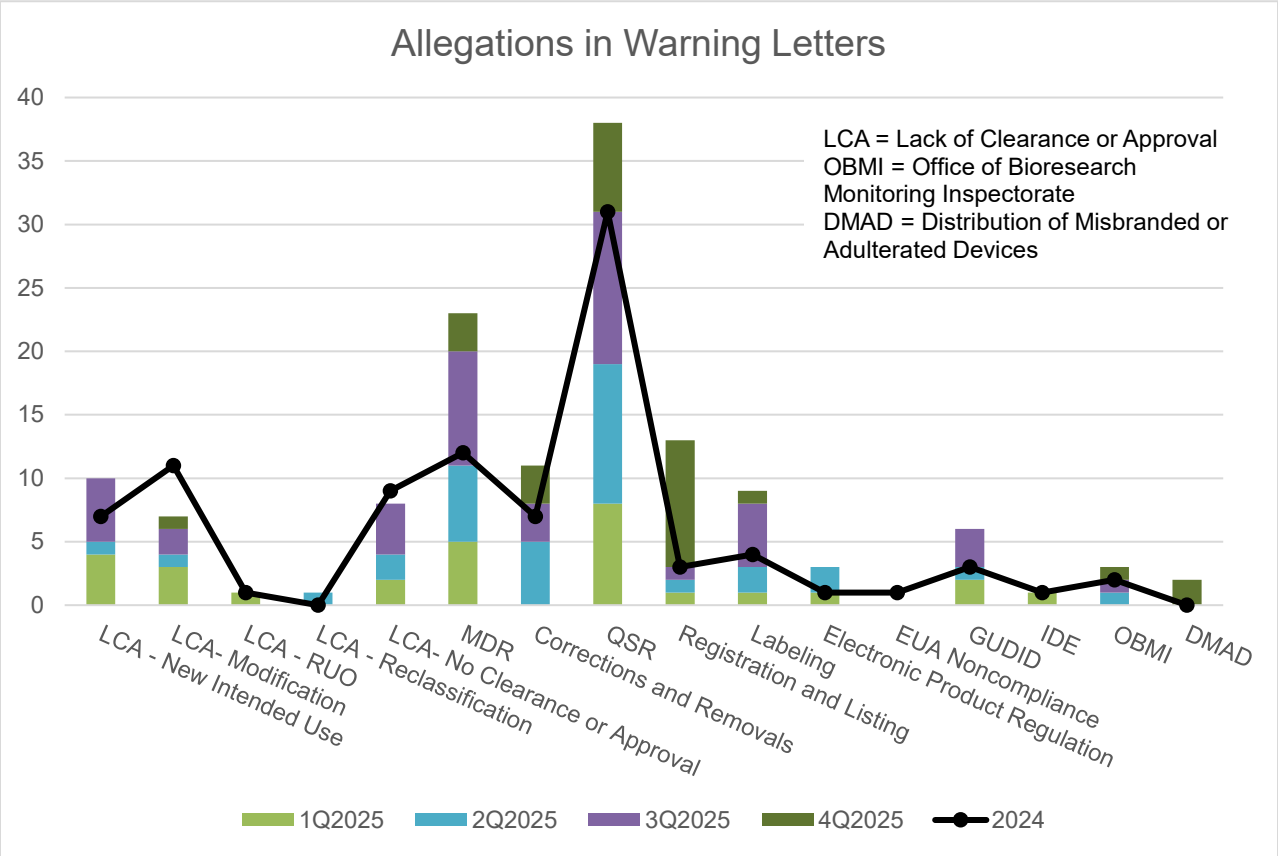
2025 Summary

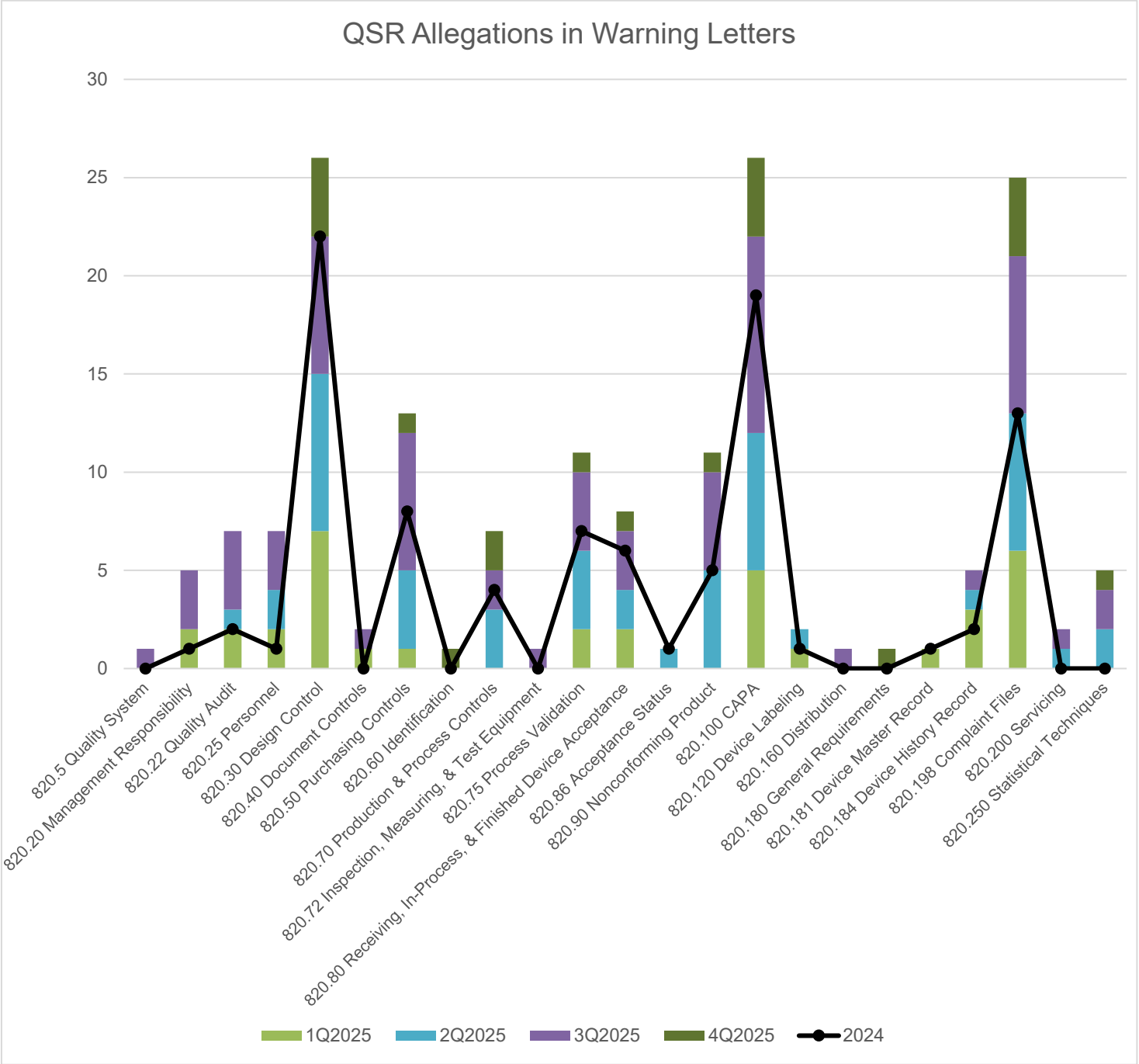
FDA issued 59 warning letters related to medical devices in 2025—an increase from the 45 letters issued in 2024. Key trends in these warning letters include:

1. The most commonly alleged violations related to QSR (38 letters), MDRs (23 letters), registration and listing (13 letters), and lack of clearance or approval for a new intended use (10 letters). The most commonly alleged QSR violations related to design controls (26 letters), CAPAs (26 letters), and complaint files (25 letters). Looking ahead, it will be interesting to see how FDA cites similar alleged violations under the new Quality Management System Regulation ("QMSR"), which went into effect on February 2, 2026.

2. Data integrity and GLP oversight for foreign non-clinical laboratories remained on FDA's radar. Throughout 2025, FDA issued three more warning letters alleging that third-party non-clinical laboratories in China and India violated GLP requirements. FDA also issued two "General Correspondence Letters" to 2024 recipients of similar warning letters, stating the Agency would reject data generated in those facilities for use in premarket device submissions.
3. Notably, we identified two warning letters in the fourth quarter of 2025 that were issued to distributors of allegedly misbranded devices, where those companies are not engaged in any manufacturing activity. Likewise, in the first quarter of 2026 (which will be covered in a future client alert), FDA issued a warning letter to a distributor of specimen collection kits for HIV testing, even though that company does not appear to engage in any manufacturing activities.

The allegations in the warning letters sent in 2025 can be grouped into the following categories:




QSR Allegations in Warning Letters
30
25
20
15
10
5
0
820.5 Quality System
820.20 Management Responsibility
820.22 Quality Audit
820.25 Personnel
820.30 Design Control
820.40 Document Controls
820.50 Purchasing Controls
820.60 Identification
820.70 Production & Process Controls
820.72 Inspection, Measuring, & Test Equipment
820.75 Process Validation
820.80 Receiving, In-Process, & Finished Device Acceptance
820.86 Acceptance Status
820.90 Nonconforming Product
820.100 CAPA
820.120 Device Labeling
820.160 Distribution
820.180 General Requirements
820.181 Device Master Record
820.184 Device History Record
820.198 Complaint Files
820.200 Servicing
820.250 Statistical Techniques
1Q2025
2Q2025
3Q2025
4Q2025
2024

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