COVINGTON

Quarterly Medical Device Warning Letters Update: October – December 2024 and 2024 Annual Summary

February 12, 2025

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 2024 (October through December), as well as trends in the warning letters issued in the 2024 calendar year.[1]

October – December 2024

As of February 11, 2025, thirteen warning letters issued in the fourth quarter of 2024 alleging violations of the Food, Drug, and Cosmetic Act ("FDCA") related to medical devices were posted by FDA.[2] One letter issued in the third quarter was posted, as well. Key trends and otherwise notable allegations in these warning letters include:

1. **Most Commonly Cited Violations:** 12 of the 13 letters allege violations of the Quality System Regulation ("QSR"). The most commonly alleged violations relate to corrective and preventive action ("CAPA") under 21 CFR 820.100 (eight letters), design controls under 21 CFR 820.30 (seven letters), and complaint files under 21 CFR 820.198 (five letters). This is the fourth consecutive quarter in which QSR violations were the most commonly cited violations with design controls as a particular focus, and the third consecutive quarter with CAPAs being a particular focus.
2. **Diagnostic Specimen Collection Kits:** FDA issued two warning letters alleging that manufacturers were distributing specimen collection kits without clearance or approval.

[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. There was one late posted letter from the third quarter of 2024: CMS #692084 (Sept. 10, 2024). The letters from the fourth quarter include: CMS #680324 (Oct. 11, 2024), CMS #692226 (Oct. 11, 2024), CMS #695010 (Oct. 18, 2024), CMS #695160 (Oct. 28, 2024), CMS #695683 (Nov. 1, 2024), CMS #691601 (Nov. 22, 2024), CMS #696569 (Dec. 6, 2024), CMS #694229 (Dec. 9, 2024), CMS #697119 (Dec. 9, 2024), CMS #696362 (Dec. 17, 2024), CMS #698214 (Dec. 18, 2024), and CMS #698850 (Dec. 19, 2024). Late posted letters will be addressed in a future client alert.

In one of those letters, FDA alleged that Blackfly Investments, LLC dba Molecular Testing Labs, offered its HIV dried blood spot card self-collection kit without clearance or approval, and rejected the company's suggestion that the device was subject to enforcement discretion, including regarding the requirement for premarket review.

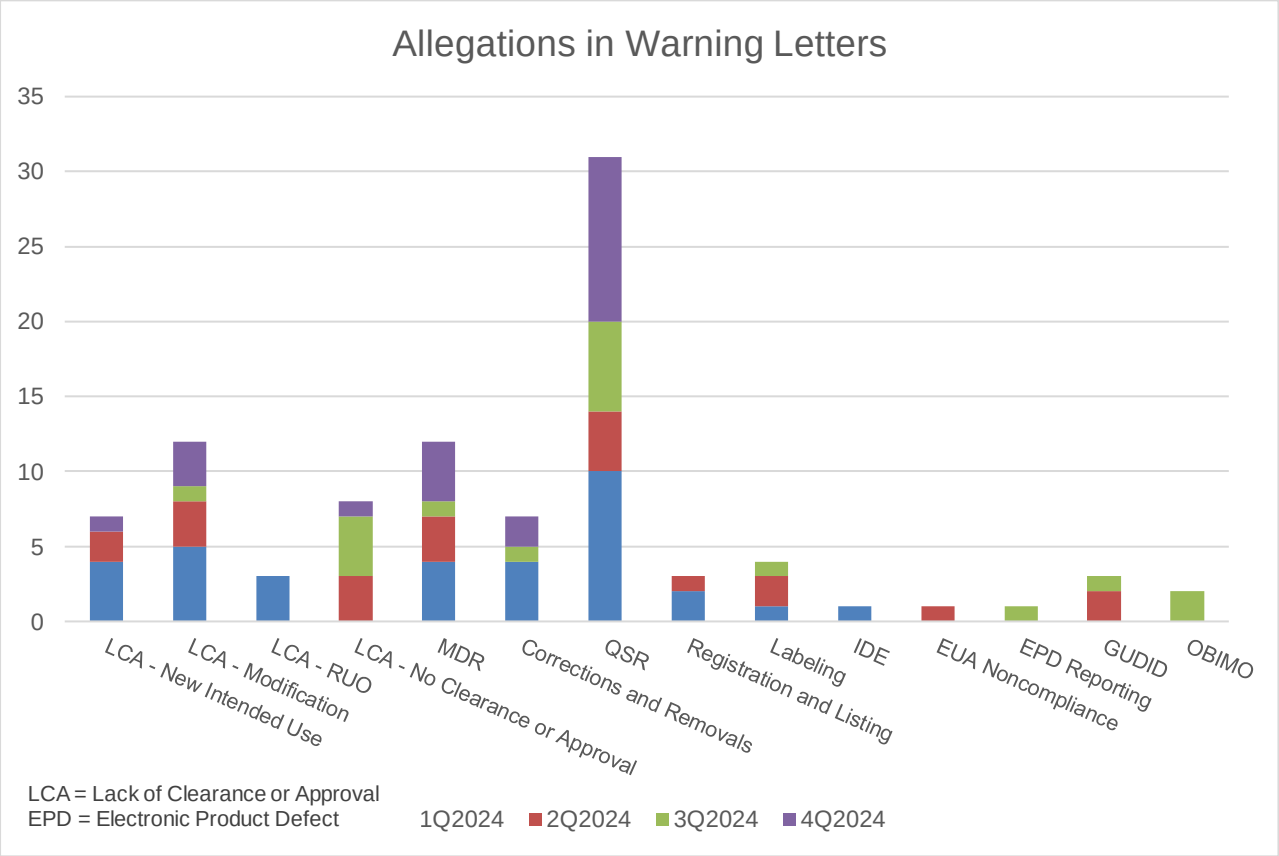
3. **Discontinuing Manufacture Not Enough:** In a warning letter to Hologic, Inc., FDA cited the company for alleged QSR violations related to design controls and CAPAs for its implantable device. FDA acknowledged that Hologic stated it will cease manufacturing the line of medical devices subject to the alleged violations but stated that, with respect to the alleged design control violations, the Agency continues to have safety concerns for patients in whom the device has been implanted. FDA stated the company should evaluate the device design to ensure that risks are mitigated for patients who already have the device implanted, as well as identify those patients who may be at risk for adverse events and therefore potentially benefit from device explantation. The warning letter also alleged violations of MDR and corrections and removals reporting requirements.
4. **Electronic Products Violations.** FDA issued a warning letter to Micro-X Ltd alleging failure to comply with electronic product radiation control requirements. Specifically, the Agency alleged the company failed to notify FDA of product defects and failures to comply with applicable performance standards. FDA also alleged that the company violated the QSR (design controls, CAPAs, and complaint files) and failed to report corrections and removals.

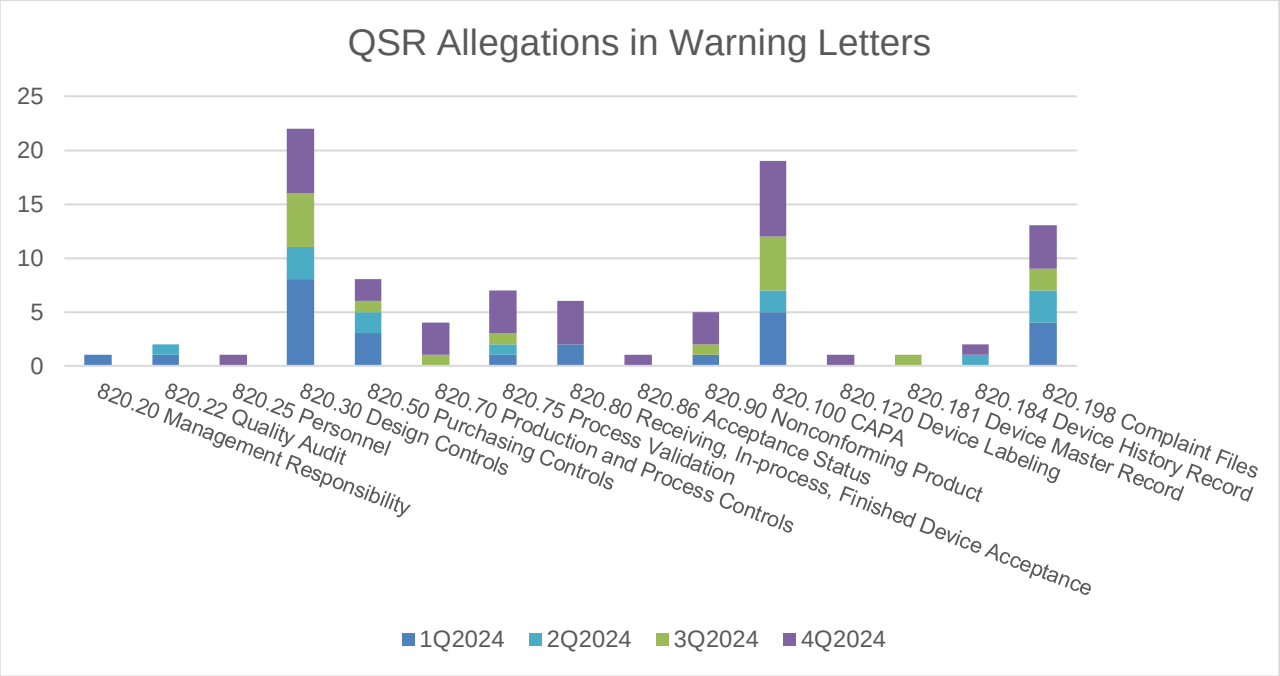
2024 Summary

FDA issued 45 warning letters related to medical devices in 2024. Key trends in these warning letters include:

1. The most commonly alleged violations related to QSR (31 letters), MDRs (12 letters), and lack of clearance or approval for a modified device (11 letters). The most commonly alleged QSR violations related to design controls (22 letters), CAPAs (19 letters), and complaint files (13 letters).
2. Warning letters often followed safety communications from the Agency. Following FDA's safety communication regarding syringes manufactured in China, the Agency issued six warning letters associated with such devices. And following FDA's safety communication regarding third-party testing laboratories, the Agency issued two warning letters to such facilities.

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


Allegations in Warning Letters
35
30
25
20
15
10
5
0
LCA - New Intended Use
LCA - Modification
LCA - RUO
LCA - No Clearance or Approval
MDR
Corrections and Removals
QSR
Registration and Listing
Labeling
IDE
EUA Noncompliance
EPD Reporting
GUDID
OBIMO
LCA = Lack of Clearance or Approval
EPD = Electronic Product Defect
1Q2024
2Q2024
3Q2024
4Q2024



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