UL Solutions

FDA warning letters: Key trends medical device manufacturers should know

Workforce training is key to building a culture of quality and reducing regulatory risk. In the 2024 fiscal year (Oct. 1, 2023 - Sept. 30, 2024), the U.S. Food and Drug Administration (FDA) issued dozens of warning letters linked to lapses in training, documentation, oversight and Quality System Regulation (QSR) compliance.

The number of Warning Letters issued by the FDA is notably increasing:

From
11 to 21
in the late 2010s and early 2020s

To a total of
47 for 2024

a **96%** increase from 2023

Of the
47 Warning Letters
issued in 2024,

27 were related to QSR compliance **(21 CFR Part 820),**

7 more than 2023

Top 5 deficiencies in the warning letters were related to

Design controls (21 CFR 820.30)
included in 21 letters

Corrective and Preventative Action (CAPA)
included in 16 letters

Complaint files (21 CFR 820.198)
included in 12 letters

Purchasing controls (21 CFR 820.50)
included in 9 letters

Quality audit (21 CFR 820.22)
included in 5 letters

> It's important to understand that FDA expects medical device manufacturers, led by individuals with executive responsibility or top management, to embrace culture and quality as a key component in ensuring safe and effective medical devices.

Keisha Thomas
Associate Director for Compliance and Quality at the Center for Devices and Radiological Health (CDRH)[1]

Effective workforce training can help medical device manufacturers:

- Create a culture of quality improvement and accountability
- Strengthen documentation practices to meet regulatory expectations
- Consistently apply standardized practices across operations
- Enhance oversight and collaboration with contract manufacturers
- Align with key standards and regulatory requirements, including:
  - Good manufacturing practices (GMPs)
  - Health Insurance Portability and Accountability Act (HIPPA)
  - Occupational Safety and Health Administration (OSHA)
  - American National Standards Institute (ANSI)

Build a compliant workforce with our Learning Management System

UL Solutions offers automated, role-based training programs to help your teams meet FDA expectations and maintain compliance with 21 CFR Part 820 and other regulations.

Create standardized processes
Make your manufacturing processes and procedures consistent and reliable across sites.

Train for high-risk processes
Create specialized training programs for processes such as sterilization, biologics manufacturing, etc.

Comply with evolving regulations
Access up-to-date training courses for compliance with GxP, Health Insurance Portability and Accountability Act (HIPPA), Occupational Safety and Health Administration (OSHA), American National Standards Institute (ANSI) and more.

Create custom training materials
Enable subject matter experts to create customized courses for employees.

*Data attributed to: ECA Academy. 2025. "FDA Warning Letter Statistics on Medical devices in the past Fiscal Year."
1. Regulatory Focus. 2025. "MedCon: FDA officials review QMSR as deadline approaches."

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