Is Your Company Recall-Ready?

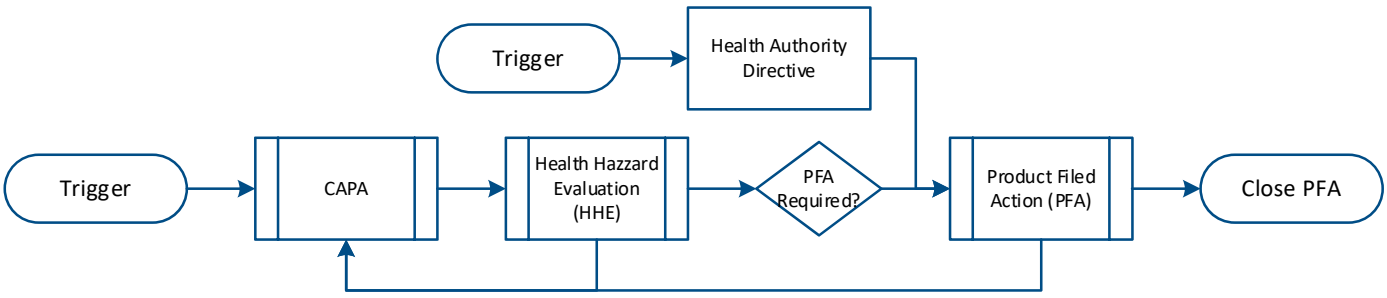
Maintain Compliance and Minimize Financial and Patient Impact

Medical devices play a crucial role in patient care, providing innovative solutions or enabling indispensable procedures that improve outcomes across the healthcare spectrum. Inevitably, there also will be product recalls: hopefully infrequent, but potentially devastating.

During the second quarter of 2022, there were 268 recall events involving medical devices, a 34% increase from the previous quarter; safety concerns, software issues, mislabeling and quality issues were listed as top causes.[1] Medical device manufacturing presents a greater level of product or usage risk that could lead to a recall than for most other products. Therefore, it is essential that manufacturers have in place a well-prepared recall readiness plan to ensure a timely, coordinated and effective response in the event of a recall. The consequences of a poorly managed product recall can be severe: significant financial loss, reputational damage, compromised patient safety, legal actions and heightened regulatory scrutiny.

Anatomy of a Recall

Not all "recalls" require return of product. Some actions (also known as "field corrective actions") may only require safety alerts or corrected labels. Recalls may be initiated by internal processes identifying a risk to patients, or by request by FDA or another health authority.



Once it's been determined a correction or removal is necessary, you are limited to 10 business days to formally notify the FDA using Form 806. The Recall Team designates a lead coordinator to serve as a project manager, ensuring the recall plan is activated and all tasks are completed. This includes but is not limited to:

A. Identifying internal stakeholders for general awareness, provide input, and manage internal and external messaging, minimize logistical inefficiencies and reduce compliance risk.

B. Disseminating an internal communication of the recall correction or removal and ask that requests for information related to the recall be prioritized and provide the due date for the FDA 806 Notification.

C. Developing and gaining internal approval of a Product Field Action Execution Plan and Record (see image).

D. Preparing and submitting the 806 Notification to FDA within the 10-business day timeline and must include:

- Identity of the product involved.
- Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
- Evaluation of the risk associated with the deficiency or possible deficiency.
- Total amount of such products produced and/or the time span of the production.
- Total amount of such products estimated to be in distribution channels.
- Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
- A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
- Proposed strategy for conducting the recall.
- Name and telephone number of the firm official who should be contacted concerning the recall.
- Statement if missing any above information.

E. Executing consignee notifications in accordance with your product field action execution strategy and 806 Notification.

F. Monitoring recall activity success rate, using defined key performance indicators.

G. Submitting 806 status reports to FDA monthly until such time FDA determines all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product.

Underlying Causes Leading to Medical Device Recalls

There are several complaint handling problems that organizations are facing today which can be easily remediated to avoid facing severe consequences.

There may be any number of underlying causes of a medical device recall. What they have in common is the potential to impact patient health or safety, either directly or through lack of proper information. Some examples of issues that have triggered recalls and other field corrective actions include:[2,3]

Device design and manufacturing defects: Design failures can result from excessive shelf life, lack of biocompatibility, or ignoring human factors and usability, and can affect both the user and manufacturer.[4]

Software design: Software itself can be a medical device or a component of a medical device, or it can be used to make or control a medical device.3 In short, software has become an indispensable component of most medical devices. Consequently, software failures such as programming anomalies, security vulnerabilities and network connection issues have contributed to software design being the leading cause of medical device recalls.

Change & process controls: Process and change control, from design conception through the product life cycle, is a daunting undertaking that is often overlooked or incomplete, with siloed repositories adding a layer of complexity.

Nonconforming components/materials: Components of medical devices can be defective or otherwise fail to meet quality standards. Nonconforming materials or components can arise from issues with suppliers, manufacturing errors, design flaws, or a lack of requisite testing or inspection of components.

Labeling or packaging issues: Inaccurate or incomplete instructions for the use of the device can lead to a lack of clarity regarding proper or intended product usage, which can result in patient harm or injury.

Key Challenges in Managing Recalls

Common issues that can cause a lack of preparedness to respond to a medical device recall may include:

Inadequate or poorly defined recall procedures: If a company does not have a clear and well-defined plan in place for handling a medical device recall, it can lead to inaction, confusion or delays in responding to the issue.

Inexperienced staff: Responding to a medical device recall can be a resource-intensive process. If a company does not have the requisite resources, such as personnel, technology or financial resources, this can impede its ability to respond effectively.

Domestic and foreign compliance: In an ever-evolving regulatory landscape, some medical device manufacturers can lack full awareness of changes in regulations, resulting in incomplete or misinterpreted adherence to specific guidelines.

Inadequate internal and external communications: When communication hierarchies do not adequately consider internal stakeholders, it can cause disconnects in providing inter-company updates on open recalls, and assessing the impact on different functional areas and priorities. Similarly, a lack of transparency in external communications with consumers can result in brand damage and difficulty in maintaining brand loyalty.

Lack of comprehensive performance reporting and analytics: Failure to adopt fact-based analytics and reporting processes can blur the line of sight for leadership and key stakeholders on recall activity, and affect the company's ability to respond in a timely manner.

Our Approach

FTI Consulting Life Sciences professionals have advanced clients' compliance and alignment with regulatory requirements and risk management challenges. We work to create a proactive approach that fits your company's needs, goals and state of readiness. Here's our approach:

- **Discovery:** By capturing the voice of the customer (VoC) within each functional area, performing a gap analysis and root-cause analysis to make recommendations for an optimal state of readiness.
- **Design:** Upon acceptance, FTI collaborates with functional teams to develop procedures and toolkits to support end-to-end processes.
- **Company-wide adoption:** FTI can support execution in the event of a recall or conduct training across the organization to educate staff at all levels.

[1] Zipp, Ricky. "Medical Device Recalls Hit Two-Year High in Q2, Report Finds." MedTech Dive, August 18, 2022. https://www.medtechdive.com/news/device-recalls-two-year-high-q2-sedgwick/629979/.

[2] Stewart, Conor. "Top Causes for Medical Device Recalls U.S. 2019." Statista, September 7, 2021. https://www.statista.com/statistics/618253/share-of-major-causes-for-medical-device-recalls-in-us/.

[3] Medical device recall report - fdanews. Accessed October 24, 2023. https://www.fdanews.com/ext/resources/files/03/03-31-14-Recalls.pdf.

[4] Digital, Johari. "8 Medical Device Design Flaws and How to Fix Them:" Johari Digital Healthcare Ltd., April 16, 2022. https://www.joharidigital.com/8-medical-device-design-flaws-how-to-fix-them/.

[5] "Medical Device Recalls up 126% in Q1 2018." Radiology Business, February 11, 2022. https://radiologybusiness.com/topics/healthcare-policy/medical-device-recalls-126-q1-2018.

ANTHONY GOTZIS
Senior Managing Director
215.622.7588
Anthony.Gotzis@fticonsulting.com

PAT SHAFER
Managing Director
646.379.8307
Pat.Shafer@fticonsulting.com

ANCY JOHNSON
Senior Director
267.407.2587
Ancy.Johnson@fticonsulting.com