2 Postmarket Compliance: US

By Shikha Malik, MPharm, MS, RAC-Devices

Introduction

Once a medical device is placed on the market after marketing approval or clearance, the medical device transitions to the postmarket phase from the premarket phase. The postmarket phase includes post-market surveillance (PMS) activities involving the active, systematic, and scientific collection of data on the quality, safety, and performance of a marketed medical device, followed by an analysis and interpretation of the information. The PMS must be proportional to the risk classification and appropriate for the device category. Postmarket surveillance ensures that an equilibrium is maintained between the benefits and risks posed by a medical device. An overview of the medical device lifecycle is described in **Figure 2-1.**

This chapter will focus on postmarket requirements for medical devices, including establishment registration and an overview of device listing requirements. A comprehensive overview of how the Medical Device Quality System Regulation (QSR) lays the framework for postmarket activities, including medical device reporting (MDR), corrections or removals (recalls), and medical device tracking also will be discussed.

Applicable Regulations and Guidance

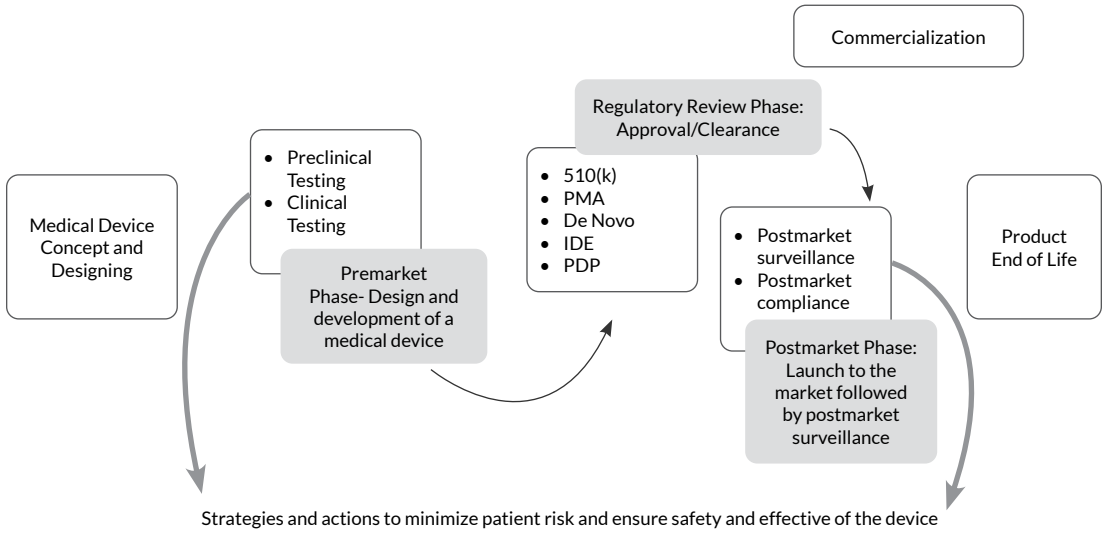
Quality System Regulation Requirements

In the US, the Quality System Regulation (QSR) (21 CFR 820)[1] enforces the statutory requirements published in the Federal Register on 7 October 1996. The quality system, as they apply to devices and other FDA-regulated products, are known as current good manufacturing practices (CGMPs). The QSR provides general framework requirements to all device manufacturers to ensure their devices are manufactured in the US according to a quality standard to ensure their safety and effectiveness. These regulations apply to the total lifecycle of a medical device, from manufacturing to commercialization, including postmarket compliance activities.

The QSR is applicable to the manufacturing of FDA-approved (or cleared) finished medical devices intended for human use that are distributed and imported for marketing in the US, including the US territories applicable under FDA's jurisdiction. 21 CFR 820.3(I) of the QSR defines "finished device" as any medical device (or an accessory to any device) that is applicable for human use or capable of functioning, whether or not it is packaged, labeled, or sterilized. Finished medical device manufacturers (both small and

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Figure 2-1. Lifecycle of a Medical Device



large manufacturers) are required to comply with this regulation. The QSR does not apply to manufacturers of components or parts of finished devices; however, they are highly encouraged to use the regulation as guidance.

In vitro diagnostic (IVD) products have the same QSR requirement as medical devices, listed under 21 CFR 820. The Federal Food, Drug and Cosmetic (FD&C) Act defines IVDs in 21 CFR 809.3[2] as "products that are those reagents, instruments and systems intended for diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease of its sequelae." Per 21 CFR 809.20,[3] IVDs also require a domestic or foreign manufacturer to implement a quality system for the design, manufacturing, packaging, labeling, and storage of a finished product intended for commercial distribution in the US market, unless such devices are exempt from QSR regulations, according to 21 CFR 862–892.[4]

Additionally, 21 CFR 820 also applies to human cells, tissues, and cellular and tissue-based products (HCT/Ps) that are regulated as medical devices. Manufacturers of blood and blood components used for transfusion are not subject to the requirements in 21 CFR 820.

The implementation of a QSR depends on the type of products manufactured, which defines the cGMP manufacturing levels, the risk classifications determined by FDA, and the potential safety concerns associated with the type or risk-level of the medical device. Per 21 CFR 820.30,[5] these regulations generally apply to all Class II and Class III devices, whereas most Class I devices are exempt from the QSR requirements, except tracheobronchial suction catheter devices, surgeon's gloves, protective restraint, manual radionuclide applicator systems, and radionuclide teletherapy system devices.

Each organization is responsible for establishing their own quality system (QS) requirements for manufacturing a finished final device meeting its safety and efficacy profile. Failure to comply with the QSR requirements results in noncompliance and may lead to FDA enforcement and statutory actions, such as a warning letter, or the device may be considered adulterated or misbranded.

Establishment Registration and Medical Device Listing 21 CFR 807[6]

Establishments or facilities involved in the manufacturing and distribution of medical devices intended for use in the US are required

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to register annually with FDA. This is known as establishment registration (21 CFR 807), a mandatory responsibility for manufacturers, including contract manufacturers.

Most establishment facilities, unless exempt under Section 510 (g)[7] of FD&C Act or 21 CFR 820 Subpart D, are required to register in the FDA database. They also are required to list their medical devices, including manufacturing activities (such as assembly, manufacturing, processing, labeling, and packaging). The owner/operator also needs to provide the FDA clearance/approval number (510(k) premarket notifications, premarket approval application (PMA), product development protocol (PDP), humanitarian device exemption (HDE), De Novo) for medical devices requiring a premarket approval or notification before being marketed in the US. The following organizations are required to fulfill the registration and device listing requirements under 21 CFR 807.20:[8]

- Device specification developer for a device that is manufactured by a second party
- Repackager or relabeler of a device
- Reprocessor of a single use device that has previously been used on a patient
- Contract manufacturers that make a device for or on behalf of a US company or specification developers
- Contract sterilizers that provide a sterilization service for another establishment's devices
- Initial importers, defined in 21 CFR 807.3 (g) as "any importer who further the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, otherwise change the container, wrapper or labeling of the device or device package"
- Component manufacturers who manufacturer components or accessories that are ready to be used for any intended health-related purposes and are packaged or labeled for commercial distribution for such health-related purposes, e.g., blood filters and hemodialysis tubing

The organizations (domestic and foreign) listed in **Table 2-1** and **Table 2-2** are required to be registered and pay an annual establishment registration fee, per 21 CFR 807.

Congress has authorized FDA to collect an annual device establishment registration fee. Small establishments do not qualify for a reduced business fee. A detailed list of the types of establishment facilities required to register and pay the fee to FDA can be found at "Who Must Register, List and Pay the Fee," as explained below:[9]

- **Initial registration:** Domestic establishments are required to register with FDA within 30 days of placing a device on the market. Foreign establishments also are required to register with FDA prior to exporting devices to the US for the first time. If prior clearance/approval is required by FDA, the establishment needs to wait for the PMA or 510(k) number to register their establishment and list the device.
- **Annual registration:** Establishment registration information must be submitted annually between October 1 and December 31 of each year, even if no changes have occurred. Establishments must certify that the registration information is accurate, and any updates are made at this time, if required.
- **Update registration and listing information:** Establishment registration and device listings can be viewed and updated electronically at any time throughout the year using a web-based system known as FDA's Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM). All owners or operators can access FURLS/DRLM (https://www.access.fda.gov) unless a waiver of electronic access is granted. All initial, annual, and updated registration and listing information must be submitted electronically unless a waiver is granted under the Food and Drug Administration Amendments Act (FDAAA) of 2007. **Figure 2-2** shows the process for annual registration and listing.

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Table 2-1. Domestic Establishments[6]

Activity	Register	Device Listing	Fee Payment
Manufacturer/remanufacturer and kit assemblers	Yes 21 CFR Part 807.20(a)	Yes 21 CFR Part 807.20(a)	Yes
Manufacturer of accessories or components packaged or labeled for commercial distribution for health-related purposes to an end user	Yes 21 CFR Part 807.20(a)(6)	Yes 21 CFR Part 807.20(a)(6)	Yes
Manufacturer of components, not otherwise classified as finished device, distributed only to a finished device manufacturer	No 21 CFR Part 807.65(a)	No	No
Custom device manufacturer	Yes 21 CFR Part 807.20(a)(2)	Yes 21 CFR Part 807.20(a)(2)	Yes
Refurbishers or remarketers of used devices already in commercial distribution in the US	No	No	No
Repackagers/relabelers	Yes 21 CFR Part 807.20(a)(3)	Yes 21 CFR Part 807.20(a)(3)	Yes
Contract manufacturers (including contract packagers)/contract sterilizers	Yes 21 CFR Part 807.20(a)(2)	Yes 21 CFR Part 807.20(a)(2)	Yes
Specification developers	Yes 21 CFR Part 807.20(a)(1)	Yes 21 CFR Part 807.20(a)(1)	Yes
Reprocessors of single-use devices	Yes 21 CFR Part 807.20(a)	Yes 21 CFR Part 807.20(a)	Yes
Initial importers	Yes 21 CFR Part 807.40(a)	No Identify manufacturers per 21 CFR Part 807.20(a) (5)	Yes
Device under IDE investigation	No	No 21 CFR Part 807.40 (c)	No
Domestic distributor (that does not import devices)	No 21 CFR Part 807.20(c)	No	No
Any establishment located in a foreign trade zone involved with the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for commercial distribution in the US	Yes 21 CFR Part 807.40 (a)	Yes 21 CFR Part 807.40 (a)	Yes
Import agent, broker, and other parties who do not take first possession of a device imported into the US	No	No	No
Specification consultant	No	No	No
US manufacturer of "export only" devices	Yes 21 CFR Part 807.20(a)	Yes 21 CFR Part 807.20(a)	Yes
Wholesale distributor that is not a manufacturer or importer	No	No	No

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Table 2-2. Foreign Establishments[6]

Activity	Register	Device Listing	Fee Payment
Foreign manufacturer/remanufacturer	Yes 21 CFR Part 807.40(a)	Yes 21 CFR Part 807.40(a)	Yes
Manufacturer of accessories or components packaged or labeled for commercial distribution for health-related purposes to an end user	Yes 21 CFR Part 807.20(a)(5)	Yes 21 CFR Part 807.20(a)(5)	Yes
Manufacturer of components that are distributed only to a finished device manufacturer	No 21 CFR Part 807.65(a)	No	No
Custom device manufacturer	Yes 21 CFR Part 807.20(a) (2)	Yes 21 CFR Part 807.20(a) (2)	Yes
Remanufacturer	Yes 21 CFR Part 807.40(a)	Yes 21 CFR Part 807.40(a)	Yes
Repackagers/relabelers	Yes 21 CFR Part 807.20(a)(3)	Yes 21 CFR Part 807.20(a)(3)	Yes
Contract manufacturers (including contract packagers)/contract sterilizers	Yes 21 CFR Part 807.40(a)	Yes 21 CFR Part 807.40(a)	Yes
Specification developers	Yes	Yes	Yes
Reprocessors of single-use devices	Yes 21 CFR Part 807.20(a)	Yes 21 CFR Part 807.20(a)	Yes
Device under IDE investigation	No 21 CFR Part 812.1(a)	No 21 CFR Part 812.1(a) 21 CFR 807.40(c)	No
Foreign exporter of devices located in a foreign country	Yes 21 CFR Part 807.40(a)	Yes 21 CFR Part 807.40(a)	Yes
Foreign manufacturers, including kit assemblers	Yes 21 CFR Part 807.40(a)	Yes 21 CFR Part 807.40(a)	Yes
Wholesale distributor that is not a manufacturer or importer	No	No	No

Postmarket Activities

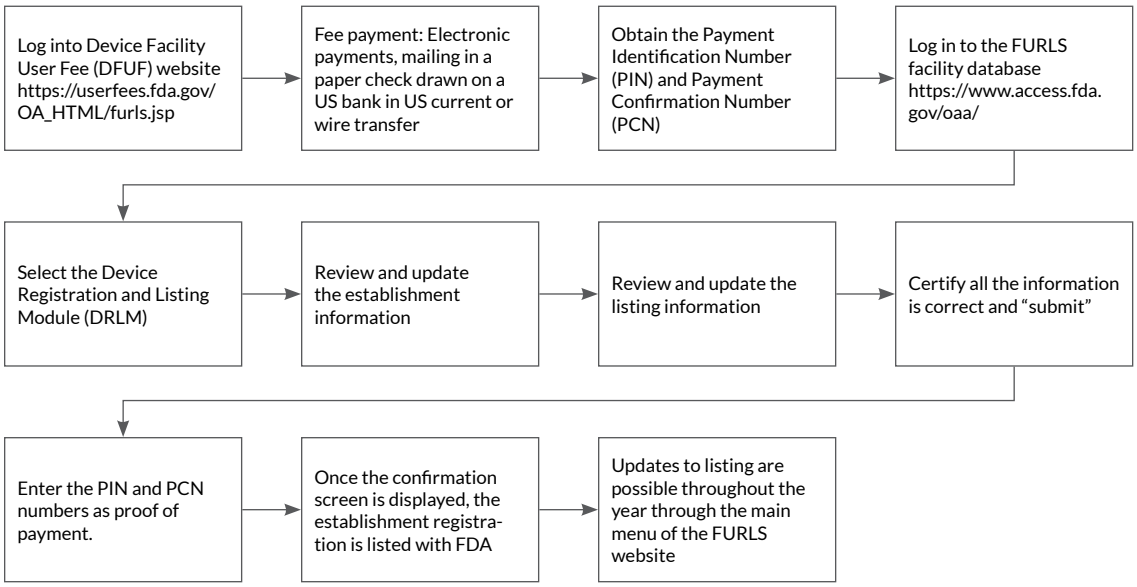
Medical device manufacturers must set up a PMS program to monitor a medical device's safety and performance after being approved or cleared for sales and prior to their market release. The PMS system is based on the PMS Plan. The PMS Plan establishes how to monitor PMS data and identify potential changes in the benefit-risk profile of a device so that corrective and preventive action (CAPA) decisions can be made. The CAPA process, in accordance with 21 CFR 820.100,[10] is used to establish requirements for assessing and addressing existing and potential quality issues by performing a cause investigation and making corrections, corrective and/or preventive actions commensurate with the issue's risk. Using an appropriate benefit-risk assessment and various other means to gather data on safety and effectiveness of a medical device allows manufacturers to address any safety issues.

CDRH's Office of Product Evaluation and Quality (OPEQ)[11] enforces premarket and postmarket compliance, as set forth in the FD&C Act and Code of Federal Regulations, to assure medical device safety. FDA has developed various guidances, including postmarket problem identification, postmarket problem assessment, and public health response to help ensure postmarket safety requirements are met.

Overall, FDA uses a multilayered approach that relies on various postmarket regulations

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Figure 2-2. Annual Registration Process



and requirements, including but not limited to, medical device tracking (21 CFR 821); medical device reporting (21 CFR 803), medical device recalls, corrections, and removals (21 CFR 7 and 21 CFR 806); postmarket surveillance, including customer service, complaint handling, and FDA inspections, including third-party inspections and enforcement activities, to ensure the device is safe and effective for its intended commercial use in the US.

Laws and Regulations Pertaining to Postmarket Activities

The following section applies to key regulatory and statutory requirements for postmarket compliance management.

FD&C Section 522 Postmarket Surveillance Studies[12]

In May 2021, FDA issued a draft guidance, Postmarket Surveillance under Section 522 of the FD&C Act, which outlines the types of regulatory submissions, such as PMAs, PDPs, 510(k)s, and HDEs, that require postmarket surveillance studies under Section 522 of the FD&C Act. This document provides FDA with the federal authority to require a manufacturer to conduct postmarket surveillance for a period of up to 36 months for Class II or Class III medical devices meeting any of the following criteria:[12]

- If device failure leads to serious adverse events or health consequences
- If the device is expected to have significant use in pediatric patients
- If the device is an implantable device for more than one year
- If the device is life-sustaining or life-supporting and will be used outside a user facility

As provided in 21 CFR 822.8,[13] a postmarket surveillance order is issued by FDA at the time of device clearance/approval or anytime thereafter as required or deemed appropriate. The manufacturer is required to submit a postmarket surveillance plan within 30 days after FDA's notification and initiate postmarket surveillance activities no later than 15 months after the date of order issuance. Once a postmarket surveillance plan is submitted to FDA, FDA will assign a postmarket surveillance (PS) order number, such

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as PSXXXX. This postmarket surveillance order number should be cited when submitting a PMS plan for FDA review. PMS plans are reviewed by FDA as supplements to the PS order number.

Per CFR 822.10,[14] typical postmarket surveillance plan information should include the following:

- Objective of the postmarket surveillance plan
- Design or methodology to be used
- Subject details such as patient population, including inclusion and exclusion criteria, and device information
- Sample size and its justification
- List of expected adverse events
- Description of data sources such as hospital records, registry data etc.
- Details of data collection plan
- Informed Consent Form
- Institutional Review Board (IRB) approval or IRB exemption forms
- Patient follow up plan
- PS plan duration

The PS order is initially reviewed to ensure that the PS plan is administratively complete. The review target time for a PS order is 60 calendar days. After the initial application review is completed, a request for additional information may be sent if FDA requires more information to complete its assessment. FDA will specify the number of days the applicant has to provide the additional information. Upon receipt of missing information from the applicant, a new 60-day review period begins. Following the review, FDA will send one of the following types of letters to the applicant:[15]

- Approval letter stating FDA's approval of the submitted PS order. FDA will ask the applicant to submit the revised information within the prescribed timelines
- Not acceptable letter issued by FDA if deficiencies are identified during the administrative process
- Major deficiency letter (also known as approvable letter), which identifies serious deficiencies relating to whether the PS plan will result in the collection of useful data for surveillance-related questions. A major deficiency letter generally requires submission of a revised PS plan to FDA within a specified duration of time.
- Disapproval letter indicating FDA's disapproval of the PS plan. This letter also states the reasons for disapproval.

Under 21 CFR 822.38,[16] manufacturers also are required to submit an interim and final postmarket surveillance report to FDA to provide occasional status updates. Interim reports should be submitted every six months for the first two years of postmarket surveillance and yearly thereafter until the completion of surveillance, per 21 CFR 822.38.[16] There are two types of interim reports:

- Enrollment reports: To provide status of the enrollment milestones as outlined in the surveillance plan
- Interim postmarket surveillance status reports: To provide subject accountability and device performance data

The final postmarket surveillance report should be submitted no later than three months after completion or termination of the postmarket surveillance requirement. Any changes to an approved postmarket surveillance plan require FDA approval before being implemented. Refer to **Figure 2-3** for an overview of the process.

Failure to comply with the FD&C Section 522 requirement renders the device as misbranded. This could lead to FDA advisory, administrative, and enforcement actions through a variety of mechanisms, including but not limited to notice of Violations (NOV) or untitled letters, warning letters, seizure of product, injunction, prosecution, and/or civil money penalties under 21 CFR 822.20.[17] The following are examples of FDA enforcement actions.[18]

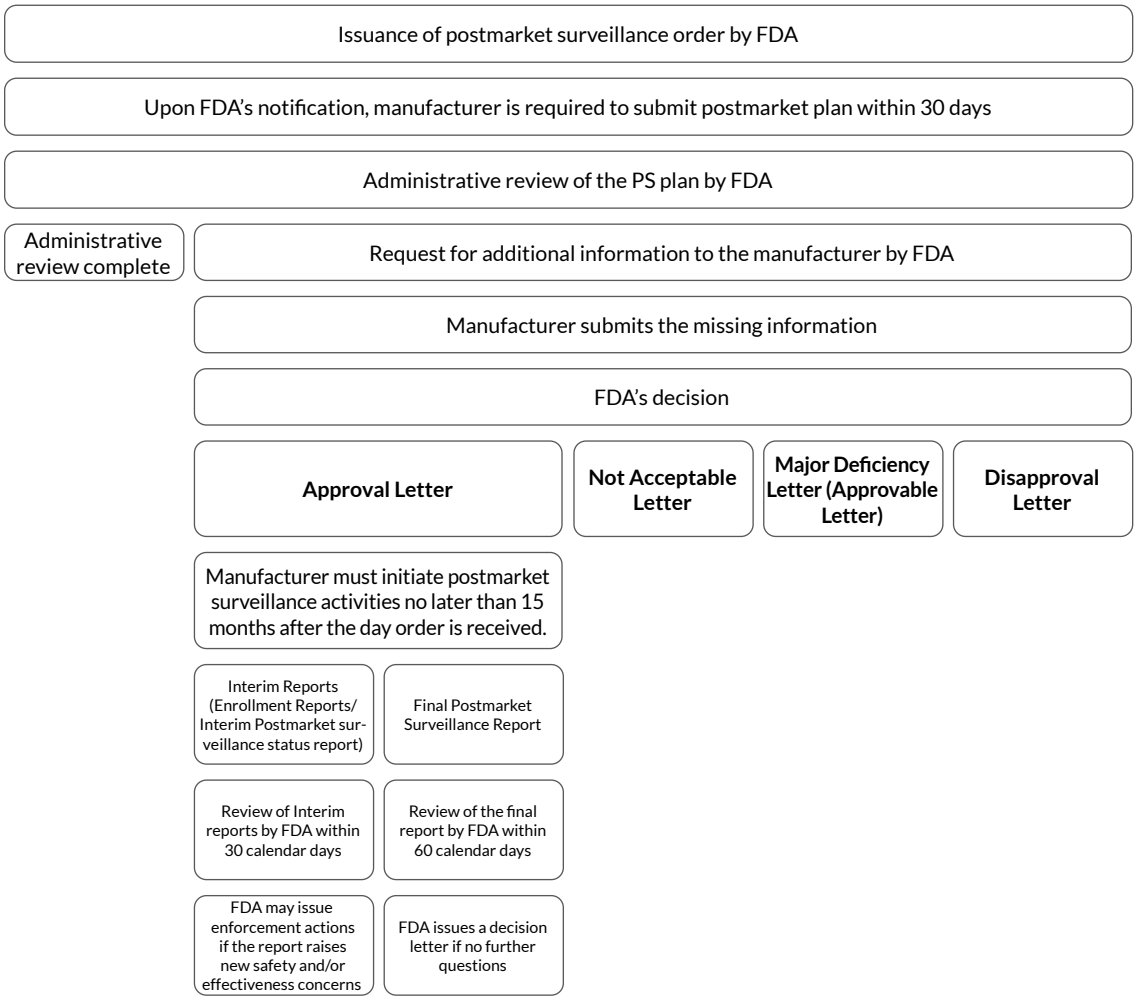
Advisory Actions

Warning Letter

This is an advisory letter sent to a firm by FDA to gain prompt voluntary compliance. Warning Letters are not final agency action. Warning letters

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Figure 2-3. FD&C Section 522 Postmarket Surveillance Process



can be issued with or without a NOV. These letters require a written response to FDA within 15 business days with a plan to correct the noted violation. After receiving the plan, FDA will review the plan and its supporting deliverables to ensure the plan is likely to be sufficient to correct the violations in scope. Additionally, FDA monitors the firm's subsequent activities as needed to ensure the firm is following all applicable regulations. Warning letters can be issued immediately by FDA if a serious violation is noted that could impact health and safety. Failure to address a warning letter could further result in other types of enforcement actions, such as criminal or civil proceedings.

Untitled Letters or Notice of Violations

An untitled letter is issued by FDA to a firm citing violations that do not meet the regulatory significance threshold for a warning letter. For example, FDA may review advertising and promotional material, such as marketing brochures, company websites, advertisements, press releases, and newsletters and it requires the firm to only stop using materials that include the claim FDA found to be violative. An untitled letter is generally considered a "prior notification" sent to a firm, where a failure to address a minor violation as noted in an untitled letter could lead to a warning letter or other type of enforcement action.

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Administrative Actions

FDA Inspections

FDA conducts inspection of medical device manufacturing facilities, including domestic manufacturers, contract testing laboratories, clinical study sponsors, investigator sites, foreign companies, and contract research organizations (CRO) to ensure regulatory compliance. FDA may conduct either a routine inspection or a for-cause inspection to ensure GMP/QSR compliance (routine surveillance, establishment license or pre-approval), GLP compliance, or GCP compliance (sponsor or investigational sites). Generally, an FDA inspection of a manufacturing facility is required prior to a PMA approval for a Class III device, referred to as prior approval inspection (PAI).

FDA may not inspect a firm's sales data, with the exception of shipment information, financial and pricing information, personnel files other than qualifications, internal audit files, and research data other than those subject to FDA inspection. An FDA inspector is required to produce a Notice of Inspection (FDA Form 482), along with its credentials, to the manufacturing site prior to inspection initiation.

FDA Form 483

In case of any observations that may constitute violation of the FD&C Act, FDA may issue inspectional observations to the management on FDA Form 483 at the end of the inspection. FDA Form 483 is discussed with the senior management of the firm, and it not a final determination of whether or not any condition observed is in violation of the FD&C Act.

Upon the receipt of FDA Form 483, a firm has 15 working days to provide a written response to FDA with an extensive corrective action plan.

Recalls

Defined as an action taken by a manufacturer, importer, or distributor of a medical device to remove a violative or defective product from the market. Recalls may be initiated by a firm voluntarily, by formal FDA request, or by FDA order under FDA's mandatory recall authority. Recalls are discussed in detail later in this chapter.

Enforcement Actions

Product Seizure

An action intended to remove a violative product from commercial distribution. FDA initiates the seizure process by filing a complaint to the US court where the product is located. A US Marshall as directed by the court seizes the products where they are found until the issue is resolved.

Injunction

An order by the court that requires an individual or firm to halt the continued production or distribution of a violative product until the individual or firm complies with FDA regulations.

Criminal Prosecutions: An action taken by FDA's Office of Criminal Investigation[17] to conduct criminal investigations against the individual or firm responsible for illegal activities involving an FDA-regulated product. They also are responsible for arresting and bringing them to the US Department of Justice for prosecution. Criminal prosecution is recommended for products that are in violation of Section 301 of the FD&C Act. [19]

There are two types of criminal prosecutions under Section 301 of the FD&C Act:

- **Misdemeanor convictions:** These types of convictions do not require any evidence for the violation of the FD&C Act. It can result in fines and/or imprisonment up to one year.
- **Felony convictions:** It is applicable in the case of a second violation or intent to defraud or mislead. It can result in fines and/or imprisonment for up to three years.

Postmarket surveillance studies are available on the FDA database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm,) which is updated on the fifth of every month. Furthermore, protocols and final study reports can be requested from FDA under the Freedom of Information Act (FOIA).[20]

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Medical Device Reporting 21 CFR 803[21]

The Medical Device Reporting (MDR) Regulations are enacted in 21 CFR 803, which defines the requirements for postmarket adverse event reporting and malfunctions or other safety concerns applicable to the marketed device by device manufacturers, user facilities, importers, and distributors. The statutory authority for the medical device reporting regulation is Section 519(a)[22] of the FD&C Act. It establishes the regulatory pathway for collecting reportable adverse event data and defines critical reporting roles, responsibilities, and timelines. On 11 December 1995, the MDR regulations for user facilities were published in the Federal Register, and on 31 July 1996, the new MDR regulations became effective for medical device manufacturers and user facilities. The Food and Drug Administration Modernization Act (FDAMA) of 1997 amendment to the medical device adverse event (AE) reporting requirement became effective on 11 February 1998. On 26 January 2000, changes to medical device reporting regulations, 21 CFR 803, were published in the Federal Register to reflect the changes in the Act.

Responsible parties are defined by FDA under 21 CFR 803.3 as follows:[23]

- "Device user facility" means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.
- "Distributor" means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If a person repackages or otherwise changes the container, wrapper, or labeling, they are considered a manufacturer, as defined in this CFR.
- "Importer" means any person who imports a device into the US and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If a person repackages or otherwise changes the container, wrapper, or labeling, they are considered a manufacturer as defined in this section.
- "Manufacturer" means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:
    - Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture
    - Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications
    - Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or is the US agent of a foreign manufacturer
- Initial distributors of foreign entities where "distributor" means any person other than manufacturer or importer who is responsible for the marketing of a device from the original place of manufacture to the person who makes final delivery to the final user but is not involved in the repackaging or changing the container, wrapper, or labeling of the device or device package.

The following are a few additional definitions associated with MDR requirements, as described in 21 CFR 803.3:[23]

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- A manufacturer is considered to have "become aware" of an event in the following scenarios:
  - A device user facility is considered to have "become aware" when medical personnel who are employed by or otherwise formally affiliated with a facility obtain information about a reportable event.
  - A manufacturer is considered to have "become aware" of an event when an employee with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities or whose duties include the collection and reporting of adverse events becomes aware of any information (including any trend analysis) that an MDR reportable event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. In this case, the event is required to be reported within five workdays.
  - A manufacturer is considered to have "become aware" of an event when any employee becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within five workdays.
  - An importer is considered to have "become aware" of an event when any employee becomes aware of a reportable event that is required to be reported within 30 calendar days.
- "Caused or contributed" to a death or serious injury means a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:
  - Failure
  - Malfunction
  - Improper or inadequate design
  - Manufacture
  - Labeling
  - User error
- "Serious injury" means an injury or illness that:
  - Is life-threatening
  - Results in permanent disability, such as permanent damage to a body structure or permanent impairment of a body function
  - Requires medical intervention to preclude permanent impairment of a body structure. Permanent means irreversible impairment or damage to a body structure or function excluding trivial impairment or damage
- "Malfunctions" means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling of a device. An MDR submission is required for a marketed device if a device malfunctioned or is likely to cause or contribute to a death or serious injury. MDR reporting to FDA is governed by a PMS program known as MedWatch.[24] All MDRs are required to be in the English language. An MDR submission should be made to FDA using the following forms:[25]
  - Form FDA 3500: Voluntary Reporting for healthcare professionals (https://www.fda.gov/media/76299/download)
  - Form FDA 3500 A: Mandatory Reporting (https://www.fda.gov/media/82655/download)
  - Form FDA 3500B: Voluntary Reporting for consumers/patients (https://accessible-techcomm.org/wp-content/uploads/MedWatch_Consumer_Voluntary_Reporting_form-FDA-3500B.pdf)
  - Form 3419: Medical Device Reporting Annual User Facility Report (C:\Users\maliks2\Downloads\FDA_3419_12-13-18.pdf)

On 14 February 2014, FDA published a final rule on electronic medical device reporting (eMDR),[26] requiring manufacturers and importers to submit MDRs to FDA in an electronic format for their review, process, and archival purposes. User facilities also can submit electronically; however, the final rule still permits user

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facilities to manually submit MDR reports using FDA Form 3500A. On 14 August 2014, FDA also issued guidance, Questions and Answers about eMDR Electronic Medical Device Reporting.[27] The main objectives of the guidance were to increase awareness about the process of submitting MDR incidents to FDA electronically with prior consent from FDA. This rule became effective on 14 August 2015.
An eMDR submission can be submitted to FDA through the Electronic Submission Gateway (ESG) using the following two options: [27]

1. Web Interface using the eSubmitter application: This is a free, downloadable application that allows users to create one report at a time. The eSubmitter program contains data elements that corresponds to 21 CFR 803.32, 21 CFR 803. 42 and 21 CFR 803.52.
2. Applicability Statement 2 (AS2) Gateway-to-Gateway using Health Level Seven (HL7) Individual Case Safety Report (ICSR) XML: This program allows users to create and submit eMDRs either individually or in batches (containing multiple individual reports in a single submission). Submitters are required to purchase AS2 system that is capable of generating HL7ICSR XML and transmitting it to the ESG.

For a full list of medical device reporting requirements, refer to 21 CFR 803.3.[23] The following is a high-level summary of the different types of medical device reporting requirements:

- Mandatory Reporting: Mandatory reporting is required by the following:
  - Device User Facilities (hospital, ambulatory facility, nursing home, outpatient diagnostic facility or outpatient treatment facility that is not a physician's office) (21 CFR 803 Subpart C)
  - Importers (21 CFR 803 Subpart D)
  - Manufacturer (21 CFR 803 Subpart E)

Table 2-3 lists the details for mandatory reporting requirements.

- Voluntary Reporting: Healthcare professionals, patients, caregivers, and consumers are encouraged to submit voluntary reports about serious adverse events, use errors, product quality issues, and therapeutic failures to the FDA. Voluntary reporting can be done online or by submitting FDA Form 3500 (healthcare professional) or FDA Form 3500B (consumer/patient) to MedWatch.[25] Please note that voluntary reporting does not satisfy the obligation to report under 21 CFR 803.

Figure 2-4 provides FDA's adverse event reporting scheme workflow.

In conjunction with the manual reporting and electronic reporting requirements, FDA has a database that archives medical device AE reports submitted to FDA by various aforementioned mandatory and voluntary reporters. This is known as the Manufacturer and User Facility Device Experience (MAUDE) database.[28] This database is public, the reports are redacted, and data is archived for the last 10 years. Additionally, this publicly searchable database of adverse event reports includes user facility reports since 1991, voluntary reports since 1993, and manufacturer reports since August 1996. The MAUDE database may not include certain reports that are exempted under 21 CFR 803.19.[29]

Medical Device Recalls, Corrections, and Removals[30]

FDA defines a medical device recall as a method of removing or correcting products for which deficiencies are reported in quality, efficacy, or safety. Recall also includes devices that are in violation of laws administered by FDA. It is a voluntary action under 21 CFR 7[31] conducted by a manufacturer and distributor to remove a violative product from the market to protect the public health. A voluntary recall can take place any time, and for any reason, by the manufacturer and distributor or upon FDA request. FDA's Office of Regulatory Affairs (ORA) is responsible for inspecting firms and enforcing regulations. FDA's ORA Division Recall Coordinator (DRC) should be notified

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Table 2-3. Mandatory Reporting Requirements[25]

Reporter	What to Report	When to report (after becoming aware of an event)	To Whom to Report	FDA Report Form Number
Manufacturer (21 CFR Part 803.50)	Device-related death or serious injury	Within 30 calendar days	FDA	Form FDA 3500A or electronic equivalent
Manufacturer (21 CFR Part 803.50)	Device malfunctions	Within 30 calendar days	FDA	Form FDA 3500A or electronic equivalent
Manufacturer (21 CFR Part 803.53)	Incident or event that requires immediate remedial action	Within five working days	FDA	Form FDA 3500A or electronic equivalent
Device User Facilities (21 CFR Part 803.32)	Device-related death in the facility	Within 10 working days	FDA and the manufacturer	Form FDA 3500A or electronic equivalent
Device User Facilities (21 CFR Part 803.32)	Device related serious injury	Within 10 working days	FDA or manufacturer (FDA only if the manufacturer is unknown)	Form FDA 3500A or electronic equivalent
Device User Facilities (21 CFR Part 803.33)	Annual reports of death and serious injury filed January 1 through 31 December (Note: Annual summary report should not be submitted if there were no adverse events during the reporting period.)	No later than 1 January of each year	FDA	Annual User Facility Form 3419 or electronic equivalent
Importers (21 CFR Part 803.40)	Device-related death or serious injury	Within 30 calendar days	FDA and the manufacturer	Form FDA 3500A or electronic equivalent
Importers (21 CFR Part 803.40)	Device related malfunctions	Within 30 calendar days	Manufacturer	Form FDA 3500A or electronic equivalent

immediately by the firm for any voluntary recall, and foreign manufacturers and importers are required to contact the local recall division for their US agents. In cases where the manufacturer or importer fails to voluntarily recall a device that is defective or presents a risk of injury or gross deception, FDA may issue a mandatory recall order to the manufacturer under 21 CFR 810.[32]

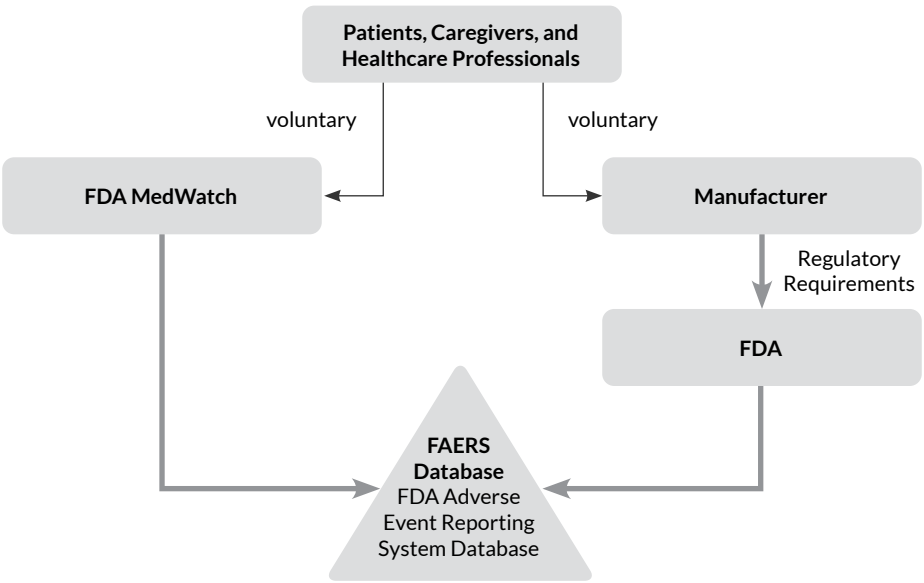
Relevant FDA regulations pertaining to device recall (corrections, removals) procedures fall under the following statutory requirements:

- 21 CFR 7: Enforcement Policy, particularly Subpart C—contains FDA guidance on recalls and product corrections and is for voluntary recalls
- 21 CFR 806: Medical Device Corrections and Recalls—contains the notification requirements for medical device corrections and recalls.
- 21 CFR 810: Mandatory Device Recall—includes the recall authority provisions

A medical device recall does not mean that a user needs to stop using the product or return it to the

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Figure 2-4. How Postmarket Reports are Sent to FDA



manufacturer. Sometimes, a device recall also is required if a medical device needs to be checked, adjusted, or fixed. Some examples of medical device recalls are provided below:

- Inspecting the device for problems
- Repairing the device
- Adjusting settings on the device
- Re-labeling the device
- Destroying the device
- Notifying patients of a problem
- Monitoring patients for health issues

Per 21 CFR 806,[33] medical device manufacturers and importers are required to a submit a report to FDA for any device correction or removals if the correction or removal was to reduce a health risk posed by the device or to rectify device violation of the act.

Under 21 CFR 806.2,[34] "Correction" means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location, and "removal" is defined as the physical removal of the device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. A report is not required if the information has already been presented to FDA under Medical Device Reporting (21 CFR 803) or Repurchase, Repairs or Replacement of Electronic Products (21 CFR 1004) or for a mandatory recall by FDA under 21 CFR 810.

Similar types of actions taken by device manufacturers or importers to improve the device's quality, safety, or performance include market withdrawals, routine servicing, and stock recoveries. Unlike recalls, corrections, and removals, these actions do not reduce risks posed by a device and do not correct violations of the act the device causes. Recall does not include market withdrawal or stock recovery.

21 CFR 7.3[35] defines the following terms:

- "Market withdrawal" is a firm's removal or correction of a distributed product that involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation, routine equipment adjustments and repairs, etc.
- "Routine Servicing" is any regularly scheduled maintenance of a device, including

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replacing parts at the end of their normal life expectancy, e.g., calibration, battery replacements, and responses to normal wear and tear. Repairs of an unexpected nature, replacing parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.
- "Stock recovery" is defined as a firm's removal or correction of a product that has not been marketed or that has not left the firm's direct control, i.e., the product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use.

Under 21 CFR 7.3, FDA classifies recalls into three numerical designations for a particular product based on the probability and severity of health consequences. Once a firm opts to correct or remove a violative product, a correction or removal action plan is submitted to FDA. FDA is responsible for reviewing the recall strategy and assessing the health hazard presented by the defective or harmful medical device and deciding whether the problem violates FDA laws and requirements.

FDA conducts a Health Hazard Evaluation (HHE) to determine the risks posed by a device and actions taken by a firm to resolve them. HHE is a critical tool for classifying a voluntary recall by a firm. An FDA physician may initiate an HHE by collecting and reviewing information such as adverse events, complaints, and problems related to the defective or harmful device. A few factors taken into consideration that are suitable for HHE include but are not limited to the following:[36]

- Diseases or injuries occurred from the use of the product
- Assessment of exposure of a hazard to various groups, such as pediatric, surgical patients, pets, livestock, etc.
- Assessment of the hazard's likelihood of occurrence
- Assessment of the hazard's consequences (immediate or long term) of occurrence

Based on the HHE determination, recalls are classified into three categories, as listed in **Table 2-4.**

Recall Procedure

Any medical device not meeting the defined quality standards must be recalled from the market. Recalls can be classified into two types: 1) voluntary recall and 2) mandatory recall (initiated by FDA). As soon as the product to be recalled is identified, the following steps are taken after the recall is initiated:

Step 1—Recall Strategy: Once FDA determines that the product is violative, a correction or removal will be considered as a recall per 21 CFR 7.46.[37] Recall applications should be submitted to FDA with the following information:

Table 2-4. Types of FDA Recalls[35]

Type of Recall	Criteria	Examples
Class I	A scenario where there is a possibility of occurrence of serious health adverse consequences or death in case of exposure to or use of a violative product	A scenario in which a catheter may rupture or kink during use, leaving remnants behind in the patient that will cause serious injuries or death
Class II	A scenario where there is a possibility of occurrence of temporary or medically reversible health consequences or where the probability of serious adverse health consequences is remote in case of exposure to or use of a violative product	A package defect in which sterility has been compromised and could lead to contamination of the medical device, resulting in patient complications
Class III	A scenario where the exposure to or use of a violative product is not likely to cause adverse health consequences	A mislabeled package where the expiration date does not appear on the product label or instructions for use (IFU)

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- Product details
- Contact details (name and telephone number) of the company official
- Rationale for the removal or correction
- The date and scenario under which the product deficiency or possible product deficiency was identified
- Risk evaluation associated with the deficiency or possible deficiency
- Total number of affected devices produced/ in distribution
- Details of the distributed product
- A copy of the issued or proposed recall communication
    - Proposed recall strategy
      A recall strategy is developed per 21 CFR 7.42[38] once a firm decides to recall a device. There are many factors to consider when developing a recall strategy. Some of these factors are HHE results, ease of identifying a product, degree to which a consumer can identify the deficiency, degree to which a product remains unused in the market, and the continuous availability of essential products. The objective of a recall strategy is to include the following information with respect to the conduct of the recall:[38]
- Recall depth: The recall strategy should clearly identify the level of distribution, such as user level, retail level, or wholesale level.
- Public warning: A public warning such as a general public warning (general news media, either national or local) or through specialized modes (professional or trade press) should be initiated for urgent recalls to alert the public that the product poses a serious health hazard.
- Effectiveness check: It is required to confirm that all consignees were made aware of the recall. Various methods are used for effectiveness checks, such as phone calls, personal visits, letters, etc. The level of effectiveness checks to be conducted are as follows:
    - Level A: 100% consignees to be contacted
    - Level B: Some percentage of consignees to be contacted (the determination is made on a case-by-case basis; generally, it falls under the range of more than 10% but less than 100% of the total number of consignees)
    - Level C: 10% of the total consignees to be contacted
    - Level D: 2% of the total consignees to be contacted
    - Level E: No effectiveness check

Step 2—Recall monitoring and status updates: A follow-up should be conducted with the consignee as necessary. Consignees that receive a recall notification should immediately follow the instructions specified by the recall firm and, if necessary, extend the recall to its consignee.

The recall firm is required to submit a periodic status update report to an FDA district office to provide a progress report to FDA. The reporting frequency is generally between two and four weeks unless otherwise specified (21 CFR 7.53).

Step 3—Recall Termination: A recalling firm can submit a written request to FDA's district office, also known as CDRH's Office of Regional Division (ORD), to terminate a recall if they believe that all recall activity has been completed and the recall is effective. Such requests should include the most current recall status report and details of the disposition of the recalled product. Also, FDA can terminate a recall by sending a written notification to the recalling firm once FDA determines that appropriate actions have been taken by the recall firm to correct or remove the violative product in accordance with the recall strategy, and disposition and corrections have been commensurate with the product hazard (21 CFR 7.55).[39]

After a recall is completed, FDA ensures that the violative product is destroyed or reconditioned. FDA also investigates why the product was defective in the first place. FDA evaluates the effectiveness of a recall by reviewing the actions taken by the firm to ensure the harmful product has been removed from the market. If FDA determines that the recall is ineffective, FDA will request that the firm take additional actions.

FDA also is responsible for publishing all enforcement actions, including recalls,

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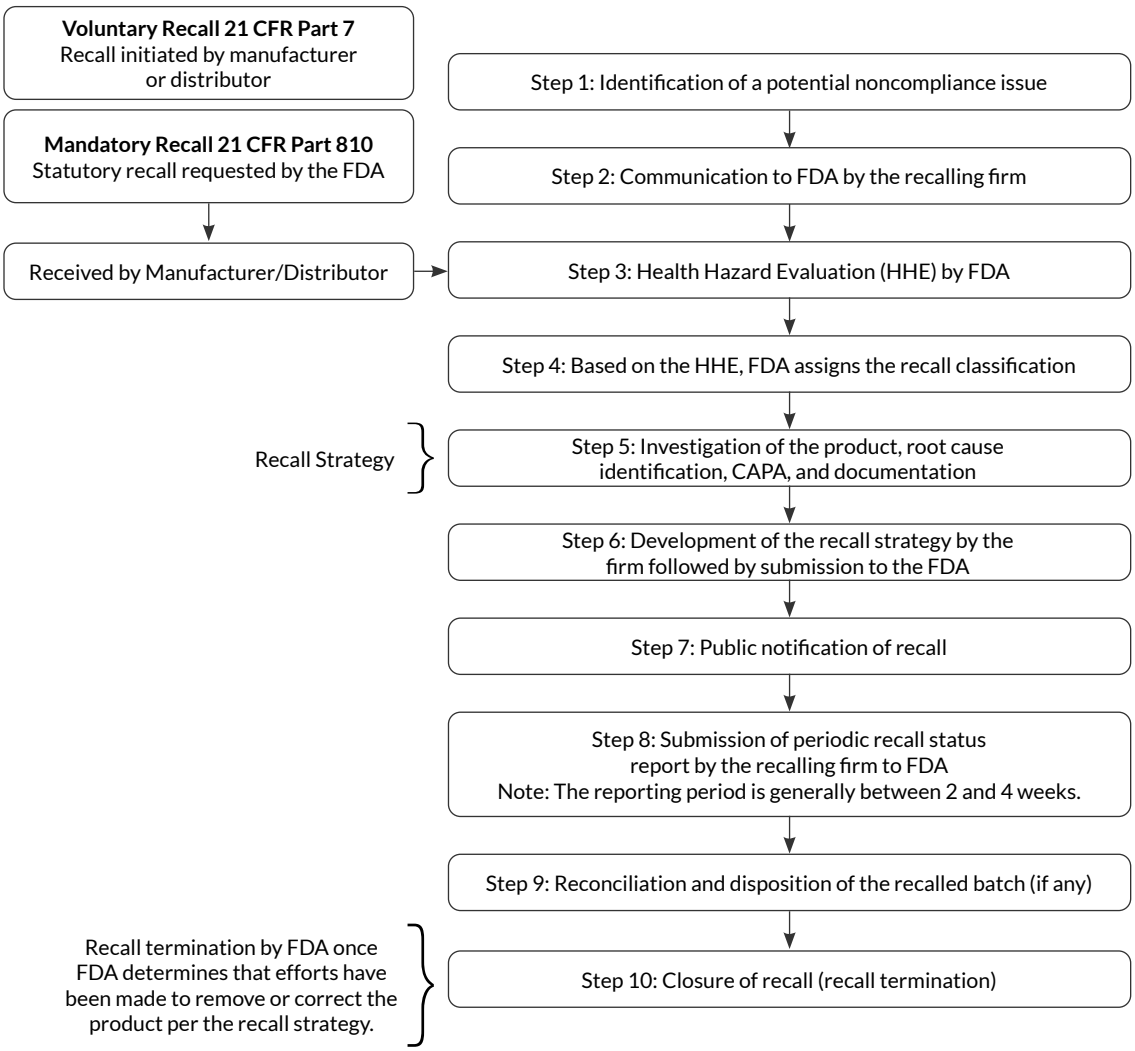
field corrections, and recall termination in the FDA Enforcement Report. Weekly FDA Enforcement Reports can be found at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities. See **Figure 2-5** for an overview of the recall process.

Medical Device Tracking 21 CFR 821[40]

On 27 March 2014, FDA finalized guidance on medical device tracking.[41] This document describes the procedures surrounding medical device tracking requirements and provides FDA with the authority to order Class II or Class III device manufacturers to establish a device tracking system if a device meets any of the following listed criteria:

- The device failure may result in a serious adverse health consequence.
- The device is intended to be an implantable device for more than one year, such as a pacemaker, heart valve, breast prosthesis, etc.
- Life-sustaining or life-supporting device used outside a user facility, such as breathing facilitator monitors, continuous

Figure 2-5. Overview of Recall Process



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ventilators, ventricular bypass devices, and DC-defibrillators and paddles, etc.

The objective of this guidance document was three-fold:

- To ensure that the device is traceable in commercial distribution, i.e., from the manufacturing site through the distribution channel (distributors, user facilities, licensed practitioners, etc.) to the person for whom the device is intended (the patient)
- To ensure manufacturers can expeditiously remove a defective or potentially defective device from the market
- Effective device tracking is required to facilitate patient notification or device recall if necessary

Tracking records should be retained for the useful life of the device, which is defined as "the time of the device is in use or in distribution for use under 21 CFR 821.60."[42]
The primary responsibility for device tracking lies with the device manufacturer; however, any other person, including the device importer or distributor, also are responsible for ensuring a functional device tracking system. Details of manufacturer requirements and additional requirements are listed below:

Manufacturer Requirements

Under 21 CFR 821.25,[43] a manufacturer is required to establish a written standard operating procedure (SOP) for tracking requirements for medical devices, including implantable devices. The SOP outlines the process for the collection, maintenance, and auditing of tracking data for medical devices meeting the tracking criteria listed above. A method of tracking must provide critical information about the tracked device's location within a short period of time. The required critical information should include the following:[43]

- Device identification (UDI, lot number, model number, batch number etc.)
- Device shipping date
- The date the device was provided to the patient
- Patient details (name, address, phone number, social security number)
- Prescribing physician details (name, address, and phone number)
- If applicable, the date the device was explanted from the patient and returned to the manufacturer

The timeline to submit the critical information to FDA is listed below:[43]

- Manufacturers will have three working days to provide the required critical information to FDA for devices that have not been distributed to the patient yet.
- Manufacturers will have ten working days to provide the required critical information to FDA for devices that have been distributed to patients or implanted in a patient

To ensure the tracking system is effective, a manufacturer shall conduct audits at six-month intervals for the first three years after receiving tracking orders and for at least annually thereafter. Tracking systems are also subject to FDA inspection to confirm that the method is effective in tracking the device to the end user.

Additional Tracking Requirements

In addition to the manufacturer, distributors, including final distributors or multiple distributors, of any tracked device should be able to ensure that the primary manufacturer can locate a device if needed and provide the primary manufacturer with the following information for tracking a device in order to stay compliant with the medical device tracking requirements under 21 CFR 821.30.[44]

- Details of the distributor, final distributor, or multiple distributors
- Device identification (UDI, lot number, model number, batch number, etc.)
- Device shipping date
- The date the device was provided to the patient

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- Patient details (name, address, phone number, social security number)
- Prescribing physician details (name, address, and phone number)
- If applicable, the date the device was explanted from the patient and returned to the manufacturer

A kit or system assembler is considered a distributor by FDA and, therefore, needs to comply with the distributor's tracking requirement. They are also responsible for ensuring that, when appropriate, anyone who receives the kit or system knows that it includes a tracked device. The manufacturer's original labeling shall remain on every tracked device included in the kit or system. Additionally, initial importer distributors also are responsible for ensuring the device is traceable throughout distribution in the US. A foreign manufacturer may act as its own initial distributor; therefore, foreign manufacturers also are responsible for medical device tracking. Failure to comply with the medical device tracking requirements may result in the imported device being detained at the US port of entry.

User facilities such as nursing homes and hospitals act as a final distributor when the device is for single use and otherwise have responsibilities as a multiple distributor when the device is reusable (multiple use). For example, a hospital that implants single use tracked devices is the final distributor for that device. A hospital outpatient clinic that rents, leases, or loans a multiple use tracked device is the multiple distributor for that device.

Patients may refuse to provide their personal information required for device tracking purposes. The refusal should be documented by the product, model, and serial number, and the information provided to the manufacturer. This required information should be retained by the manufacturer for the useful life of the device. A patient's refusal to provide personal information does not discharge the manufacturer of its duties to account for the tracked device.

Any failure to comply with the tracking regulations, either by the manufacturer or distributor (including initial importer, final distributor, or multiple distributor, is considered a violation of the FD&C Act, and the device will be labeled as misbranded.

Device tracking is no longer required by FDA once the manufacturer, importer, or distributor (including final distributor or multiple distributors) can confirm:

- The device has been returned, destroyed, or explanted
- The patient has died

For Class III PMA devices that are subject to tracking orders, the need for continued tracking may be reassessed either at the sponsor's request or FDA's initiative, 10 years from the date of the original PMA approval.

Additional information on the medical device tracking system, including the current list of devices to be tracked, can be found on FDA's website under 21 CFR 821.

Unique Device Identification

The unique device identification (UDI) system was established by FDA to adequately trace a medical device through its distribution and use. FDA UDI requirements are listed under both 21 CFR 801[45] and 21 CFR 830.[46]

A UDI is a unique numeric or alphanumeric code that consists of the following:

- **Device identifier (DI):** The DI is a mandatory and fixed portion of the device, critical for the identification of device (specific device model or version) and its manufacturer/labeler
- **Production identifier (PI):** The PI is a conditional and variable portion of the UDI, critical for providing traceability of a device to the patient level. The following information, if included on the device label, must also be included in the PI part of the UDI:
  - Device serial number
  - Device lot or batch number within which it was manufactured
  - Device expiration date
  - Device manufacturing date
  - For an HCT/P, a distinct identification code is required by 21 CFR 1271.290(c)

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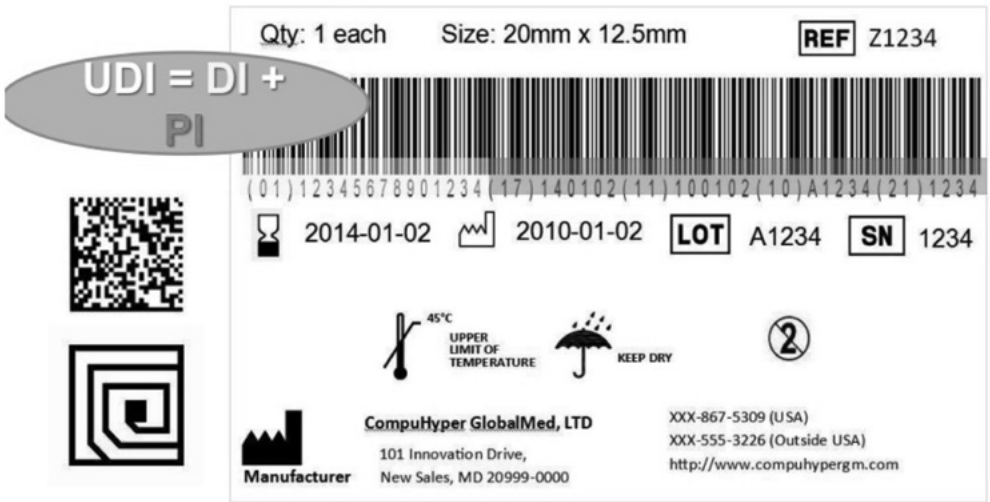
An example of a UDI is presented in **Figure 2-6.**

The UDI rule[47] was passed by FDA on 24 September 2013 and became effective on 23 December 2013. Its provisions offer methods for the identification of medical devices sold in the US, from manufacturing and distribution to patient use; therefore, UDI enhances the effectiveness of postmarket safety-related activities for devices. The lack of UDI hinders the identification of devices throughout their distribution and use, the reporting and analysis of AE data, and the timely removal of recalled devices from use. Regulations under 21 CFR 830.20[48] require UDIs to meet the following requirements:[48]

- UDI must be issued by FDA or FDA-accredited agencies such as the Global Language of Business GS1, Health Industry Business Communications Council (HIBCC), and International Council for Commonality in Blood Banking Automation (ICCBBA)
- It should conform to the following listed international standards:
  - ISO/IEC 15459-2 : Information Technology—Unique Identifiers—Part 2: Registration Procedures
  - ISO/IEC 15459-4 : Information Technology—Unique Identifiers—Part 4: Individual Items
  - ISO/IEC 15459-6 : Information Technology—Unique Identifiers—Part 6: Unique Identifier for Product Groupings
- The UDI should only use numbers and characters from the invariant character set of ISO/IEC 646: Information Technology—ISO bit-coded character set for information technology

In addition, this rule requires the label and package of medical devices to include a UDI meeting the requirements in 21 CFR 801.20 and 830. This rule provides general exceptions or alternative placements. The "device labeler" is responsible for complying with the UDI label requirement, data submission, and record provisions. The UDI should be provided as a plain-text (human readable form) and in a machine-readable form that uses automatic identification and data capture (AIDC) technology[48] (See **Figure 2-7**).

Figure 2-6. UDI Example



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Figure 2-7. Unique Device Identification System: Three Distinct Concepts

1. Development of a standardized Unique Device Identification (UDI) system

2. Placing UDI in human readable form and machine-readable form using AIDC technology

3. GUDID-FDA database for registering UDI data

Labeling Requirements for Unique Device Identification

The following requirements briefly outline the UDI compliance process:

- Under 21 CFR 801.[45,49] if a device is a reusable device and intended to be reprocessed before each use, the UDI should be permanently marked on the device itself. This rule is not applicable if a reusable device intended to be reprocessed before each use meets any of the following listed criteria:
  - Any type of direct marking on the device that would interfere with the device's safety or effectiveness
  - It is not technologically feasible to put a direct mark on the device
  - The device is approved or cleared for single use only
  - The device is already directly marked with the UDI on the device
- Stand-alone software devices are required to follow the same general UDI labeling requirement as any other medical devices. There is no special requirement for stand-alone software per 21 CFR 801.[50]
- If a device label includes a printed expiration date, date of manufacture, or any other required date, the dates should be in standard format YYYY-DD-MM, consistent with international standards and practice Combination products and electronic radiation-emitting are exempted from this regulation (21 CFR 801.18).[50]

Global Unique Device Identification Database

On 27 June 2014, FDA issued the Global Unique Device Identification Database (GUDID) guidance,[51] which outlines the information a device labeler is required to submit to the FDA GUDID database. The GUDID database is an online repository of device identification (DI) information, available for public search, retrieval, and use. Production Information (PI) is not submitted to the GUDID, although the DI record can indicate which PI attributes are on the device label, unless excepted. The GUDID must include all the data elements required by 21 CFR 830.310.[52]

Additionally, this guidance was instrumental in defining how to compile and submit device information within a database. UDI data can be submitted to the database using the following two options:

1. Manual entry into the database using GUDID web application
2. Health Level Seven (HL7) Structured Product Labeling (SPL) submission via the FDA ESG pathway

The steps for submitting UDI data to the GUDID database are summarized in **Figure 2-8**.

FDA may deny or eliminate the submitted DI information in any of the following scenarios, as per 21 CFR 830.300:

- If it does not conform to requirements in 21 CFR 830.20
- If the device has not been manufactured in the US

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- IF FDA determines that it is a banned device under Section 516 of the Federal Food, Drug and Cosmetic (FD&C) Act
- If FDA determines the device is not approved/cleared for sale by FDA
- If FDA confirms it is not a device or a combination product that includes a device constituent part
- If FDA has suspended the accreditation of the issuing agency

Per 21 CFR 830.[50,53] if FDA becomes aware of an event in which information submitted to the GUDID portal is incorrect or misleading, FDA may notify the device labeler to delete or amend the information as needed. Corrected information or a rationale explaining why the information is correct must be submitted by the device labeler within 30 days of FDA's receipt of notice.

The UDI implementation may come with its share of challenges due to customers, financial implications, changing regulations, and supply chain considerations. However, FDA has successfully implemented the UDI system to both safeguard and support the use of medical devices in patients by fulfilling the following objectives:[54]

- Reduction of medical errors
- Medical devices' traceability, especially for field safety corrective actions
- Accurate identification of medical devices through distribution and use
- Easy and rapid identification of adverse events related to medical devices
- Documenting and capturing longitudinal data on medical devices

The UDI system has been successfully implemented by enabling easy access to device information through distribution and use on patients. This system benefits patient by enhancing the ability to deliver safe and high-quality care through the use of devices.

Conclusion

When developing a medical device, 21 CFR 820 (QSR) requires a manufacturer to develop processes that ensure the safety and effectiveness of a medical device and that the device functions as intended without causing unacceptable risks of hazards or harm. The risk management process during medical device development helps manufacturer identify possible product safety issues. Therefore, manufacturers are required to collect and monitor user experiences with devices that have been placed on the market to generate data on use of the device, to identify any device design and/or usage issues and characterize real-world behavior and clinical outcomes. This, in turn, ensures devices continue to remain safe and effective and perform according to their intended use. In summary, postmarket compliance activities are an integral part of the medical device lifecycle process demonstrating the long-term safety and performance of a marketed medical device. Key topics addressed in this chapter include the following:[55]

- Establishment registration and device listing for both domestic and foreign manufacturers involved in manufacturing, distribution or importing medical devices
- Postmarket surveillance studies
- FDA's enforcement actions such as notice of violations (NOV) or untitled letters, warning letters, seizure of product, injunction, prosecution, and/or civil money penalties
- Medical device reporting of adverse events
- Classification and responsibilities of manufacturers and importers with regard to recalls, corrections, and removals
- Medical device tracking and UDI implementation

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3 Postmarket Product Changes: Canada

By Karen Fan, MSc, RAC, PEng, PMP

Introduction

Medical device manufacturers often make changes to their marketed products during the product lifecycle to adapt to changing regulatory requirements, evolving user needs, potential safety concerns, and raw materials availability. All medical devices that have been authorized by Health Canada meet the safety and effectiveness requirements of the Canadian Medical Devices Regulations (CMDR).[1]

There is a wide range of postmarket product changes, varying from very simple administrative changes (e.g., updates to the device identifier or device name) to complex changes in the design or manufacture of the device.

This first section of the chapter discusses medical device licensing in Canada. The second section explains the medical device license amendment framework under the CMDR. The third section reviews the types of postmarket product changes within the CMDR framework, and the last section illustrates the amendment application review process.

Medical Device Licensing

Medical Device Licenses

Medical device licenses (MDL) are required for Class II–IV devices sold or imported in Canada and are issued to manufacturers. These manufacturers also can be considered original manufacturers. Device licensing requires manufacturers to comply with the CMDR requirements for safety and effectiveness in Sections 10–20 and labeling in Sections 21–23. A third-party registrar, which is an entity approved by Health Canada, issues and renews the manufacturer's quality management system certificate and is responsible for assessing a manufacturer's initial and ongoing compliance to the CMDR.

Health Canada maintains a database of all licensed Class II–IV medical devices offered for sale in Canada in the medical devices active license listing (MDALL).[2] MDALL is a tool for users to search for medical devices licensed for sale in Canada. Devices can be searched by company name, license name, device name, company ID, license number, or device identifier.

Health Canada sends all existing MDL holders an annual license renewal (ALR) package by 1 September of each calendar year.[3] The

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