



**U.S. FOOD & DRUG
ADMINISTRATION**

Medical Device Enforcement and Quality Report

November 2018

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1. The FDA has increased its oversight through additional device inspections

Medical device manufacturing has become an increasingly global enterprise, with over 21,000 registered manufacturers located in 106 countries. Each year, the U.S. Food and Drug Administration (FDA) conducts inspections of thousands of medical device manufacturing establishments to assess compliance with regulatory requirements, including the Quality System regulation.

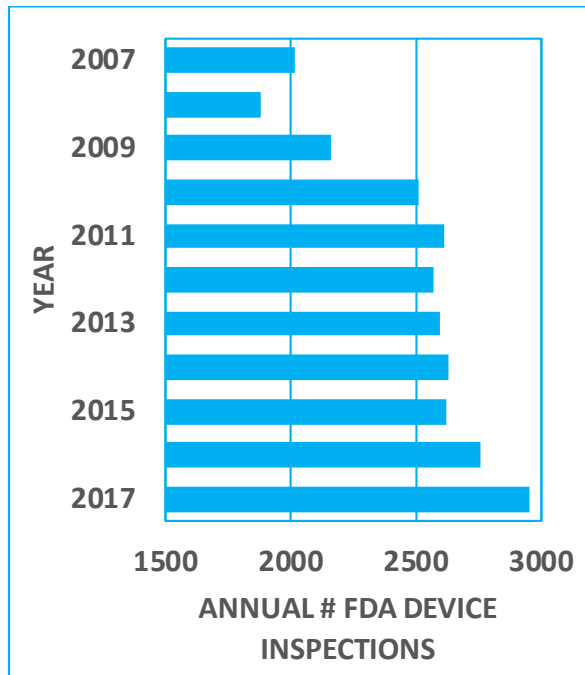
In the past decade, the FDA has increased its oversight by increasing the annual number of device manufacturing establishment inspections. In 2017, the FDA conducted 2952 inspections of medical device firms, representing a 46% increase compared to a decade earlier (FIGURE). In addition, the FDA has increased the number of foreign inspections during the same time-period by 243%.

46% INCREASE

IN THE ANNUAL NUMBER OF DEVICE INSPECTIONS SINCE 2007.

243% INCREASE

IN THE ANNUAL NUMBER OF FOREIGN DEVICE INSPECTIONS SINCE 2007.



The FDA, in collaboration with international regulatory partners, also helped establish the [Medical Device Single Audit Program \(MDSAP\)](#). The program involves the conduct of a single regulatory audit of a medical device manufacturer’s quality management system to satisfy the requirements of multiple regulatory jurisdictions. After a successful [3-year pilot](#), the FDA accepts MDSAP audit reports. In addition to the device inspections conducted by the FDA, we received and classified nearly 600 MDSAP audits from 2013 to 2017, increasing our oversight of manufacturing facilities.

2. The FDA has taken a targeted, risk-based enforcement approach to address specific device areas of concern

When appropriate, the FDA employs a targeted, risk-based approach to address specific device areas of concern. The FDA monitors medical device malfunctions, industry compliance trends, and public health concerns. When the FDA identifies device quality or manufacturer compliance concerns, we inspect firms, take enforcement actions as needed, collaborate with stakeholders to address contributing scientific and policy challenges, and publicly communicate to ensure transparency and reduce the chance of similar, recurrent issues.

CASE STUDY: INFUSION PUMPS

An infusion pump is a medical device that delivers fluids into a patient’s body in controlled amounts. They can deliver nutrients or medications, such as insulin, antibiotics, chemotherapy drugs, and pain relievers. From 2005 through 2009, the FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps, including numerous injuries and death. As a result, the FDA launched an **Infusion Pump Improvement Initiative** in 2010.



INFUSION PUMP RELATED INSPECTIONS AND ENFORCEMENT BY FDA FROM 2010 TO 2017

496 INSPECTIONS

165 MANUFACTURING FACILITIES

40 WARNING LETTERS

The FDA issued **40 warning letters** to infusion pump manufacturers, citing the firms for failing to comply with quality systems and reporting regulations, a **Letter to Infusion Pump Manufacturers** describing reported problems and design deficiencies, and a **Final Guidance for Industry and the FDA Staff: Infusion Pump Total Product Life Cycle**.

The FDA enforcement activity led to an initial 3-fold increase in voluntary recalls from affected firms, as the FDA worked with companies to address identified device design and manufacturing deficiencies. As a result of the FDA’s actions, there has been a 56% reduction in annual recalls related to these devices since 2014, and an 82% reduction in annual medical device reports since 2015.

CASE STUDY: AUTOMATED EXTERNAL DEFIBRILLATORS (AEDs)



AEDs are medical devices that diagnose life-threatening abnormal heart rhythms and deliver electrical energy to the heart to restore a normal rhythm. They are used in emergency situations on patients who have collapsed due to sudden cardiac arrest and are demonstrated to improve survival when used in the first few minutes following collapse.

The FDA issued **6 warning letters** to AED manufacturers, citing the firms for failing to comply with quality systems and reporting regulations, held a **meeting of the Circulatory Systems Medical Devices Advisory Committee**, issued an **order calling for Premarket Approval Applications**, eliminated the use of 510(k)-cleared AEDs as legal predicates, and approved 6 AEDs for marketing under the new, more rigorous premarket approval standards.

AED RELATED INSPECTIONS AND ENFORCEMENT BY FDA FROM 2010 TO 2017

115 INSPECTIONS

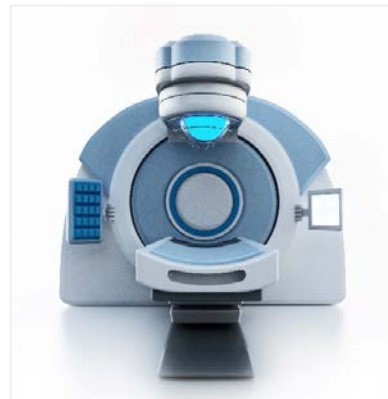
39 MANUFACTURING FACILITIES

6 WARNING LETTERS

The FDA's enforcement activity led to an initial 3-fold increase in voluntary recalls from affected firms as we worked with companies to address identified device design and manufacturing deficiencies. As a result of the FDA's actions, there has been a 70% reduction in annual recalls and a 27% reduction in the number of medical device reports related to these devices since 2010.

CASE STUDY: RADIATION THERAPY DEVICES

Radiation therapy is delivered by devices that aim radiation to treat cancer at a specific location in the body. In 2010, the FDA launched an **Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging**. The FDA also identified accidental radiation therapy overexposures due to device software failures as a recurring issue.



RADIATION THERAPY DEVICE RELATED
INSPECTIONS AND ENFORCEMENT BY THE
FDA FROM 2010 TO 2017

188 INSPECTIONS

78 MANUFACTURING
FACILITIES

6 WARNING LETTERS

To improve the safety of radiation therapy devices, the FDA conducted industry-wide inspections, issued **6 warning letters**, citing the firms for failing to comply with quality systems and reporting regulations, and hosted an **FDA Public Meeting**. The FDA's enforcement activity led to an initial 4-fold increase in voluntary recalls from affected firms, as we worked with companies to address identified device design and manufacturing deficiencies. As a result of the FDA's actions, there has been an 80% reduction in annual recalls related to these devices since 2011.

3. The FDA's focus on violative products and adverse event reporting during inspections has led to an increase in voluntary recalls and adverse event reporting

Medical device recalls are usually conducted voluntarily by the manufacturer. Under 21 CFR Part 806, Medical Devices Reports of Corrections, manufacturers are required to make a report to the FDA of any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device to remedy a violation of the Act caused by the device which may present a risk to health. For example, a recall can include a labeling change, a design change, or training.



The FDA's focus on identifying 21 CFR Part 806 reporting deficiencies during inspections has resulted in an increased number of reported voluntary recalls. Firms with Part 806 reporting inspectional observations reported 20% more voluntary recalls in the year following inspection compared to the year prior to inspection. In addition, they were 8 times more likely to report a recall following inspection than the industry average. Overall, the FDA's focus on industry correction and removal compliance has contributed to a 50% increase in the annual number of voluntary recalls reported since 2009.

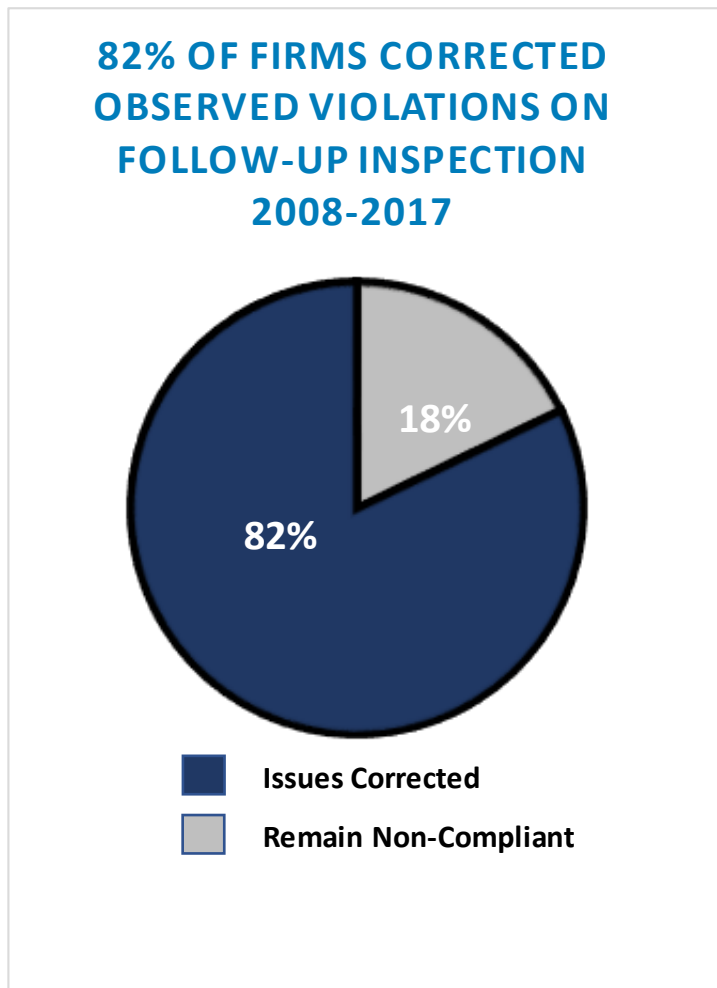
Firms are 8 TIMES MORE LIKELY TO REPORT A RECALL and REPORT 3 TIMES MORE ADVERSE EVENTS following inspection citations

Similarly, during inspections, the FDA's investigators examine whether firms have appropriately reported or documented adverse events as required by 21 CFR Part 803. The FDA's focus on identifying manufacturer adverse event reporting deficiencies has contributed to an increase in Medical Device Reports received by the FDA. Over the past decade, the FDA has identified adverse event reporting inspectional observations at more than 2000 medical device establishments. In 2017, firms cited for adverse event reporting violations reported more than three times the number of medical device reports compared to the year prior to the inspection. Overall, the FDA's focus on industry medical device reporting compliance has contributed to the doubling in the annual number of adverse events reported to the FDA since 2009.

4. Most firms have corrected violations on follow-up inspection

The FDA has increased the annual number of device inspections it conducts, and through implementation of a risk-based inspection approach that focuses on “high-risk” firms and/or products, the annual number of Official Action Indicated inspections has increased 59%. In total, the effort to increase the number of inspections and to focus on firms and products most likely to be violative, has increased the number of firms identified as needing corrective actions.

The FDA took a more aggressive approach to the issuance of Warning Letters for violative manufacturers beginning in 2008 and reaching a peak in 2012, when 189 Warning Letters were issued, representing a more than 7-fold increase in the annual number of Warning Letters in 2012 compared to 2007. More recently, the FDA has been more interactive with violative firms, recognizing that, where appropriate, it can be an effective approach to achieving more timely and effective corrective action. In particular, the FDA’s staff review firm responses to the Form 483 (which notifies the company of objectionable conditions), provide feedback on firm’s proposed corrective action plans, and monitor progress towards remediation. Issuance of Warning Letters has focused on firms who have severe violations or who fail to implement or follow-through on their corrective action plan in a timely fashion.



This more interactive approach has resulted in a decrease in the annual number of Warning Letters, with an increase in Untitled Letters, regulatory and other meetings, while maintaining a high rate of firms that demonstrate correction of their violations on follow-up inspection. Between 2008 and 2017, 82% of firms were found to have corrected observed violations on follow-up inspection.

5. The FDA has taken steps to promote device quality not just compliance with regulations

The FDA launched the [Case for Quality](#) in 2011 to elevate the focus of the medical device industry from baseline regulatory compliance to sustained practices that advance medical device quality and safety to achieve better patient outcomes. This initiative stemmed from our recognition that our traditional compliance and enforcement actions, while important, were not sufficient to drive improved device quality. A focus on quality enables better alignment of patient safety and business objectives, leading to improved product quality, better safety outcomes and reduced costs. The initial focus for the initiative was centered around increasing stakeholder engagement and collaboration, focusing on quality not just compliance, and developing transparency on medical device performance data.



In 2014, the FDA enlisted the [Medical Device Innovation Consortium \(MDIC\)](#) to develop an open and public [collaborative forum](#) involving regulators, industry, providers, payers and patients to discuss the limits of focusing on compliance and how quality is experienced by patients and users, and to develop strategies to enable an increased focus on quality.



In 2018, the FDA's Center for Devices and Radiological Health launched a [voluntary quality maturity appraisal pilot](#). Maturity appraisal is an approach that has been successfully applied in other economic sectors. Third-party teams certified by the Capability Maturity Model Integration Institute conduct quality system maturity appraisals to drive continuous improvement and organizational excellence among participating medical device manufacturing sites. To date, 18 participating firms involving 36 manufacturing facilities have undergone 32 appraisals. Among the participants, 94% reported that the appraisal was beneficial to the firm and 86% reported the appraisal had a positive impact on product quality. In 2019, we will explore whether or not to develop a formal appraisal program to complement our traditional oversight activities.

86% of maturity appraisal pilot participants report a positive impact on product quality
