Uncovering and Maximizing the Value of FDA Inspections

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Disclaimer

Credit: Giphy, Inc.

FDA Inspections Can Be Intimidating

- May be your first inspection
- Reason for inspection may be "for cause"
- No matter how good your QMS is, things can always go wrong
- You know you have room for improvement, but you can't fix everything at once

- Management may see compliance as your job, not theirs

FDA Inspections Provide Benefits

- Patient Safety
- Design Robustness
- Quality System Robustness
- Reduce Failure Cost
- Using Inspections to Avoid Quality Events
- Benefits to Smaller Firms
- Inspection Data as a Benchmarking Tool

Patient Safety and Inspections

- FDA inspections focus on patient safety
- The public counts on FDA to protect them
  - An FDA inspection with no or minor 483 observations is viewed positively by stakeholders
- Are you comfortable using your firm's device?
- You may have an excellent QMS and be confident in your product quality/safety
  - But what about your competitors?
  - Other device types?

Compliance Officer Perspective

Sean Moynihan, MPH
Compliance Officer
OMDRHO Division 1
Baltimore District Office
Baltimore, MD

Patient Impact: Routine Visits

- Approximately 84% of adults and 93% of children have contact with a healthcare professional each year[1]
- Even a routine office visit depends on the safety and efficacy of several medical devices
  - Pulse oximeter, blood pressure cuff, stethoscope, ophthalmoscope, otoscope, needle/tubing, evacuated collection tubes

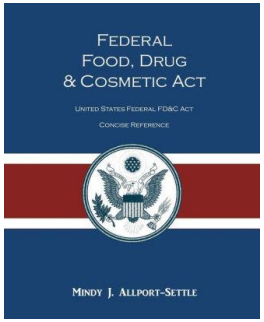
Patient Impact: Implant Prevalence

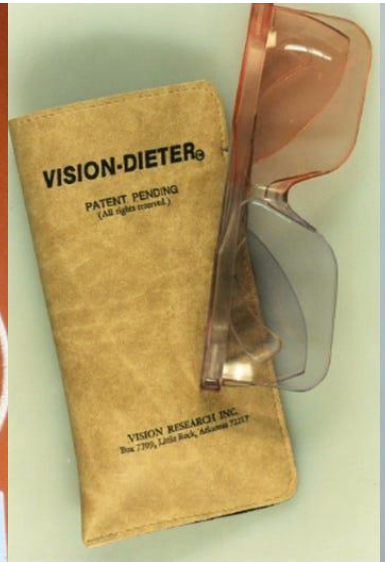
- Each year, Americans receive:
  - **370,000** cardiac pacemakers[2]
  - **1.0 million** total hip and knee replacements[2]
  - More than **600,000** coronary stents[3]

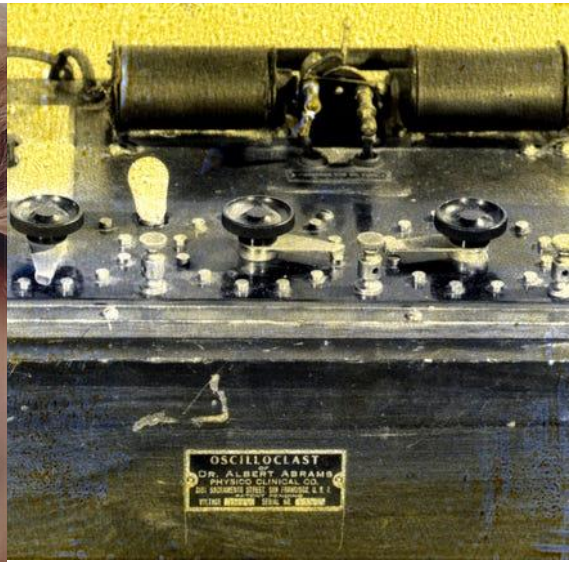
- **7.2 million** Americans have had total hip arthroplasty (THA) or total knee arthroplasty (TKA) and are living with implants[4]

FDA Inspections: Historical Perspective

- FDA became a public health Agency out of necessity
- 1938 Food, Drug, and Cosmetic Act (FDCA)
  - Formally authorized factory inspections







COVID-19 Operational Activities

- FDA has identified many nefarious actors seeking to exploit consumers during the COVID-19 pandemic by selling unproven medical products, often with fraudulent claims
- Sampling Activities
  - Face Filtering Respirator (FFR)
  - COVID-19 Test Kits
- Investigating Consumer Complaints
  - Questionable COVID-19 Test Kits

MQSA Specialist Perspective

LCDR Matthew Morrison, MHS, MT (ASCP), MHT (ASHI)
Radiation Health / MQSA Specialist
OMDRHO Division 2
Kansas District Office
Lexana, KS

FDA Device Inspectional Landscape

- FY2019
  - 1,225 Domestic Inspections Completed
  - 458 Foreign Inspections Completed
  - Additionally:
    - Mammography Inspections
    - Radiological Health Inspections

Foreign Cadre Perspective

"International inspections encourage consistent product quality and highlight areas that need more attention, preventing non-conforming product from reaching the American public."

Brittani Franklin
Consumer Safety Officer, Foreign Cadre
OMDRHO Immediate Office
Chicago, IL

Benefit to Design Robustness

- FDA investigators see what works and what doesn't work across many firms making the same or similar commodities
  - Questions asked by investigators during inspections can give you insights into best practices
  - Can aid firms in developing more effective feedback mechanisms from the field into the product and process design stage
- Inspection data can be used to inform your ongoing risk management process

Benefit to Quality System Robustness

Before an inspection:

- Preparing for successful inspections should not be a one-time event
- Being perpetually ready for inspections is good for business and device quality
- Publicly available data from industry peers can be used to make improvements

Benefit to Quality System Robustness

After an inspection:

- Observations can inspire management to invest
  - Can also be used to strengthen your internal audit program
- Firms can act on discussion items communicated to management at close-out meeting
- FMD-145 - Release of the EIR
- It isn't just about what FDA finds during an inspection
  - "Near misses" are invaluable to your continuous improvement efforts

Benefits to Reducing Failure Cost

- Notion of FDA finding an issue during an inspection can inspire firms to take more robust preventive or corrective actions
- Developing a robust recall strategy, knowing that FDA will likely look at it closely during inspection, aids in development of more robust investigation and corrective actions
  - This in turn can reduce chances of recurrence

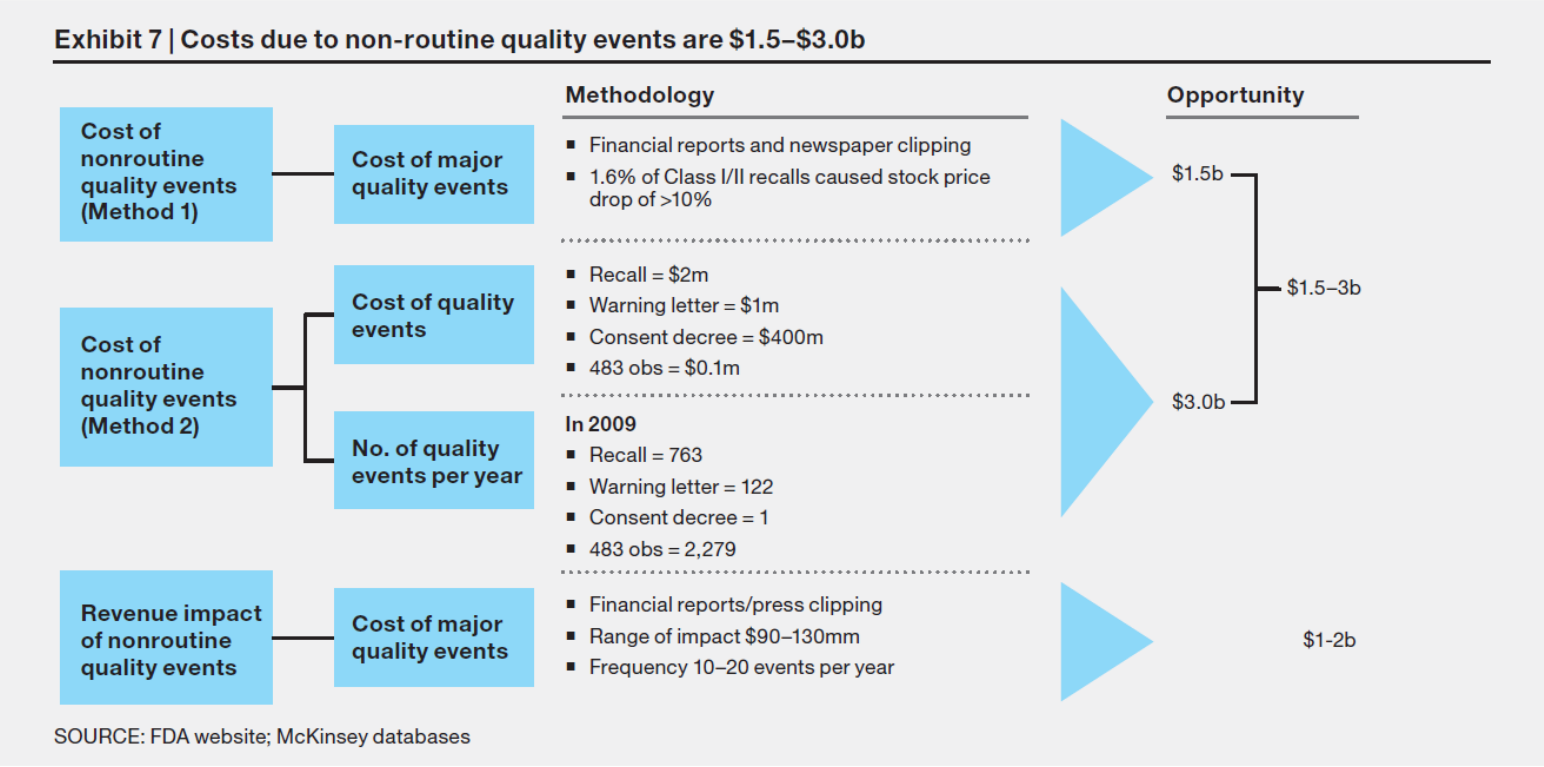
Recall Coordinator Perspective

"Consider letting us use our expertise to review your next recall notice before it's distributed so we can ensure clarity to customers and potentially save you time and resources needed to reissue."

Theresa Kirkham, MBT
Recall Coordinator
OMDRHO Division 3
Los Angeles District Office
Irvine, CA

*"Non-routine quality events—such as **major observations, recalls, warning letters, and consent decrees, along with associated warranties and lawsuits**—cost the industry between $2.5 billion and $5 billion per year on average. This includes $1.5 billion to $3 billion per year on non-routine costs, plus $1 billion to $2 billion in lost sales of new and existing products…**We estimate that adopting best practices would cut these costs in half.**"*

--From "The Business Case for Medical Device Quality," McKinsey Center for Government, October 2013



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Using Inspections to Avoid Quality Events

Best practices to improve quality include:

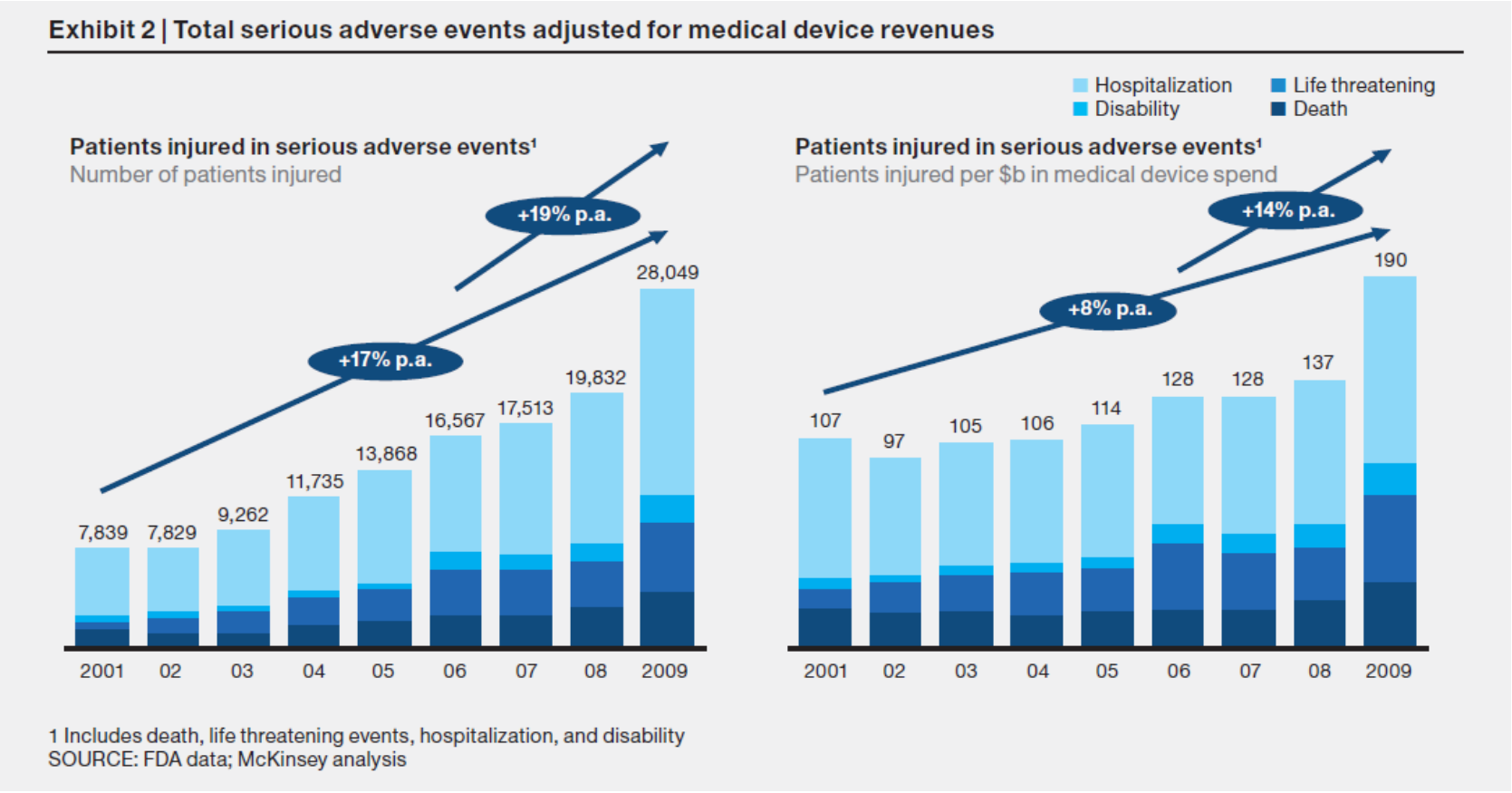
- Looking at issues found at other firms during FDA inspections
- Listening closely to FDA questions during inspections to determine what is driving questions
- Taking copious notes during inspections and investigating "near misses"
- Look critically at competitor recalls and MDRs prior to an inspection of your firm to assess robustness of your reporting decisions

Benefits to Smaller Firms

- > 80% of medical device firms consists of fewer than 50 employees, limited resources[5]
- FDA inspections:
  - Improve the quality system of numerous small to mid-size companies
  - Provides guidance documents, standards, and applicable regulations
  - Gradually increases firm's quality system
  - A more mature quality system results in robust products in the market, reduced risks to patients
  - Positive inspection results are looked upon favorable by stakeholders

SAEs Outpacing Market Growth

Serious adverse events (SAEs) increased about twice as fast as overall medical device market growth from 2001 - 2009



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Quality Improvements Over Time

- 2008 – 2017:
  - 82% of firms corrected observed violations on follow-up inspections
- FY2018 – 2021:
  - 89% of firms corrected observed violations on follow-up inspections
- FDA inspections facilitate compliance; compliance fosters quality improvements and benefits patients

Increased Inspection Consistency

- FDA/ORA's 2017 Program alignment has improved investigator
  - Expertise
  - Focus
  - Training
  - Discernment

Medical Device Specialist Perspective

"Hello, my name is Adaliz Santaliz-Cruz. I am a Medical Device Specialist in OMDRHO Division 2. In complex inspections, I provide an objective review and a regulatory perspective which further strengthen the firm's quality system. My inspections have resulted in regulated establishments that will remain in compliance for years down the road."

Adaliz Santaliz-Cruz, RN, MLT-ASCP
Medical Device Specialist
OMDRHO Division 2
San Juan District Office
Aguada Resident Post
Aguada, Puerto Rico

Inspection Data as a Benchmarking Tool

- Use publicly available data of industry peers to benefit your organization
  - FDA 483 Observations
  - Warning Letters
  - Recalls
  - MDRs
- Investigators ensure compliance with recall and MDR regulations → more reliable data

Inspection Data and Risk Management

- Risk management involves identifying ***known and foreseeable hazards*** based on:
  - Device intended use
  - Reasonably foreseeable misuse
  - Normal and fault conditions
- Use publicly available data (recalls, MDRs, etc.) to help identify such hazards and mitigate associated risks:
  - During design and development
  - Throughout the TPLC
- Resources:
  - QSR Preamble
  - GTHF risk management guidance (SG3/N15R8)
  - ISO 14971:2019 and ISO/TR 24971:2020

Top 5 Device QSR FDA 483 Observations (FY2019)

#	CFR Reference	Description
1	820.100(a)	Corrective and Preventive Action
2	820.198(a)	Complaints
3	820.50	Purchasing Controls
4	820.90(a)	Nonconforming Product
5	820.75(a)	Process Validation

Key Takeaways

FDA inspections can be intimidating, but are beneficial to industry and patients

- Inspections foster quality improvements over time
- Inspections can be used to avoid quality events
- Publicly available inspection data can be used to benefit your organization

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[1] CDC National Center For Health Statistics (2018 Data), https://www.cdc.gov/nchs/

[2] Centers for Disease Control, "Number of Procedures in Short-Stay Hospitals" (2010), http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm.

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