Class II Recall Analysis

FDA Small Business Regulatory Education for Industry (REdI)

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U.S. Food and Drug Administration

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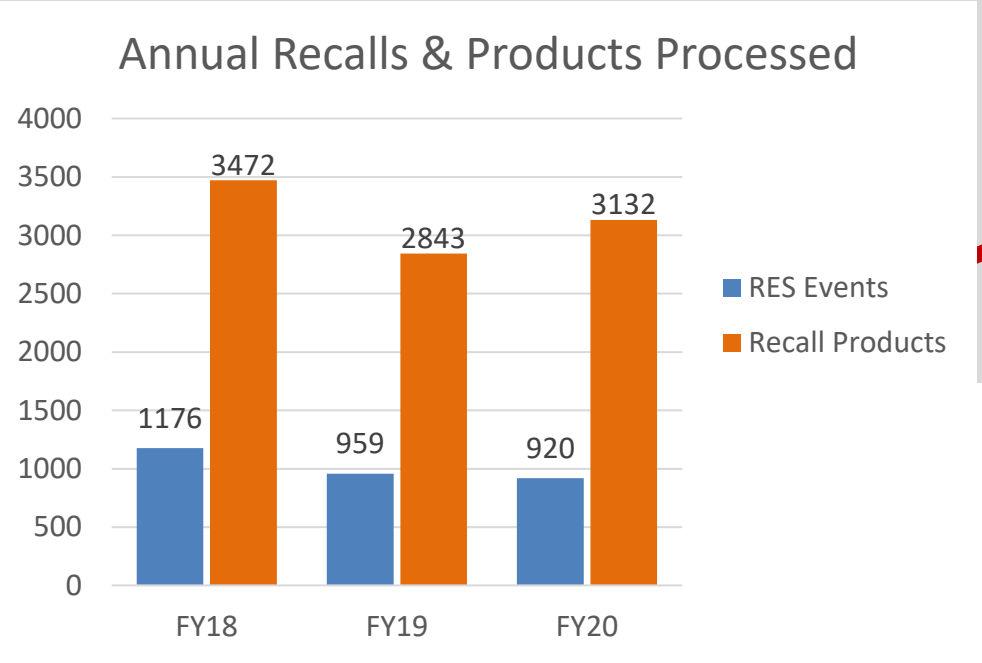
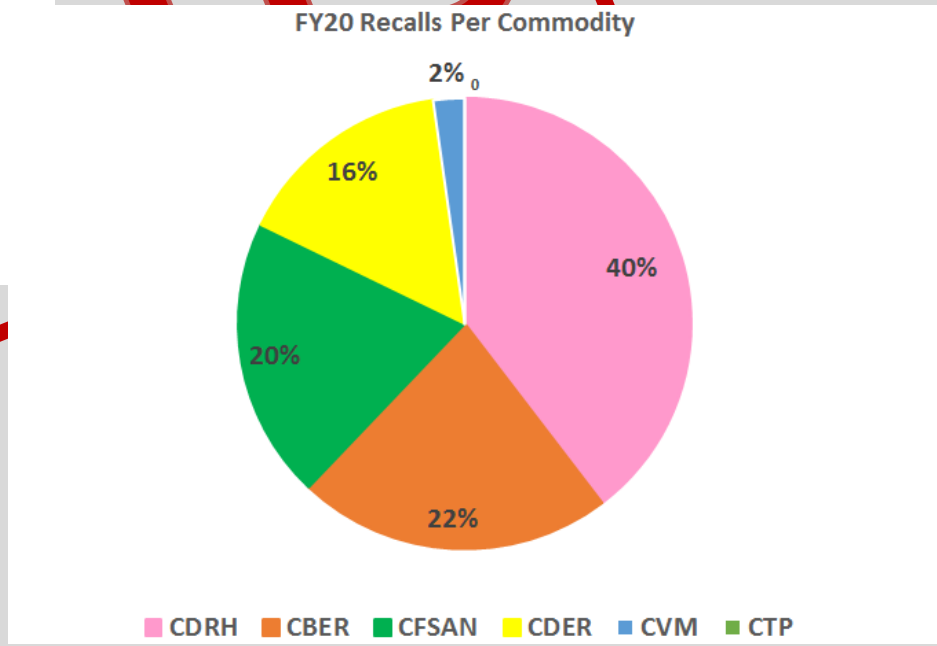

Annual Recalls & Products Processed
4000
3500
3000
2500
2000
1500
1000
500
0
3472
2843
3132
1176
959
920
FY18
FY19
FY20
RES Events
Recall Products


FY20 Recalls Per Commodity
2%
0
16%
40%
20%
22%
CDRH
CBER
CFSAN
CDER
CVM
CTP

Learning Objectives

- Review Basics of Recall Classifications
- Review Previous Class I Recall Analysis Summary
- Discuss current Class II Recall Analysis project
- Discuss Key Takeaways from Analysis
- Identify some Best Recall Practices
- Discuss what to expect during follow-up inspections

Recall Review

Recalls 101

Recall Classifications

- **Class I:** Reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II:** Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III:** Use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Device Classifications

- **Class III:** General Controls and Premarket Approval
- **Class II:** General Controls and Special Controls
- **Class I:** General Controls

❖ **Class I and II may require 510k submission**

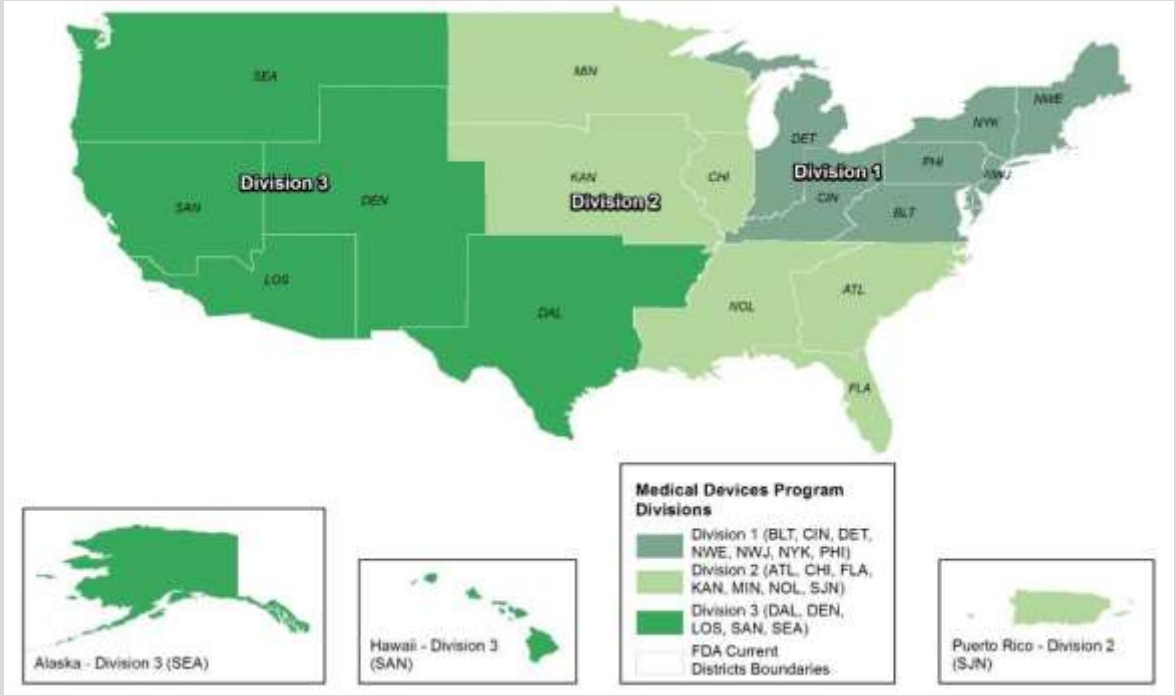
Previous Class I Recall Analysis Summary

Background

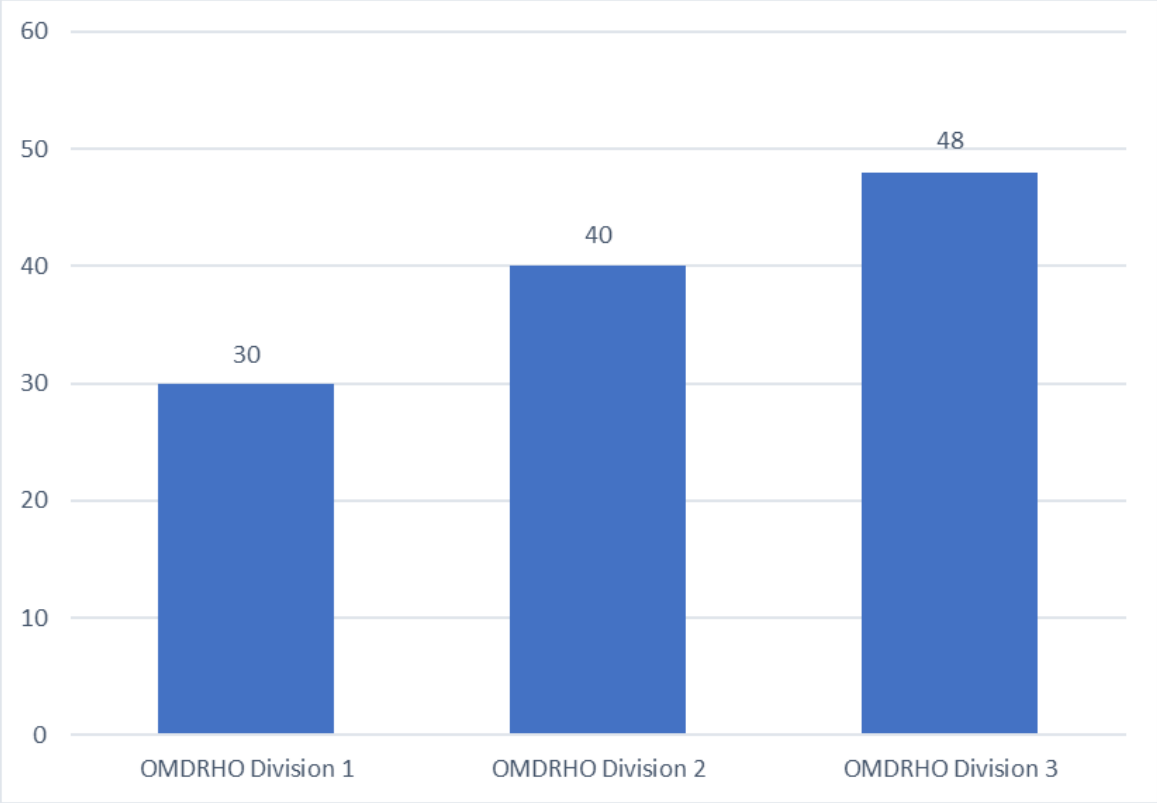
- **<u>118 Class 1 Recalls:</u>**

  Jan 2016 - Dec 2018

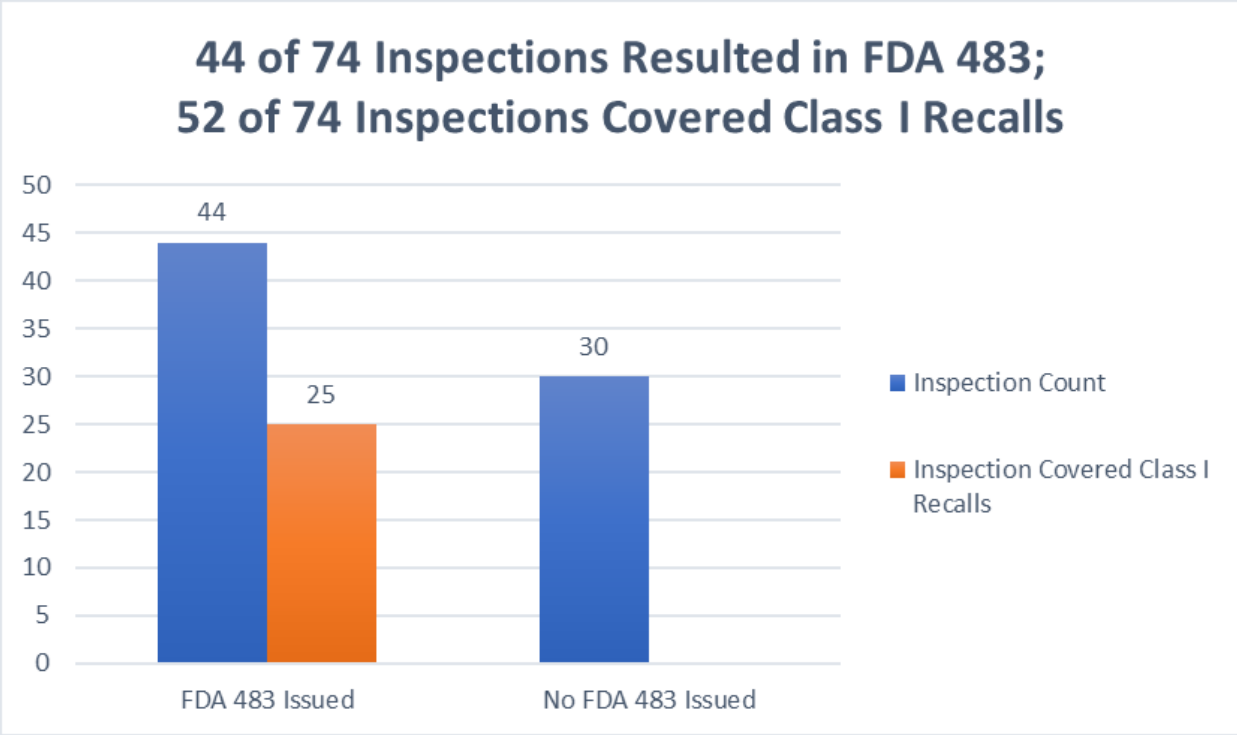
- All Office of Medical Devices and Radiological Health (OMDRHO) Divisions included in analysis – US & international

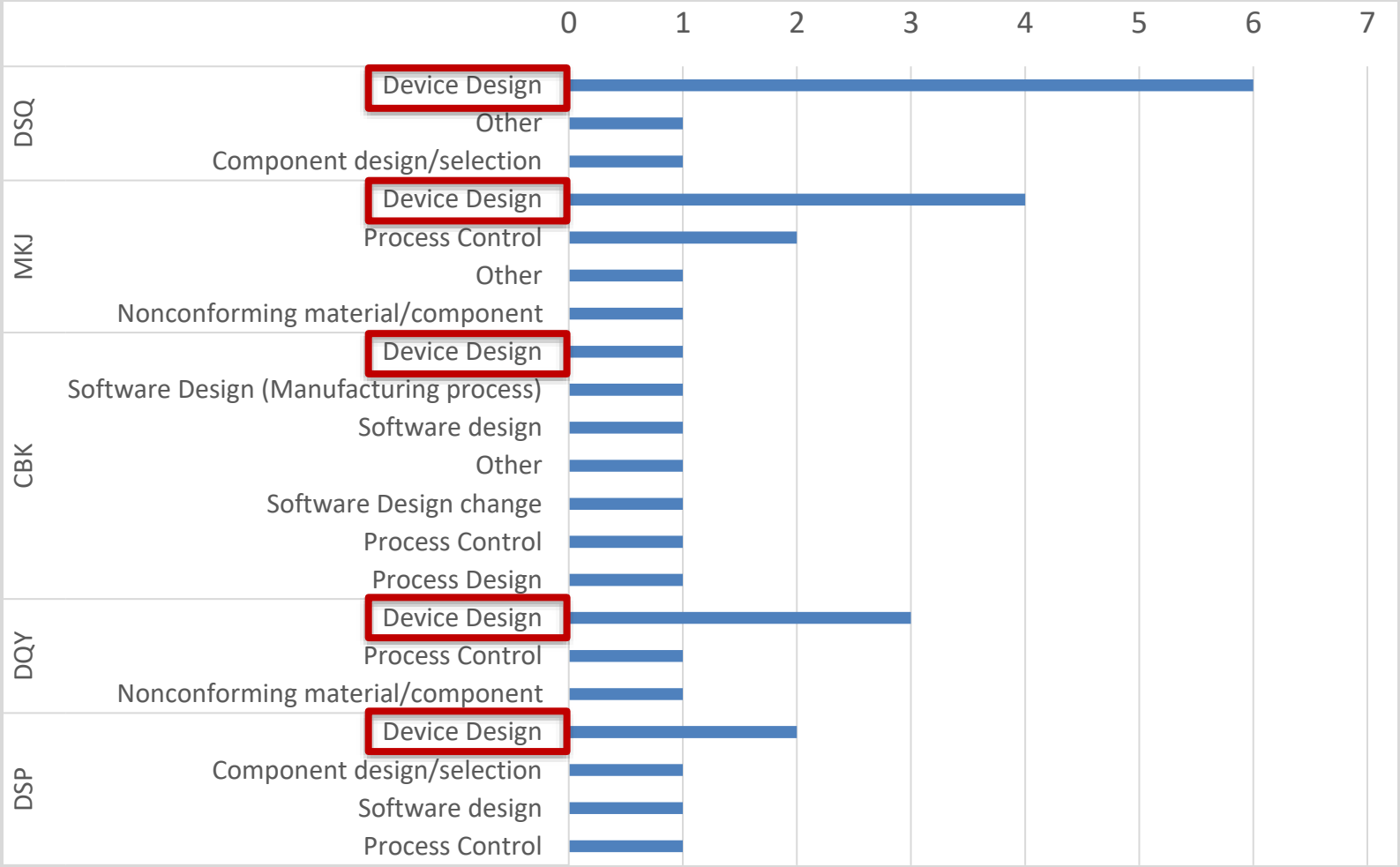


Class I Recalls by Division



Quality Issues Related to Class I Recall



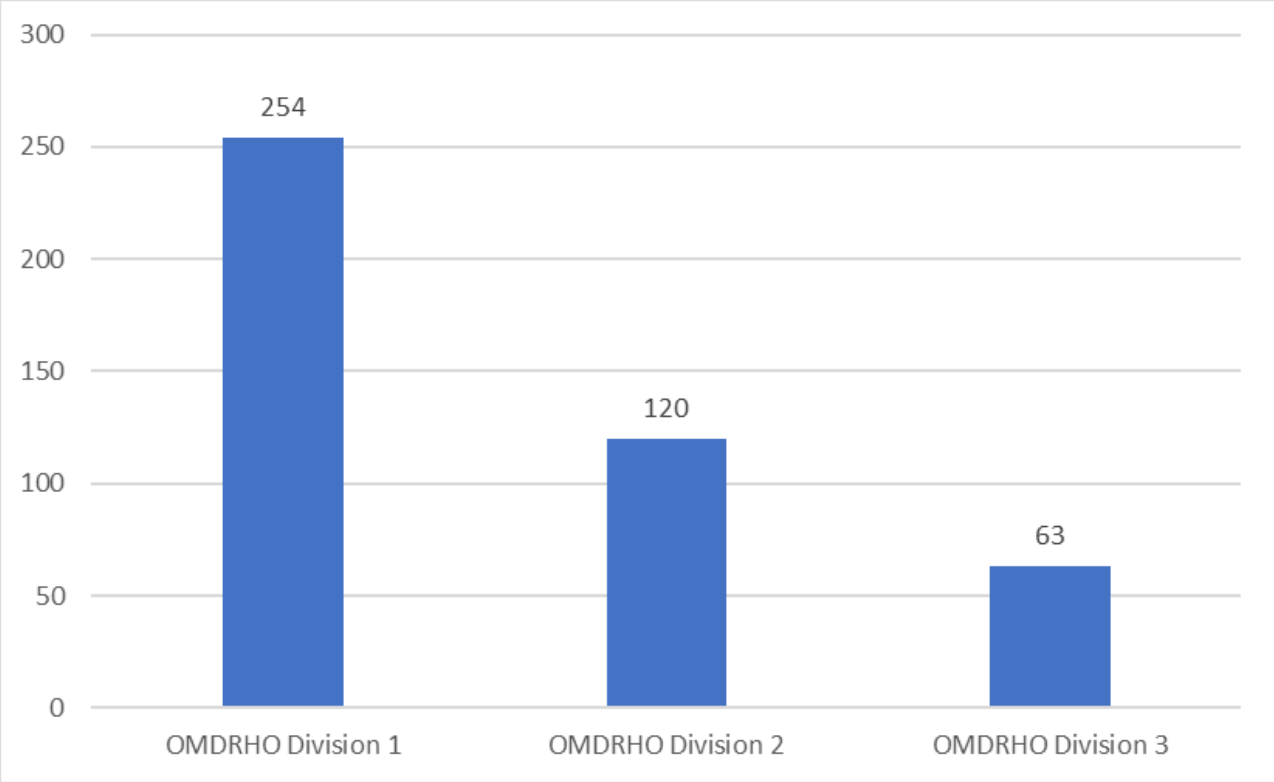

0
1
2
3
4
5
6
7
DSQ
Device Design
Other
Component design/selection
MKJ
Device Design
Process Control
Other
Nonconforming material/component
CBK
Device Design
Software Design (Manufacturing process)
Software design
Other
Software Design change
Process Control
Process Design
DQY
Device Design
Process Control
Nonconforming material/component
DSP
Device Design
Component design/selection
Software design
Process Control

Class II Recall Analysis

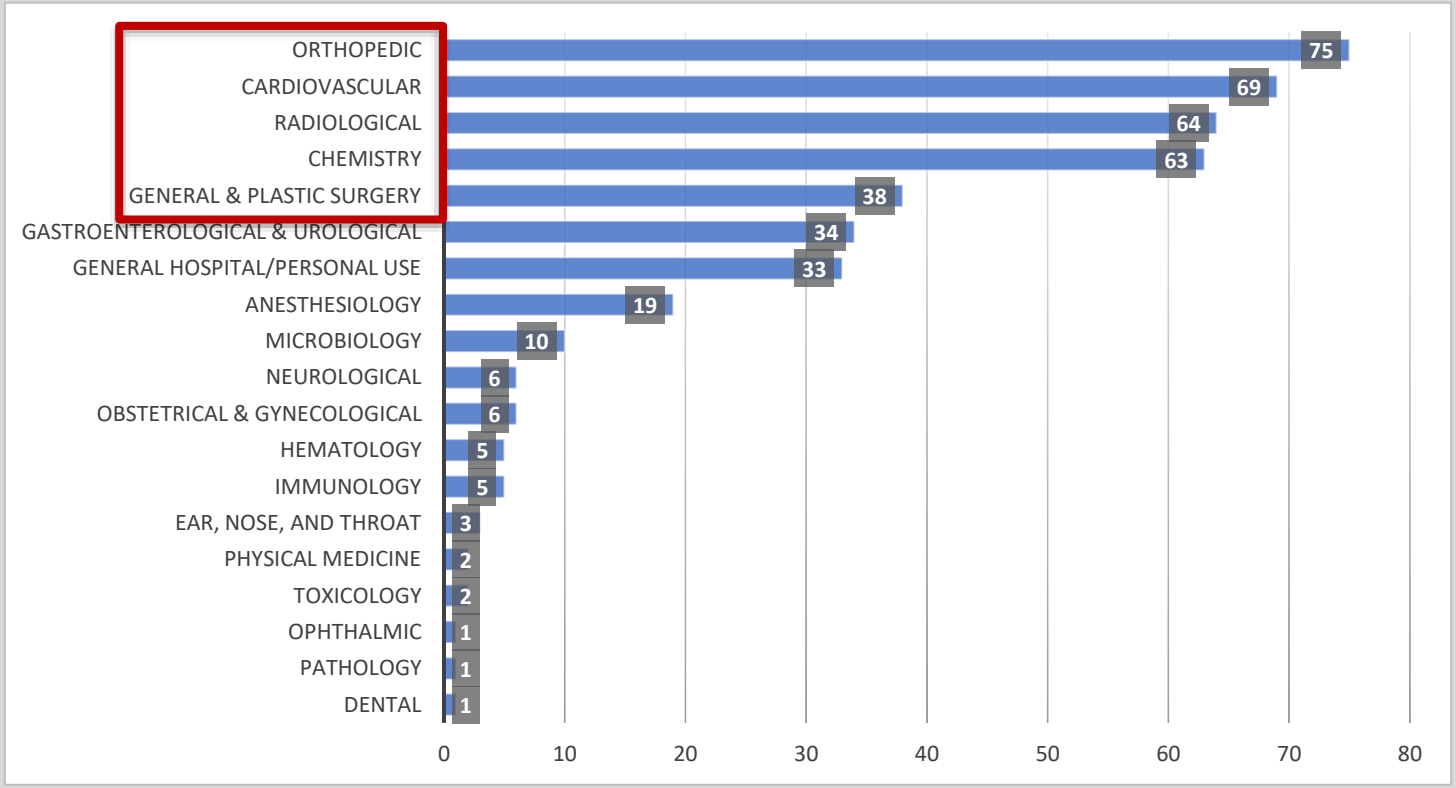
Class II Recall Analysis

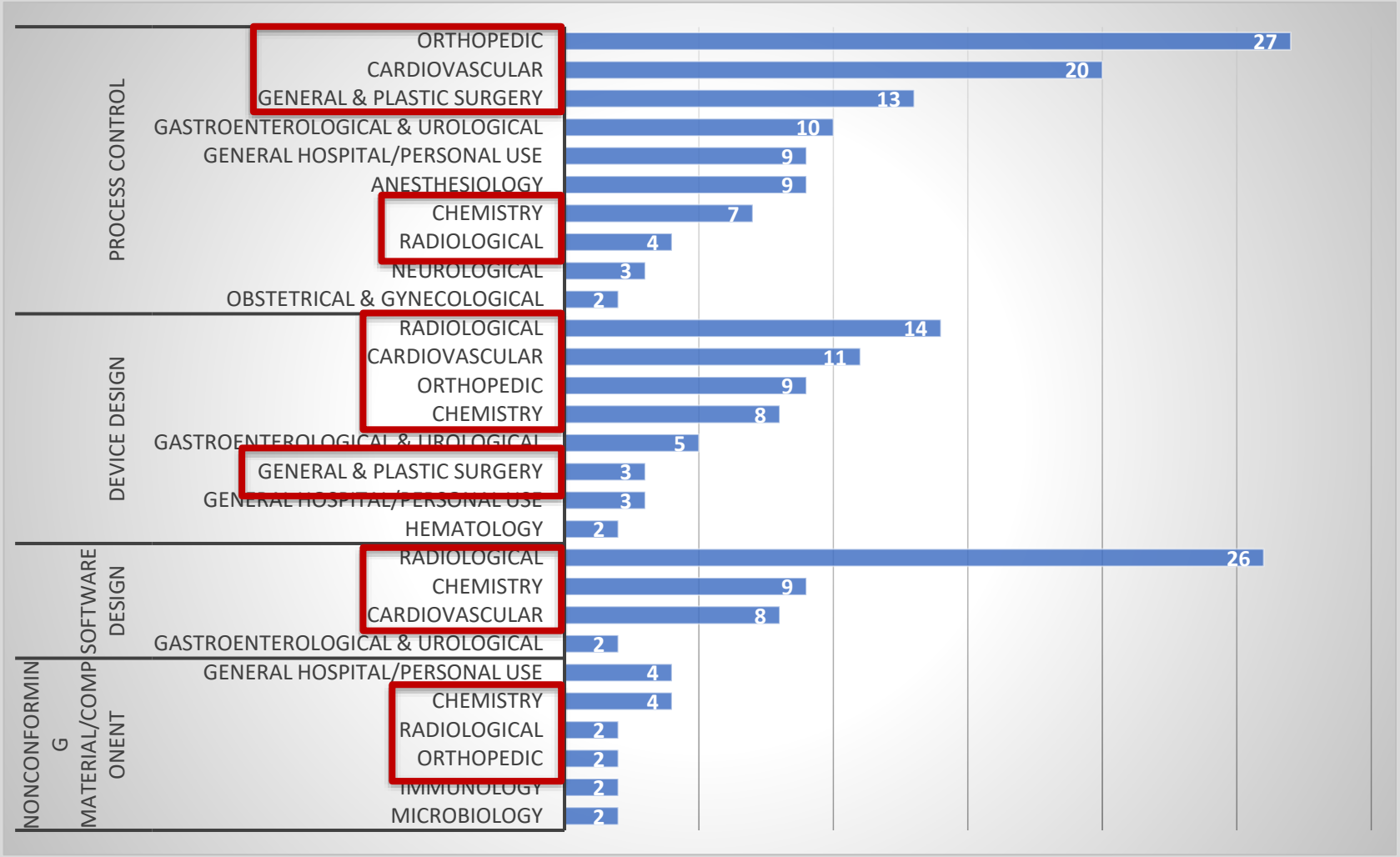
Background	Goal
• Review of 437 Class II Recalls: October 2019 - September 2020 • All OMDRHO Divisions included in analysis	• In-depth root cause analysis • Identify trends and obtain information to 1. Provide industry with feedback on their corrective actions 2. Identify internal (OMDRHO) and external (Industry) best practices

Class II Recalls by OMDRHO Division

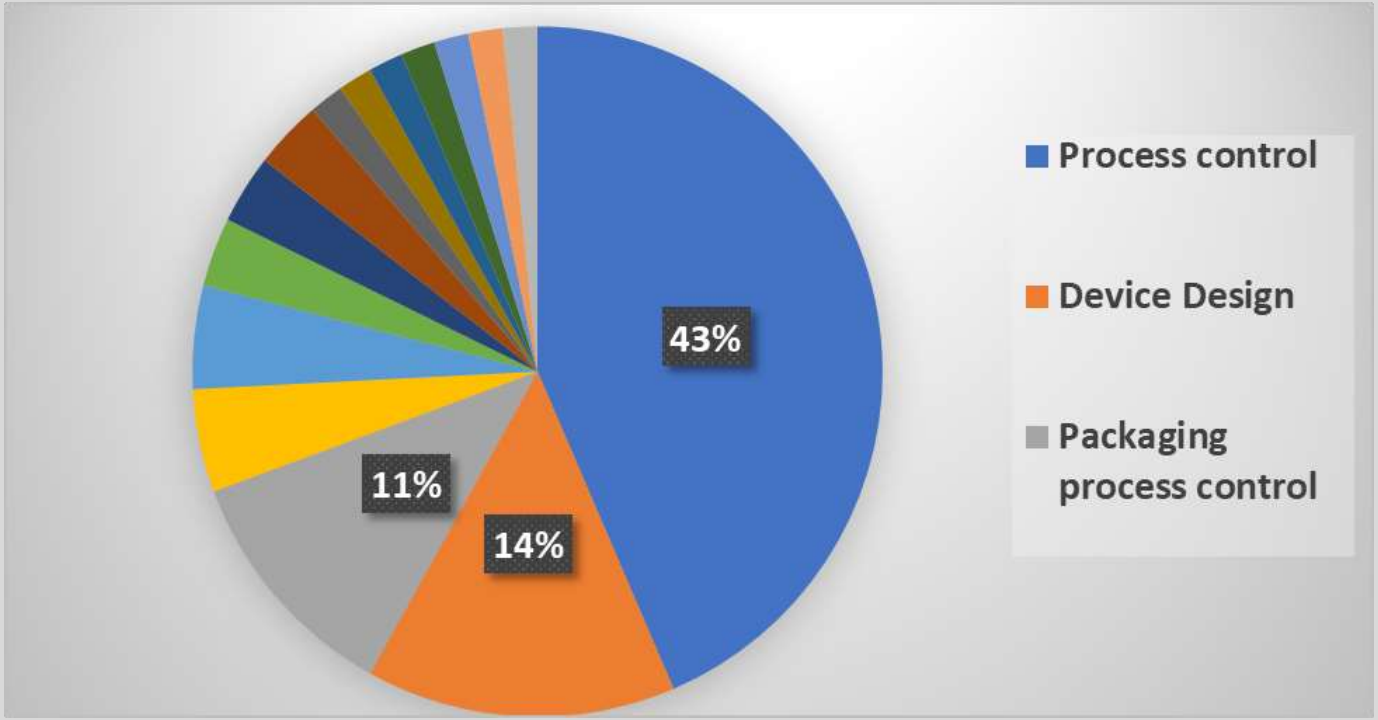


Recall Totals by Industry Type

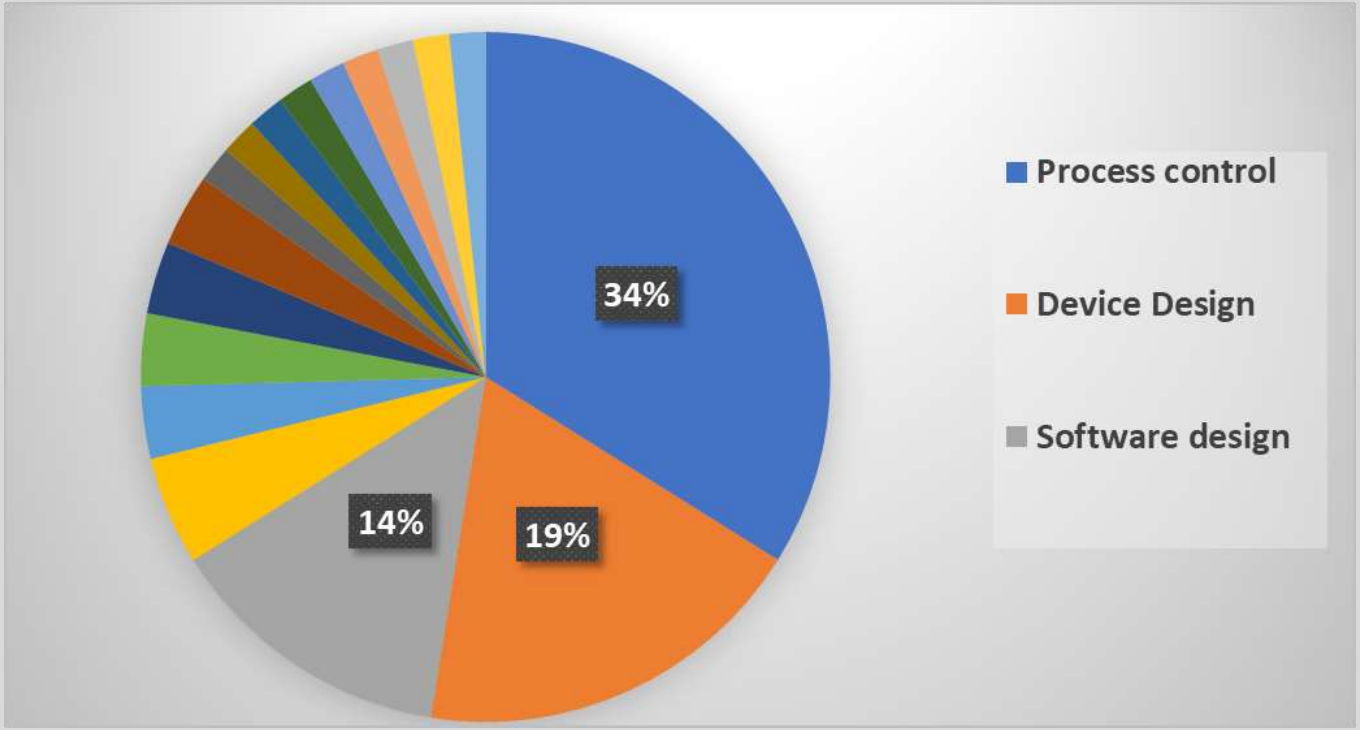



PROCESS CONTROL
ORTHOPEDIC 27
CARDIOVASCULAR 20
GENERAL & PLASTIC SURGERY 13
GASTROENTEROLOGICAL & UROLOGICAL 10
GENERAL HOSPITAL/PERSONAL USE 9
ANESTHESIOLOGY 9
CHEMISTRY 7
RADIOLOGICAL 4
NEUROLOGICAL 3
OBSTETRICAL & GYNECOLOGICAL 2
DEVICE DESIGN
RADIOLOGICAL 14
CARDIOVASCULAR 11
ORTHOPEDIC 9
CHEMISTRY 8
GASTROENTEROLOGICAL & UROLOGICAL 5
GENERAL & PLASTIC SURGERY 3
GENERAL HOSPITAL/PERSONAL USE 3
HEMATOLOGY 2
SOFTWARE DESIGN
RADIOLOGICAL 26
CHEMISTRY 9
CARDIOVASCULAR 8
GASTROENTEROLOGICAL & UROLOGICAL 2
NONCONFORMING MATERIAL/COMPONENT
GENERAL HOSPITAL/PERSONAL USE 4
CHEMISTRY 4
RADIOLOGICAL 2
ORTHOPEDIC 2
IMMUNOLOGY 2
MICROBIOLOGY 2

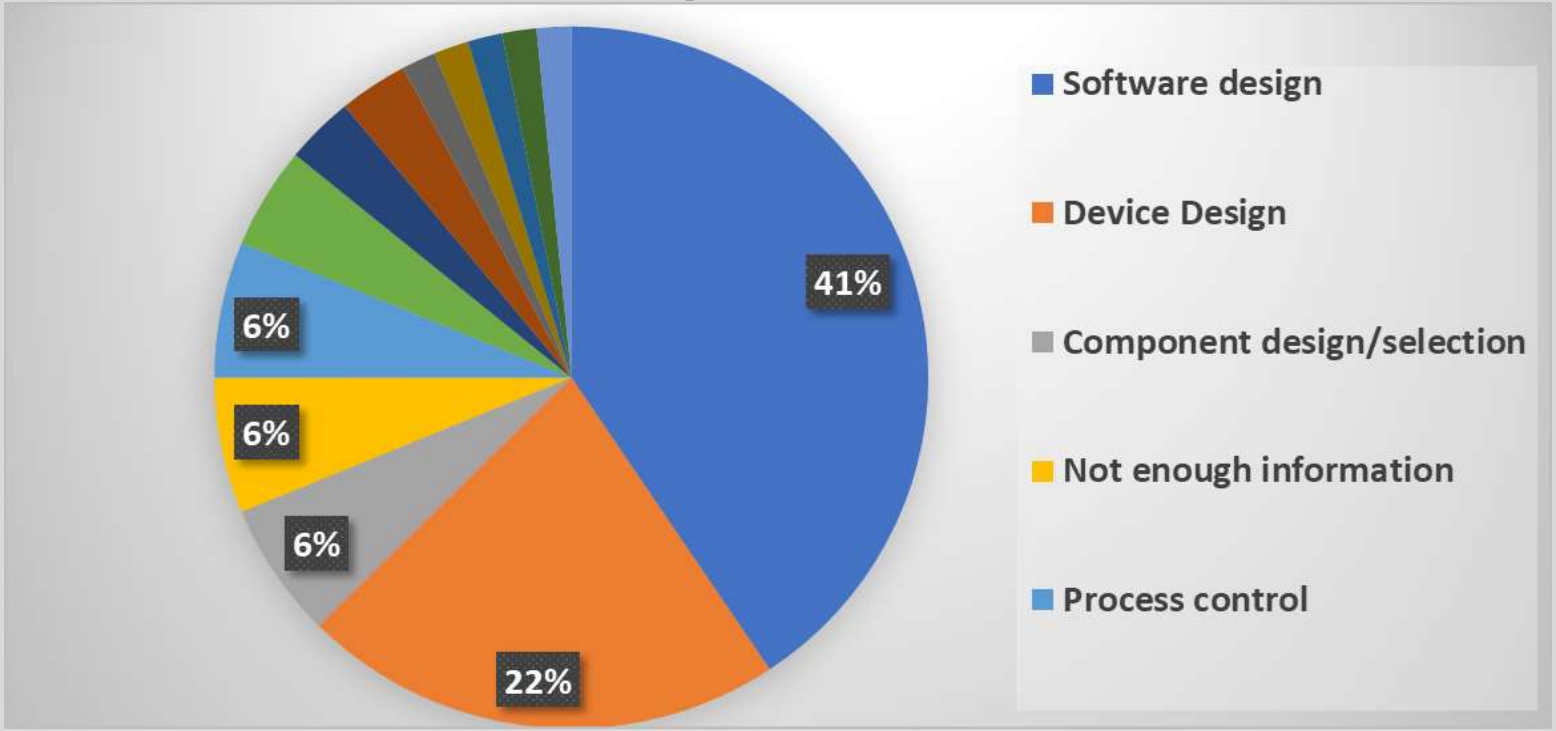
Top Root Causes: Orthopedic Devices



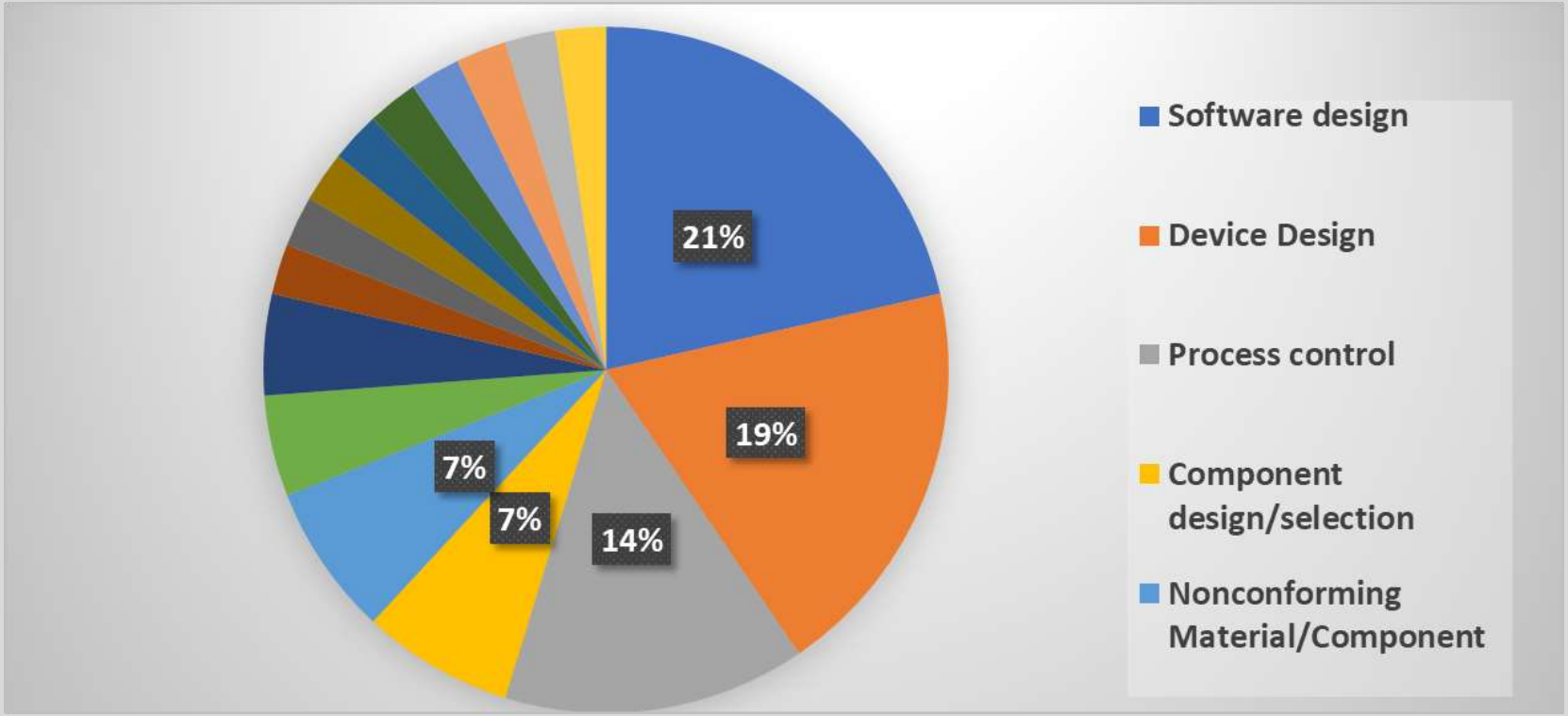
Top Root Causes: Cardiovascular Devices



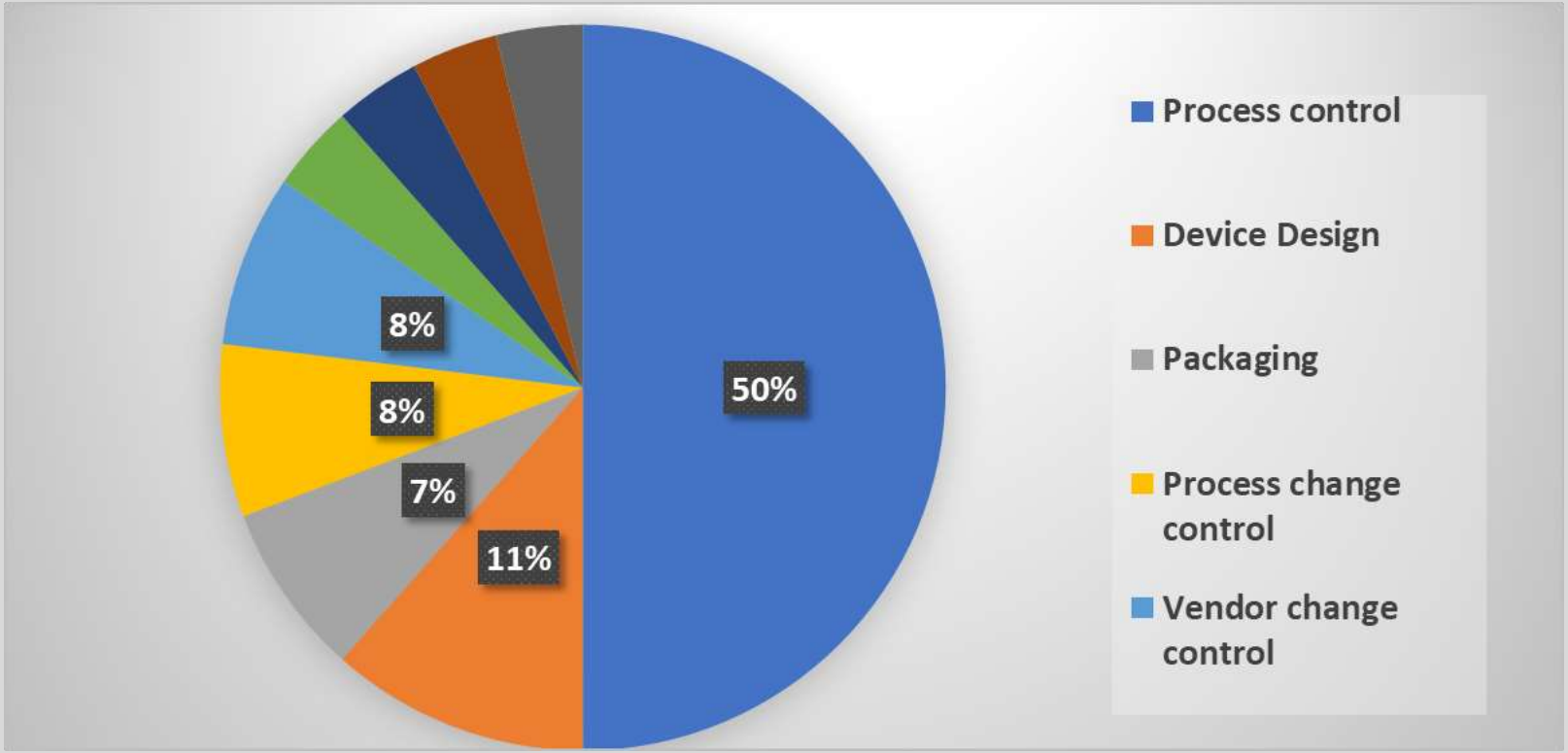
Top Root Causes: Radiological Devices



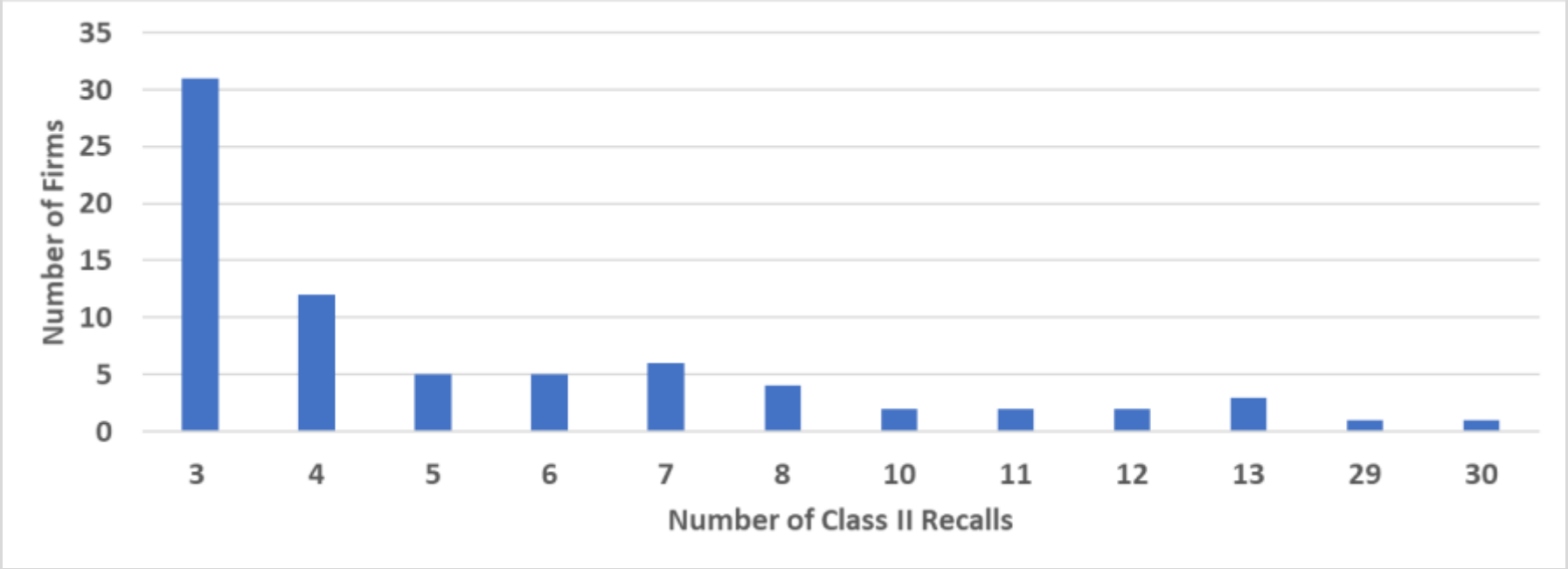
Top Root Causes: Chemistry Devices



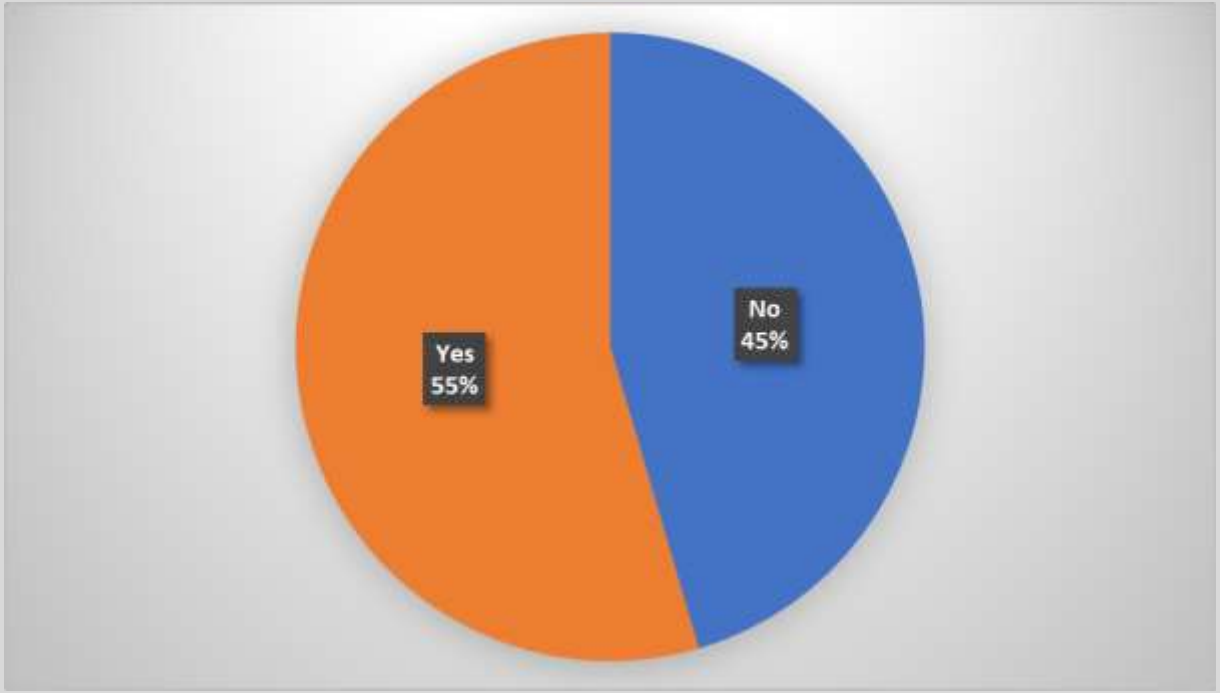
Top Root Causes: Surgical Devices



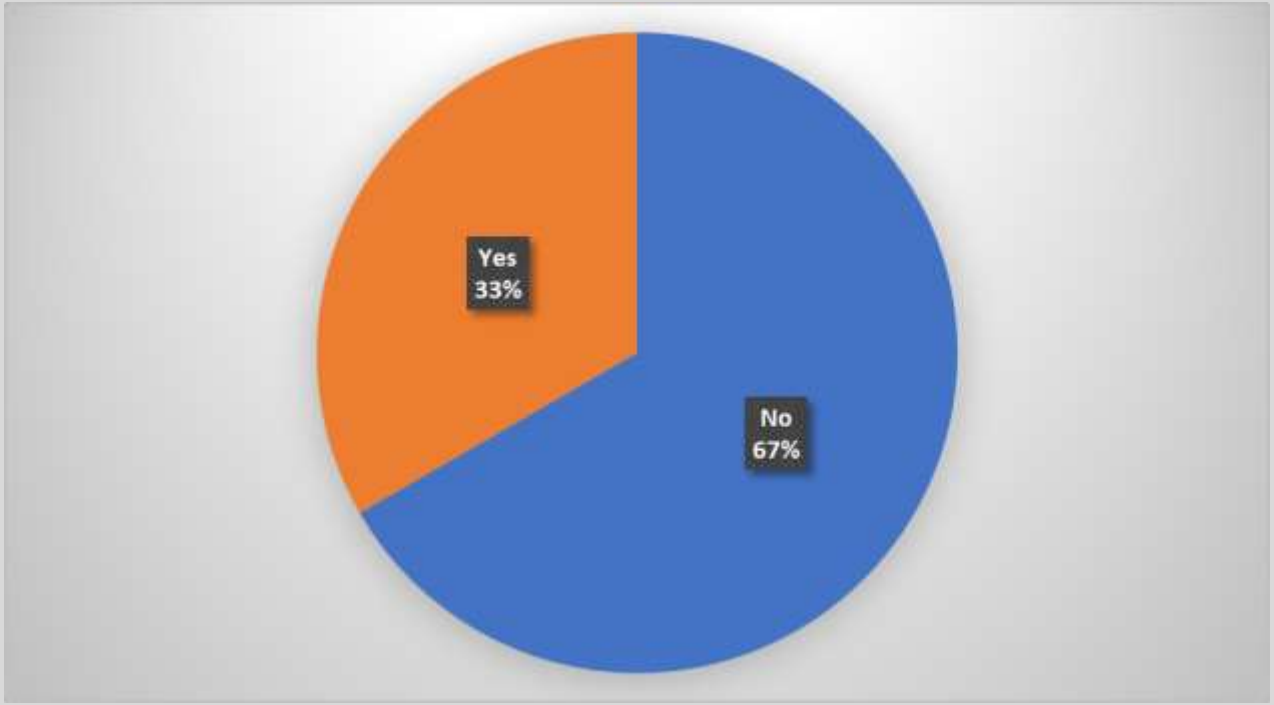
Firms with Multiple FY'20 Class II Recalls



Next Inspection Identified Quality Issues



Quality Issues Related to Class II Recall



Knowledge Check

True or False?

The top root cause identified in the Class II analysis was Process Control?

TRUE **FALSE**

Key Takeaways

Key Takeaways

1. In our analysis of Class 1 and Class 2 recalls, top root causes were attributed to process control or device design issues
2. Root cause investigation should be conducted in a **systemic manner** to ensure the root cause(s) are accurately identified for the recall
3. Firms with multiple recalls - systemic issues

Best Practices

Production & Process Controls

Common Root Causes observed:

- Packaging/Labeling issues
- Inadequate equipment and/or process validation
- Inadequate process procedures
- Production Process Change
- Component failures
- Supplier issues

Production & Process Controls

- Manufacturers should establish production processes to ensure medical devices conform to specifications
- These include...
  - Frequency of monitoring
  - SOPs, drawings, production method and instructions (e.g., steps, sequence, startup requirements, required checks)
  - Testing/Inspection and monitoring procedures
  - Establishing process parameters and qualification of specific production equipment (process validation)
  - Documentation requirements

Identify Root Cause(s)

Important to establish the true root cause(s)

- Requires thorough and broad investigation including using objective evidence
- Performed to degree commensurate with significance and risk
- Should focus on Quality System to ultimately prevent future recalls

❖ **Necessary so that appropriate corrective actions can occur**

Corrective Actions

- Actions taken to eliminate root cause are appropriate for the magnitude of the problem and risks encountered
- Effectiveness verification/validation of production process or design change to ensure the action taken is effective and does not adversely affect the finished device
- Analysis of available quality data is a proactive activity designed to identify existing or potential problems that might otherwise go undiscovered

Knowledge Check

True or False?

Root cause investigations do not need to include the Quality System

TRUE **FALSE**

Follow-Up Inspections

FDA Inspections

- During FDA inspections, Class II recalls are reviewed
- Coverage of CAPA subsystem verifies problems are detected and resolved
- In covering recalls, inspections may focus on various key elements of the CAPA process to determine if actions taken where appropriate, followed established procedure as well as the regulatory requirements/intent
- Firms are subject to follow-up inspections, even if under MDSAP

Summary

- Class I Analysis – Top root cause was Device Design
- Class II Analysis – Top root cause was Process Control
- Recall coverage during inspections are resulting in related 483 items
- Ensure you identify true root cause in order to take appropriate corrective actions

Resources

- **Division Contacts**
  - **Division I:** oradevices1recalls@fda.hhs.gov (CT, DC, DE, IN, KY, MA, MD, ME, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV)
  - **Division 2:** oradevices2recalls@fda.hhs.gov (AL, FL, GA, IA, IL, KS, LA, MN, MO, MS, NC, ND, NE, PR, SC, SD, TN, WI and the US Virgin Islands)
  - **Division 3:** oradevices3recalls@fda.hhs.gov (AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA, WY)

- **Industry Guidance:**

  www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

Questions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