FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Office of Medical Devices and Radiological Health Recalls

Cultivating Compliance Virtual Conference 2020

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Outline

- Class I Recall Analysis
- Terminations

Class I Recalls Analysis

Background

- Review of 118 **Class 1 Recalls** - January 2016 to December 2018
- All OMDRHO Divisions included in analysis

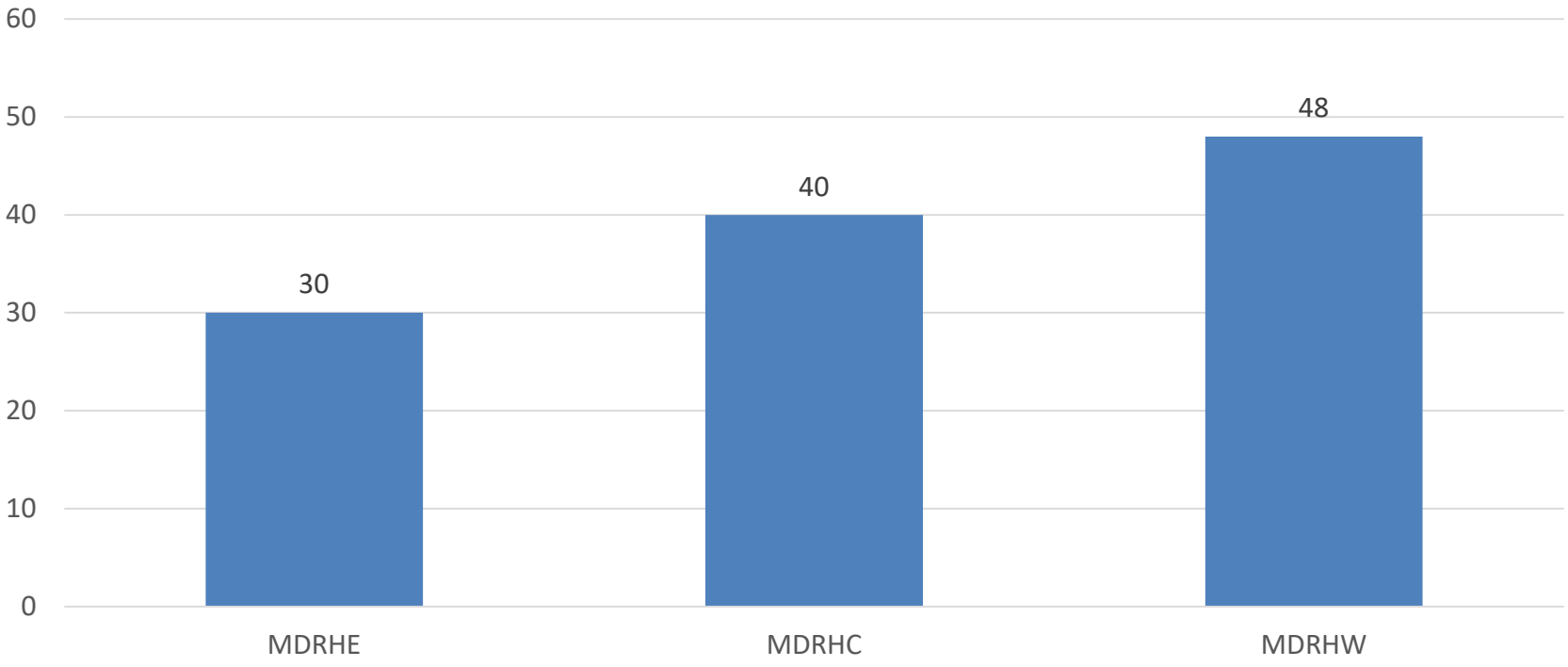
Class I Recalls Analysis

Goal

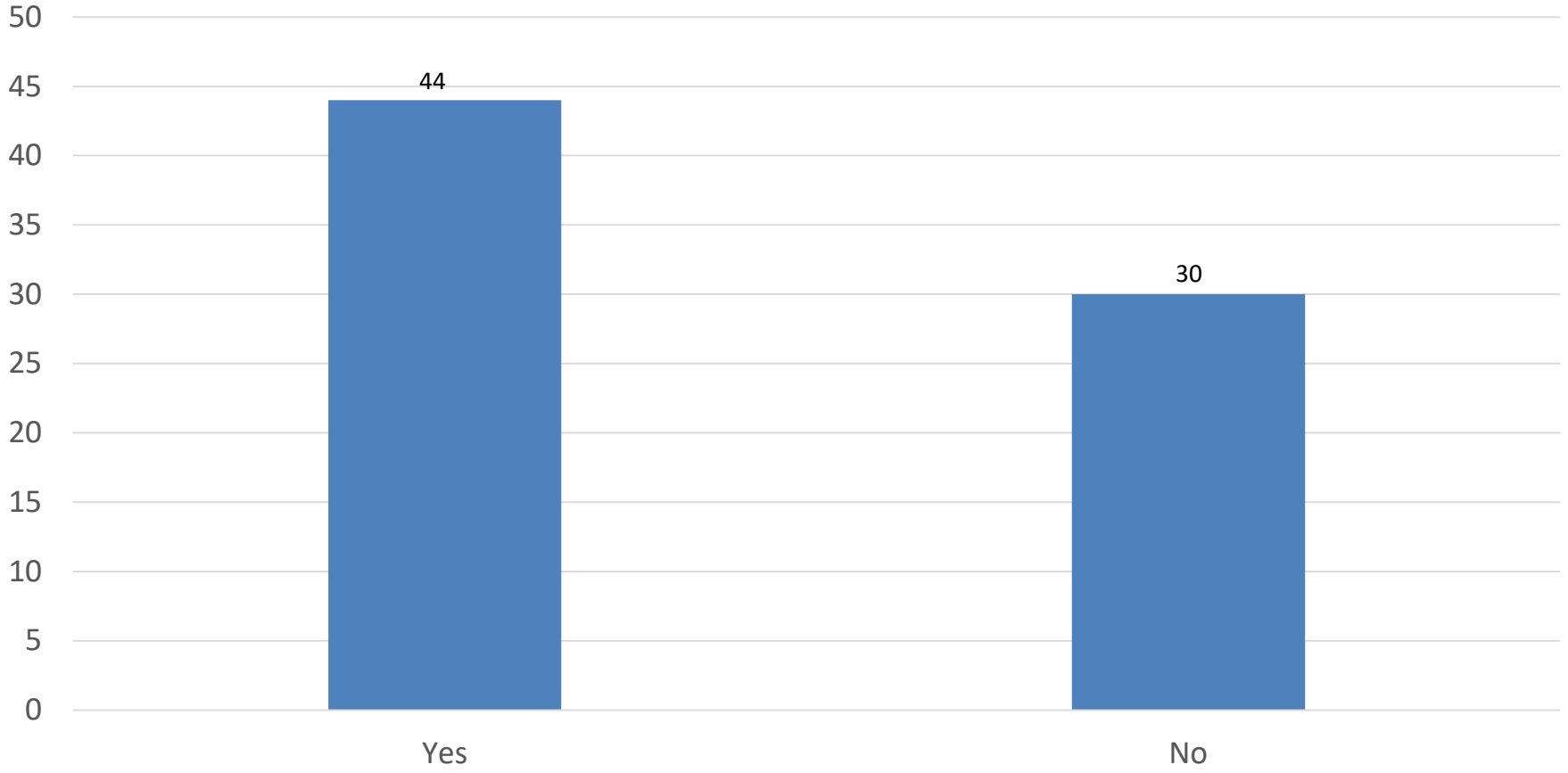
Identify trends and obtain information to

- Provide industry with feedback on their corrective actions
- Identify internal (OMDRHO) and external (Industry) best practices

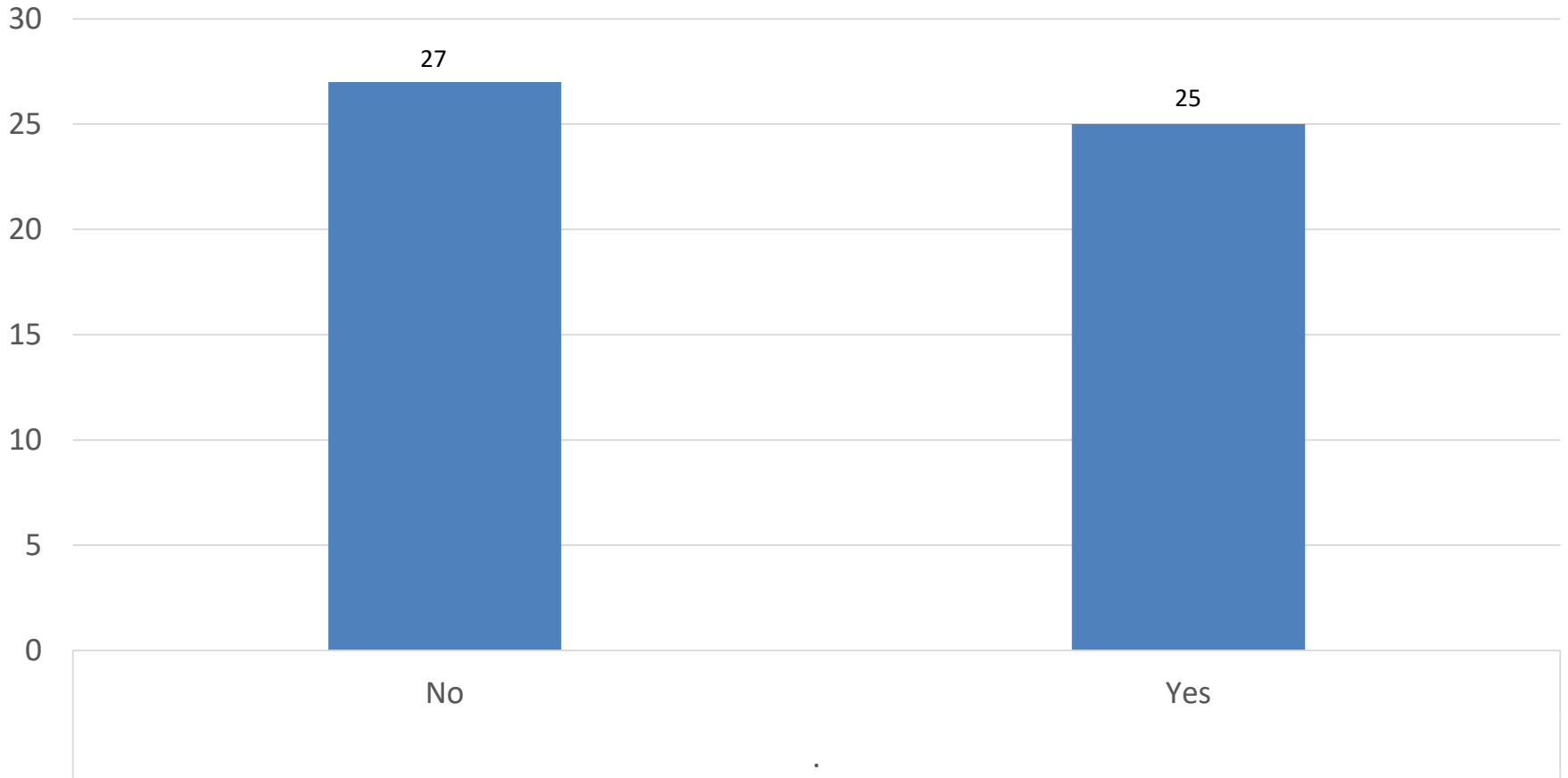
Class I Recalls by Division



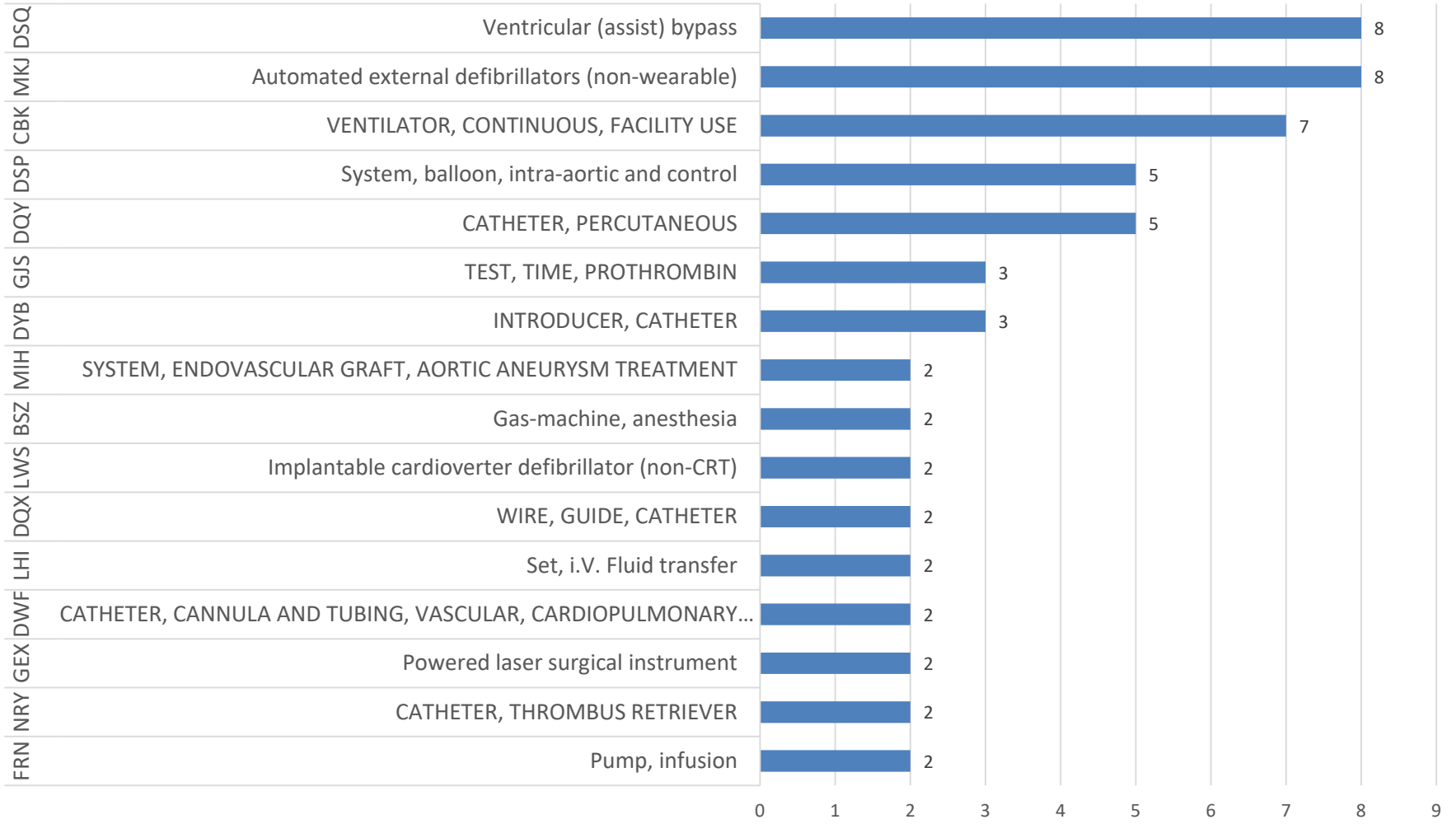
Next Inspection Identified Quality Issues



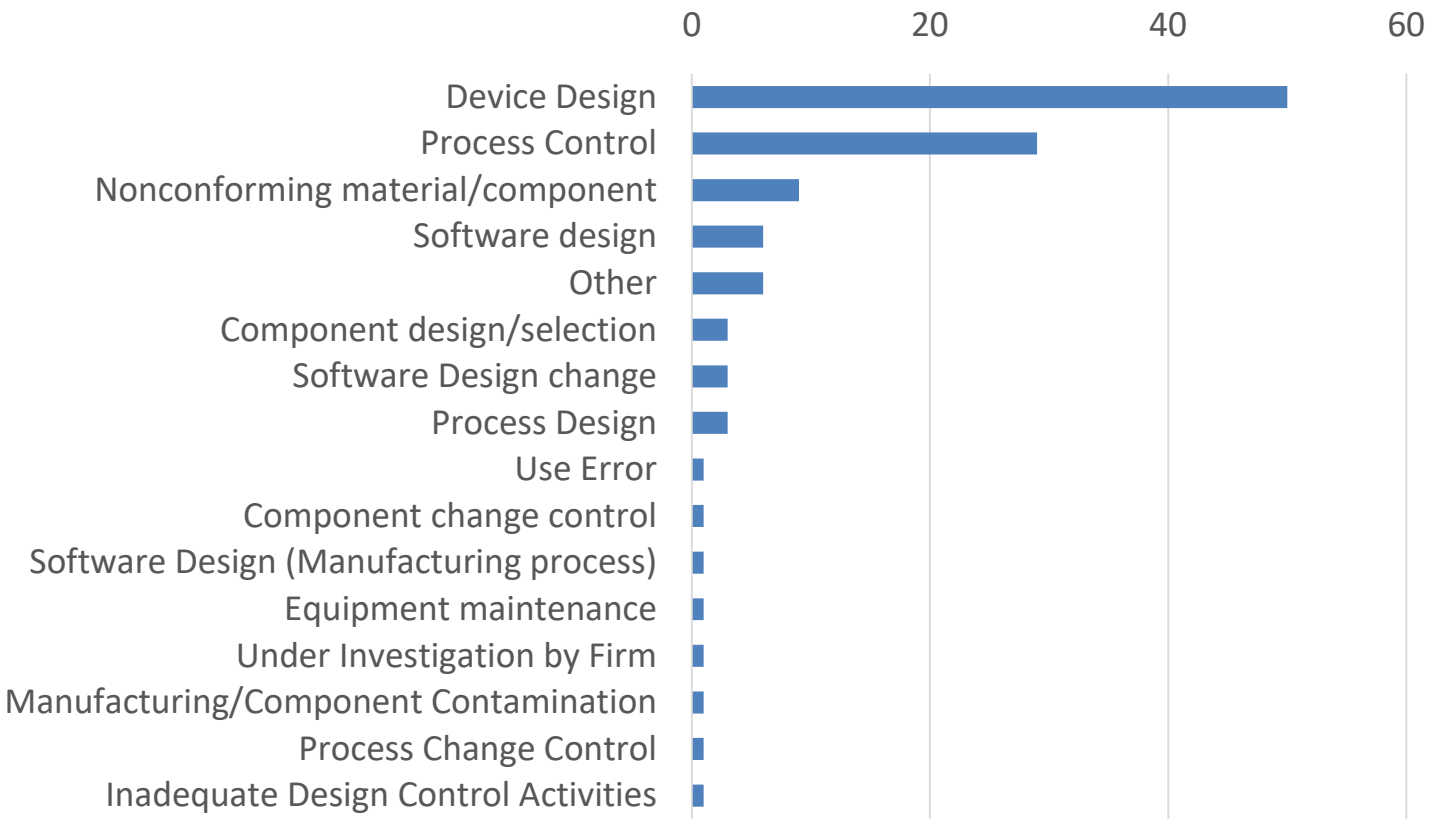
Quality Issues Identified Related to Class I Recall



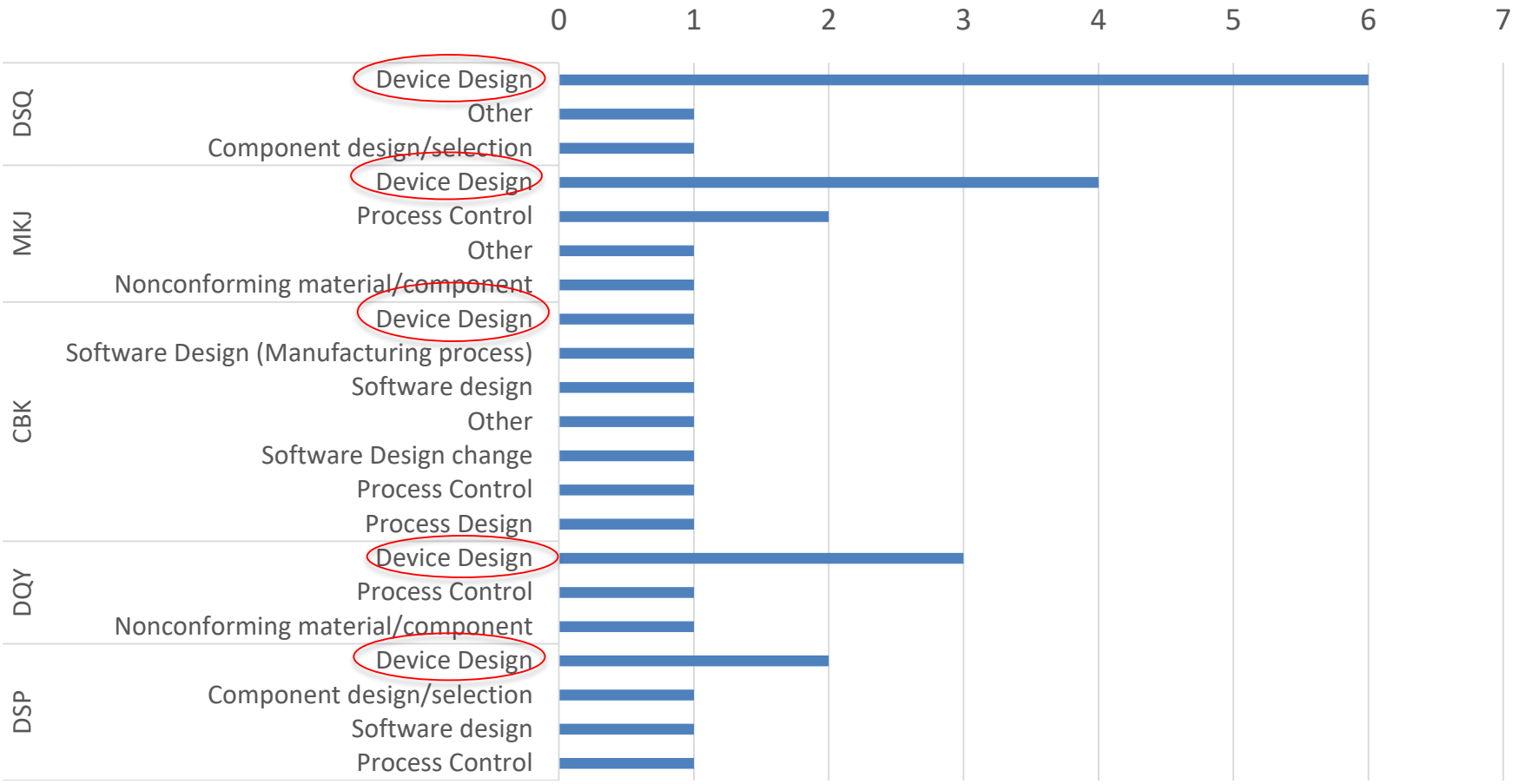
Top Class I Recalls by Product Code/Type



Class I Recalls Root Cause Quantities



Root Cause by Product Code (Top 5)



Identify True Root Cause

Important to establish the true root cause

- Requires a thorough and complete investigation
  - Unbiased
  - Okay to have preliminary root cause initially
- Should really focus on Quality System to ultimately prevent future recalls
- **Appropriate corrective actions can occur**
- **Appropriate preventative measures can be initiated**

FDA Follow Up Inspections

- Expect FDA follow up at some point (beginning or end of recall)
- Could be combined with other recall coverage
- Intent is to follow up on all Class I recalls, where FDA deems appropriate
- Firms are subject to follow-up inspections even if participating in MDSAP

Terminations

21 CFR Part 7: Enforcement Policy

- **Subpart C** – Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

- **Sec. 7.55** – Termination of a recall (Correction/Removal)

PART 7 Sec. 7.55 (a)

- A recall will be terminated when the FDA determines that:

  - All reasonable efforts have been made to remove or correct the product in accordance with the recall strategy;

  - It is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product.

PART 7 Sec. 7.55 (b)

- A recalling firm may request termination of its recall:
  - Submitting a written request to the appropriate FDA Division
  - The request should justify why the recall is considered effective in accordance with 21 CFR Part 7 Sec. 7.55(a)
  - The request should include the most current recall status report and a description of the disposition of the recalled product.

Termination Points

Final Status Report/Termination Request will look similar to status reports submitted during the recall (21 CFR Part 7.53)

- Quantity Recovered / Number of Units Corrected
- Product Disposition (destruction records/photos)
- Number of Consignees Responding to Notification
- Assessed Effectiveness (consignee responses/results)
- Root Cause
- Preventative action(s) taken by recalling firm

Product Reconciliation & Disposition

- Quantity of affected devices recovered
  - The amount distributed in the 806 Report should equal the final amount distributed at termination
  - If it does not, it should have been explained in status reports. Should be reconciled in termination request
- Quantity of devices returned/corrected
  - Provide documentation for destruction
  - We will request portion of documentation for corrections

Consignee Response

- The number of consignees in the 806 Report should equal the total number of consignees at termination.
- If it does not, it should have been explained in status reports.
- Should be reconciled in termination request. Provide an updated/final consignee list.

Assessing Effectiveness

- Has the consignee received the notification?

  **FDA does not consider delivery receipts as a customer response
- If the recall notification was received, were the instructions read/followed?
- If not followed/received, were necessary steps taken?
  - These steps may involve sending out a follow up notification
  - Our recommendation is a minimum of 3 attempts at contact using various methods of contact
  - Document all attempts at contact
  - Are there other means to demonstrate the consignee was aware of the recall and followed instructions?

Identify True Root Cause

- Initial root cause might change as investigation is conducted. That is OK.
- Ensure Division is notified if root cause has changed
- It is VITAL to identify the true root cause
  - Appropriate corrective actions can occur
  - Appropriate preventative measures can be initiated

**FDA will likely not process a termination request when the Root Cause is still pending.

Corrective Actions & Preventative Actions

- Sufficiently explain corrective actions
  - Planned or underway
  - Accomplished
  - FDA expects that all reasonable corrective actions are complete at termination
  - Provide supporting documentation (Completed CAPA, updated procedures, dates accomplished, documentation of employee training, etc.)

Take Home

- Identification of the true root cause is VITAL
- When investigating the root cause, focus on the whole quality system.
- The numbers should make sense
  - Affected devices
  - Affected consignees
- Recall Effectiveness – It is the recalling firm's responsibility to ensure the recall is effective!