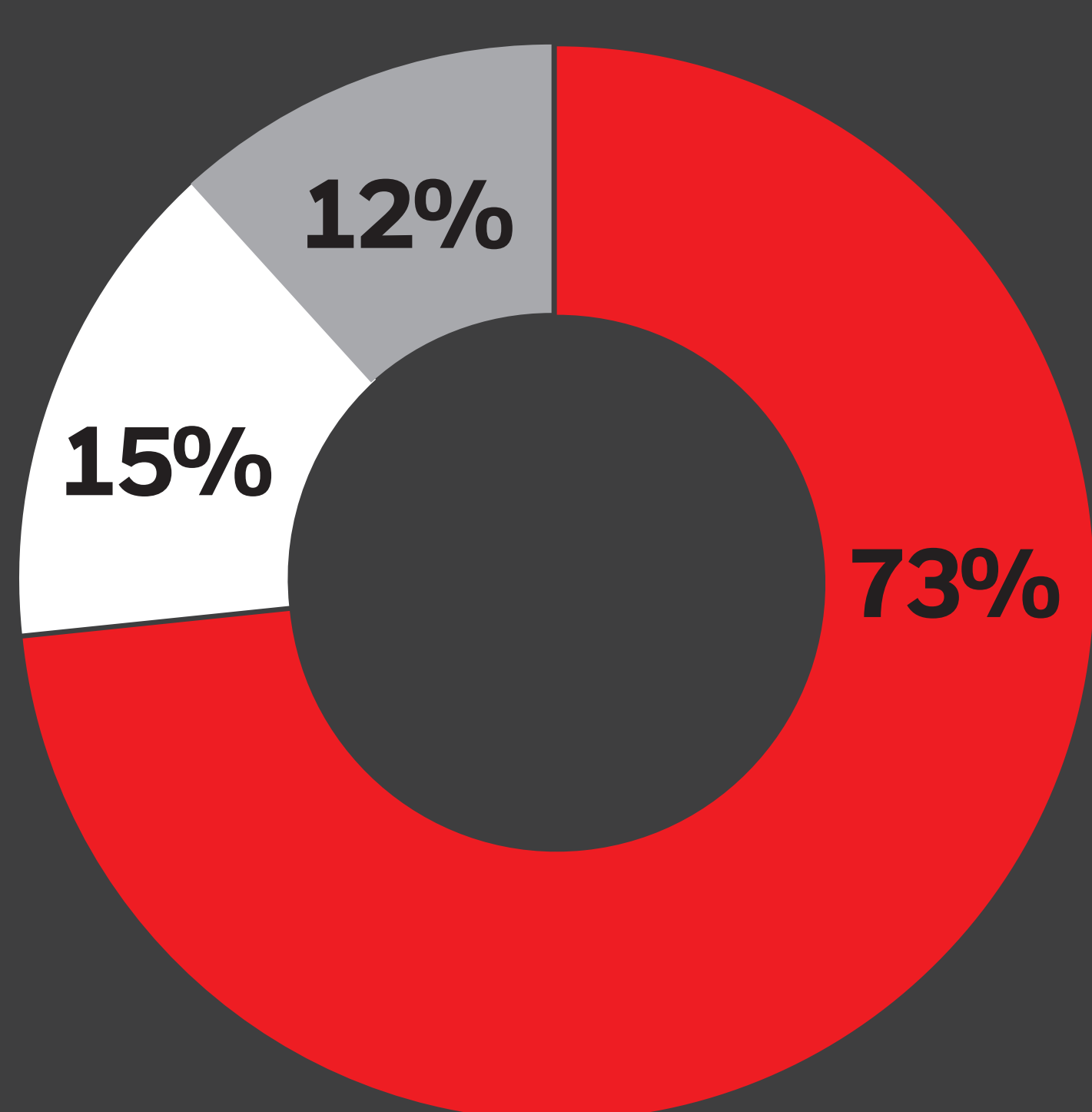




# LIFE SCIENCES RECALLS:

## CAUSES, IMPLICATIONS, AND THE PATH FORWARD

### RECALLS BY PRODUCT TYPE<sup>1</sup>



Medical Device (CDRH)

Pharmaceutical (CDER)

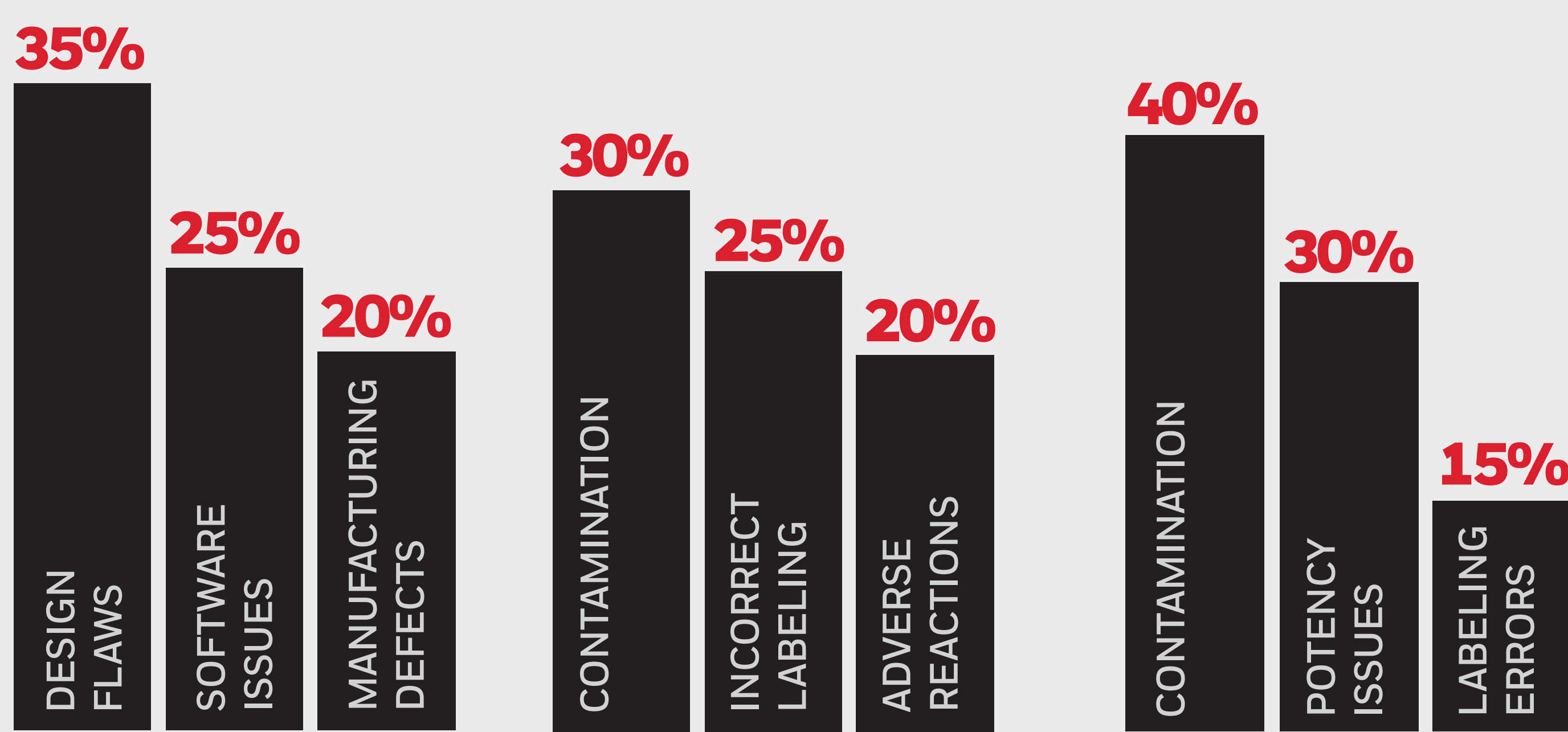
Biologics (CDER)

4,478

From the FDA:

# of Recalls for Fiscal Year 2024<sup>1</sup>  
(September 2023 – October 2024)

### COMMON REASONS FOR RECALLS<sup>1</sup>



#### MEDICAL DEVICE

- Design flaws (35%)
- Software issues (25%)
- Manufacturing defects (20%)

#### PHARMACEUTICAL

- Contamination (30%)
- Incorrect labeling (25%)
- Adverse reactions (20%)

#### BIOLOGICS

- Contamination (40%)
- Potency issues (30%)
- Labeling errors (15%)

### TOP 5 CHALLENGES IN RECALL MANAGEMENT<sup>2</sup>



**Investigation**  
(scope/impact/ bounding)



**Recall Initiation**



**Product Logistics**



**Consignee Notice**



**Documentation**  
(effectiveness/proof of action)

### IMPACT OF RECALLS

#### PATIENT SAFETY

13.8%

In 2024, medical device recalls increased by 13.8% in Q1, reaching 296 events<sup>3</sup>

#### FINANCIAL IMPACT

\$10M – \$100M

The average cost of a recall, depending on the severity and scope<sup>4</sup>

#### REPUTATION

5–10%

Average stock price decline following a major recall announcement<sup>4</sup>

# Honeywell

LIFE SCIENCES

Sources

1 FDA, <https://datadashboard.fda.gov/ora/cd/recalls.htm>

2 AlphaSights, Medical Device and Pharmaceutical Recall Process: Quantitative Survey

3 24x7 Magazine: "Medical Device Recalls Up Nearly 14% in 2024."

4 Faster Capital, "The Impact Of Product Recalls On Businesses"

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