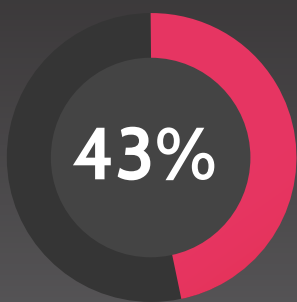


# 3 Overlooked Quality Challenges for Medical Devices

1



**Inadequate External Supplier Quality**



of manufacturers have limited or no visibility into their supplier network  
- [KPMG](#)

**Obvious Indicators**

- Manual processes and communications
- Overdue audits

**Invisible Indicators**

- Limited supplier traceability
- Unidentified supplier changes and corrective actions

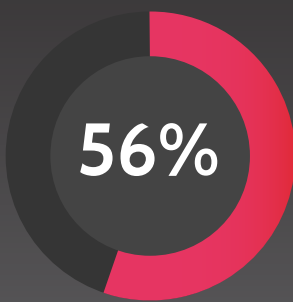
**Business Impact**

- Lack of supply chain continuity
- Reduced speed-to-market

2



**Lack of Oversight into Quality Related Risk**



of recalls are due to design flaws and manufacturing issues  
- [FDA](#)

**Obvious Indicators**

- Over-reliance on Excel
- Fragmented processes and disparate data

**Invisible Indicators**

- Limited QMS oversight
- Absence of risk-based decision making

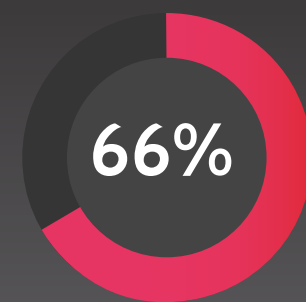
**Business Impact**

- Higher risk exposure
- Inability to improve product quality

3



**Inefficient Complaint Handling and Reporting**



of quality leaders indicate "sufficient staffing/ resourcing" as a top quality system challenge  
- [The FDA Group](#)

**Obvious Indicators**

- High volumes of records
- Repeat complaints

**Invisible Indicators**

- Unresolved complaints
- No actionable insights to improve product quality

**Business Impact**

- Slower response and reporting times
- Potential higher risk issues going unresolved



Increased Total Cost of Quality



Lower product quality



Higher risk of recalls



Impacted patient safety



Patient & customer dissatisfaction



Limited brand protection

[Find out how Sparta can help manage medical device quality](#)

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