

Quality Management in the Medical Device Industry

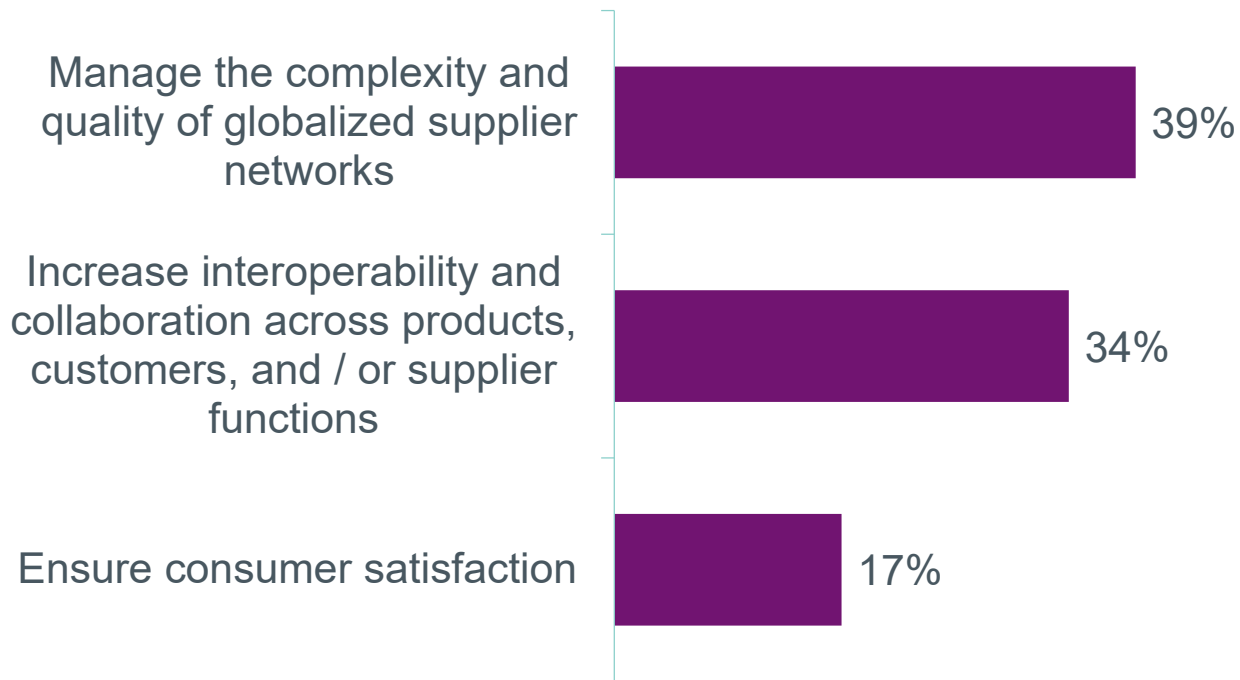
How Prioritizing Customer Satisfaction Has Influenced Approaches to Quality

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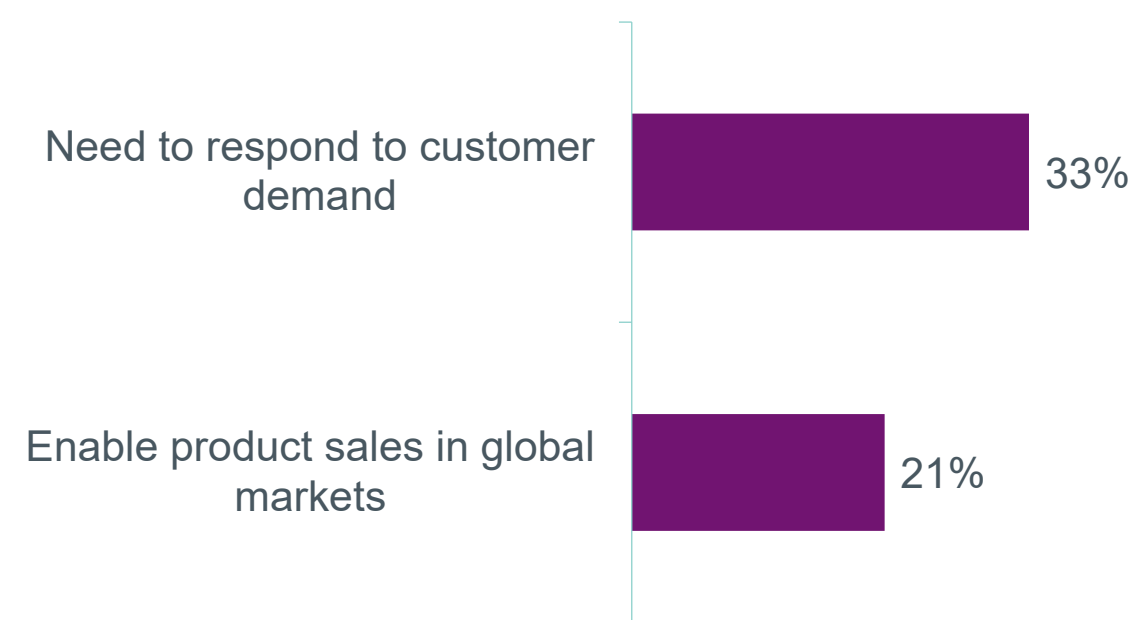
April 2020

Greater Pressure From Customers and Global Markets

Pressures to Improve Quality Management



Pressures to Improve Product Compliance

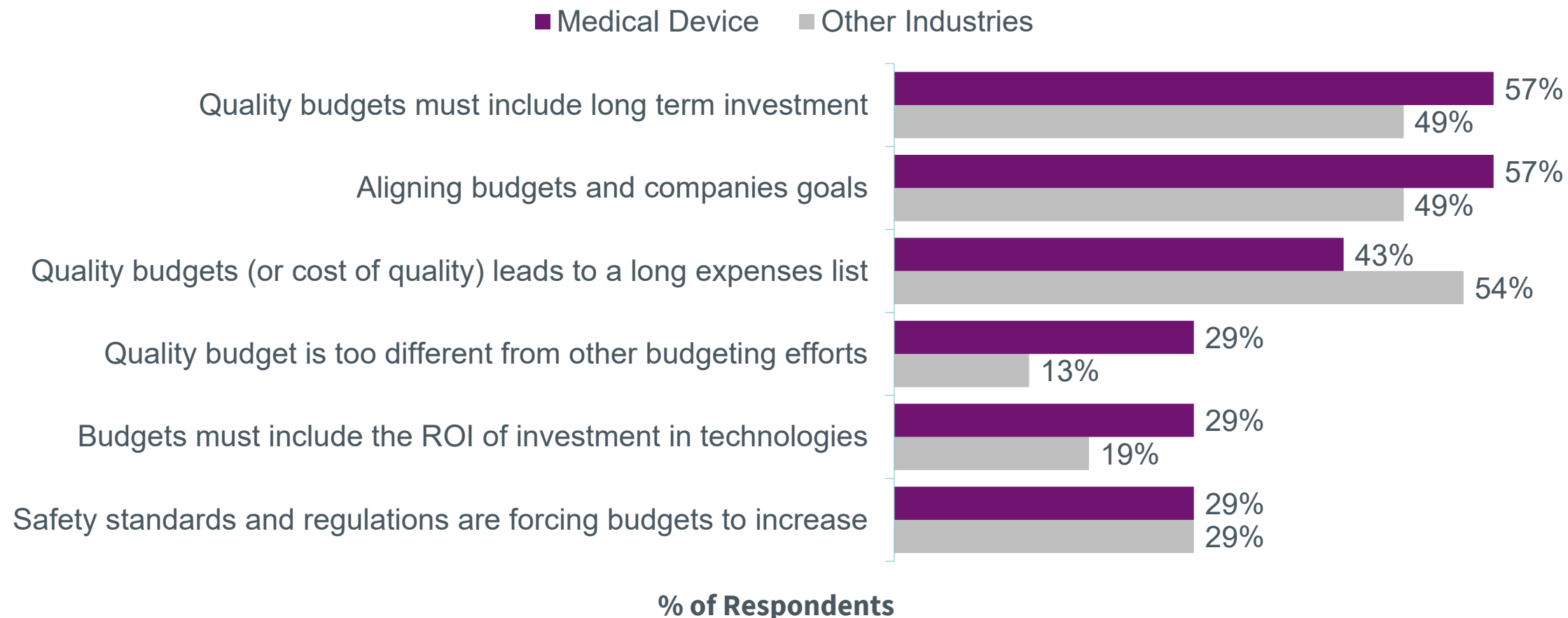


% difference between medical device respondents and all others

n = 305, Source: Aberdeen Group, April 2020

The largest differences in prevalence of pressures to improve quality management and product compliance revolve around the high expectations from medical device customers and the global nature of the medical device industry.

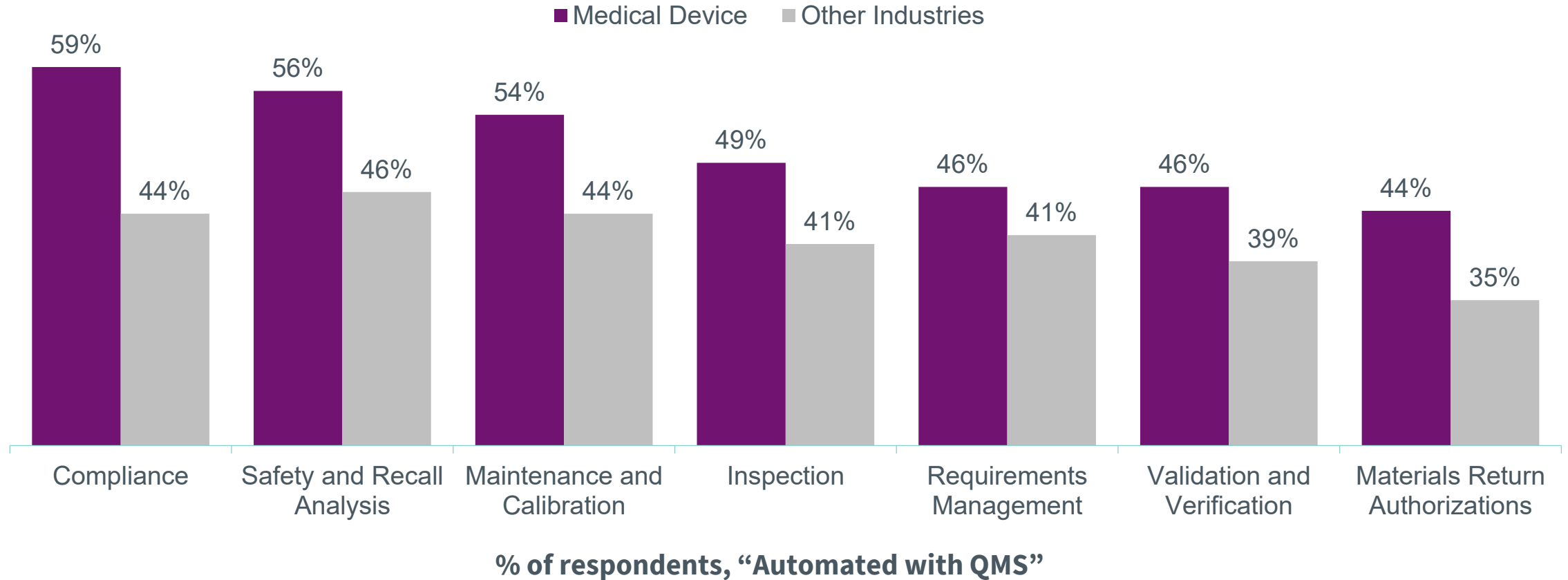
Challenges With Quality Budgets



n = 305, Source: Aberdeen Group, April 2020

While other companies struggle with the cost of quality, medical device manufacturers are concerned with long term investments and alignment with overall goals and budgeting efforts.

Advanced Automation of Technology Enablers



n = 305, Source: Aberdeen Group, April 2020

Medical device manufacturers are ahead of other industries with integrating additional capabilities into their QMS systems. The approximately 10% margins for these technologies show that medical device companies are investing in robust quality solutions.

Quality Management Program Distribution

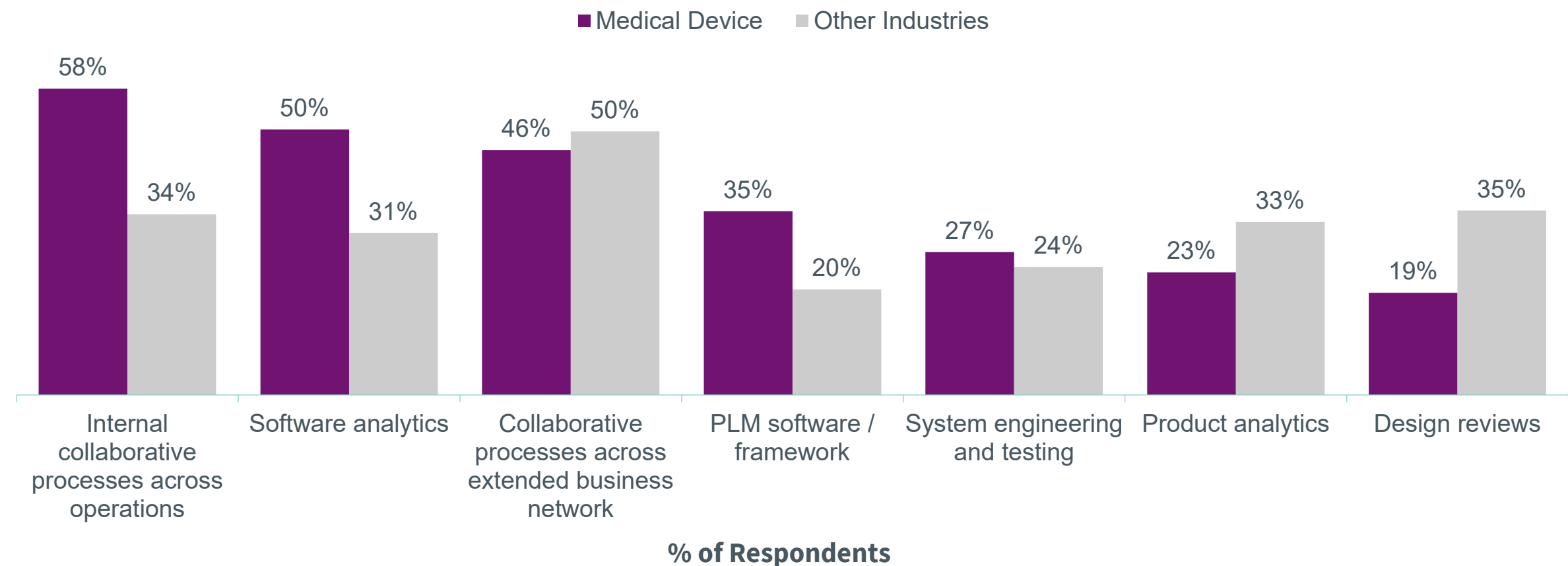
Automatic QMS Programs	IT or Enterprise Level	Business Units or Department Level
Data Federation	+150%	-100%
Automatic Data Integration	+112%	-100%
Master Data Management	+107%	-57%
Data Alignment with Business Model	+71%	-55%
Automatic Data Aggregation	+61%	-57%

Percentage Difference Between % of Respondents
for Medical Device and Other Industries

n = 305, Source: Aberdeen Group, April 2020

Medical device manufacturers are more likely to handle automatic quality data processes at the enterprise level. The disorganized transfer of data from enterprise teams down to department levels may be a detriment to the structure and volume of data.

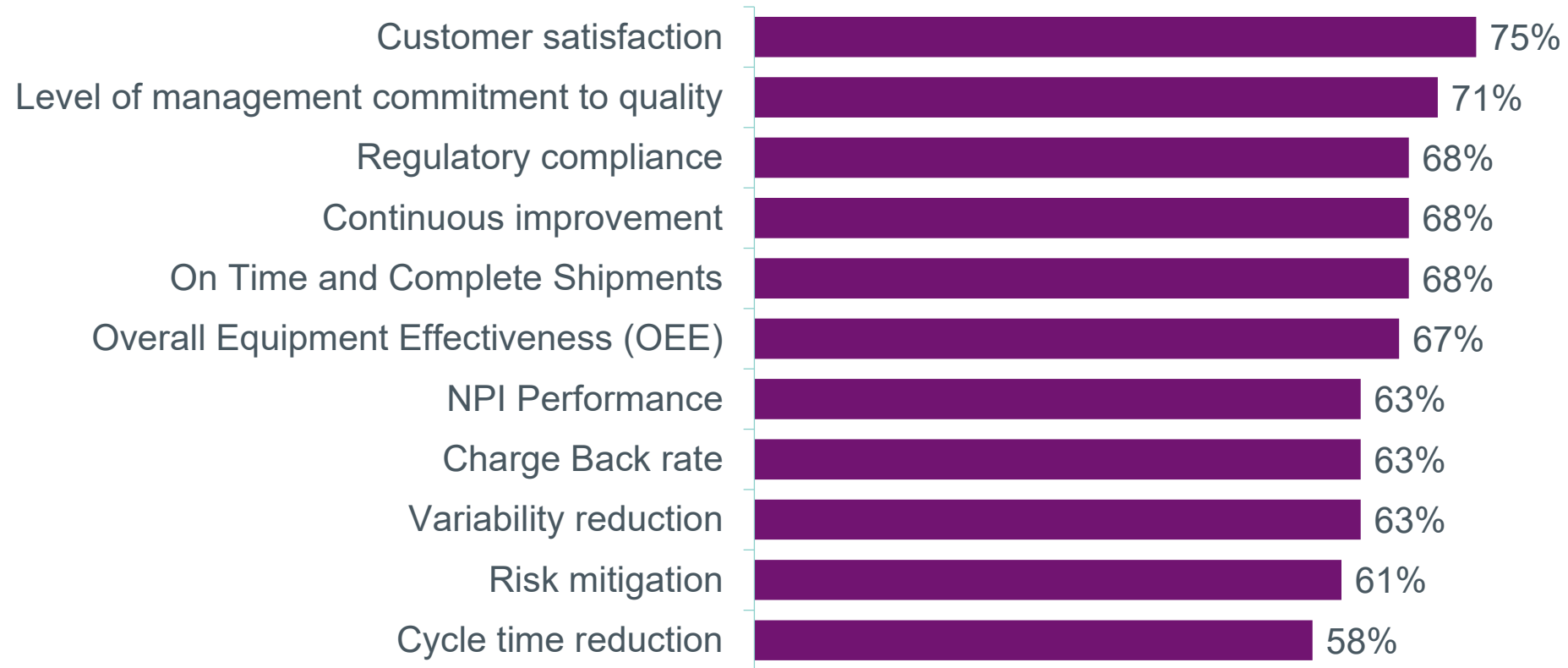
Methodologies Impacting Product Quality



n = 305, Source: Aberdeen Group, April 2020

The medical device industry is impacted more significantly by internal collaboration and PLM than other industries. With greater collaboration and a holistic view of products from design to deployment, medical device companies can optimize quality management.

Current Performance for Medical Device Manufacturers



Average % performance for medical device respondents

n = 305, Source: Aberdeen Group, April 2020

Prioritizing customer satisfaction has paid off for medical device manufacturers. Robust quality solutions, a holistic approach to quality, and global collaboration could be instrumental in seeing even greater business results.

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