greenlight guru

2021 BENCHMARK REPORT

STATE OF MEDICAL DEVICE QUALITY MANAGEMENT AND PRODUCT DEVELOPMENT

CHARTING A PATH FOR HIGH PERFORMANCE IN A POST-COVID ENVIRONMENT

CHARTING A PATH FOR HIGH PERFORMANCE IN A POST-COVID ENVIRONMENT

Last year we published our first annual Medical Device Product Development and Quality Management benchmark report to help organizations understand the strategies, tactics, and technologies that differentiate market-leading companies.

This year's report continues in this same direction while also exploring the growing market demands, operational challenges, and the weight of a global health crisis that is pressuring medical device companies to rethink strategies and solutions moving into 2021.

We surveyed hundreds of professionals working in the medical device industry — in both quality management and product development — to understand their approach to technology, risk management, process improvement, and even how they are weathering the pandemic.

Our goal is to give you a clear understanding of the critical industry benchmarks, technological shifts, and overcoming internal divides within organizations that will help you navigate through uncertainty and maintain a competitive advantage in the new year.

We hope this report enlightens and supports you in finding further success in the coming year.

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CRITICAL INDUSTRY BENCHMARKS

What can industry leaders learn about competitors' achievements in risk management, quality and efficiency? And how are companies faring in the face of pandemic pressures?

2021 OUTLOOK

Though the COVID-19 pandemic has buoyed the fortunes of some medical device companies due to spikes in demand, the crisis has largely wreaked havoc on supply chains and revenue projections. Earlier in the year, McKinsey was predicting a 40% to 50% decline in third-quarter demand for elective procedures in the US and Europe, a historic drop in revenue for the industry.[1]

Greenlight Guru surveyed hundreds of professionals working in the medical device industry — in both quality management and product development — to understand their approach to technology, risk management, process improvement, and even how they are weathering the pandemic.

Overall, survey respondents took a negative view about how the pandemic is affecting their company's prospects and financial viability. Some 63% report the pandemic is negatively affecting funding at their companies, a turnabout with critical implications, particularly for smaller companies with little excess capital or high leverage. And 59% say COVID-19 is negatively affecting time to market.

More than one-third of respondents (39%) report the crisis is threatening the financial viability of their organizations — not surprising given the findings noted above. Medical device companies rely on the free flow of capital through financial markets, something the pandemic has disrupted. As well, many companies are facing significant cash-flow pressures due to deferred demand and/or shrinking orders from existing suppliers/customers.

Yet looking ahead, the picture appears to be more favorable. About 38% say they expect strong revenue growth in 2021, and 41% expect modest revenue growth. Just 5% project revenues will shrink next year.

1 Healthcare innovation: Building on gains made through the crisis. McKinsey (11/2020)

Share (%) that agree the pandemic is affecting funding, time-to-market and financial viability.

EFFECTS OF THE GLOBAL PANDEMIC

Respondents say the pandemic has had serious repercussions on their organizations' financial health. not a strategic imperative.

Source: Greenlight Guru | 2020

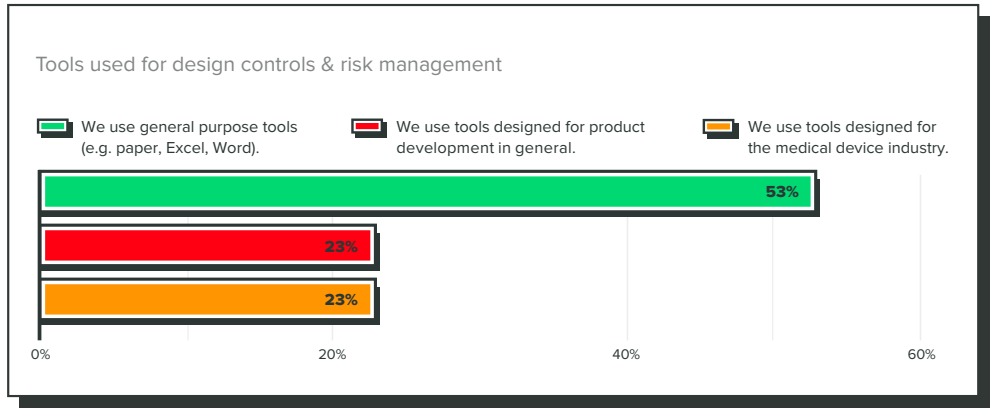
TECH ADOPTION

Similar to last year's findings, tech maturity remains stubbornly low in the industry. Roughly half of all respondents say they use general-purpose tools to support design control and risk management processes (53%) and for quality management processes (49%). Only 23% use design control and risk management software designed specifically for the industry and just 20% use a QMS specifically designed for the medical device industry. One survey taker explained, "[Our systems] are too manual; higher-ups do not appreciate the value of automation."

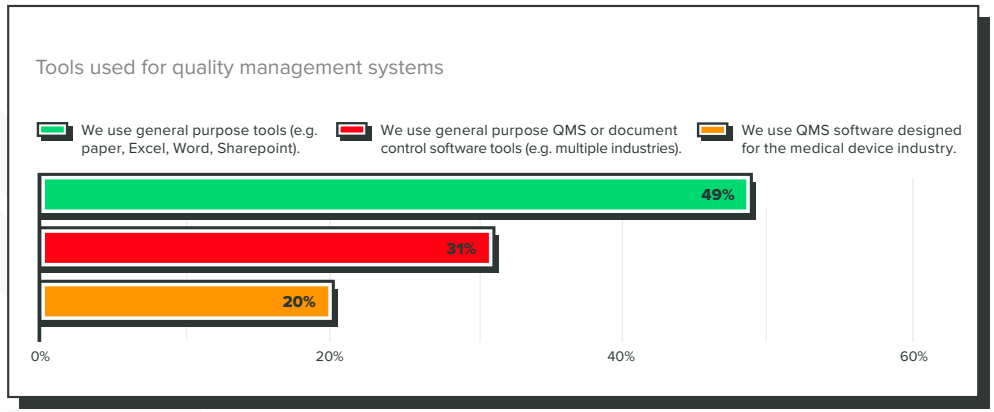
In practice, this means the majority of those not using purpose-built tools still rely heavily on storing and accessing documents on a shared network (3 in 4 report doing this) or accessing files under some type of document control (59%). Consider also: **these document-sharing solutions can introduce significant risks for organizations that now have teams working from home**; even for those who can access documents remotely, there are security challenges to contend with. Many document storage and sharing solutions not purpose-built for the medical device industry lack sufficient access controls, application controls, event logs, and end-to-end data encryption for sensitive files.

TECH MATURITY IN THE MEDICAL DEVICE INDUSTRY

Source: Greenlight Guru | 2020



Q: What solution(s) does your company use to support design controls & risk management processes?



Q: What solution(s) does your company use to support quality management processes?

RISK MANAGEMENT

Survey takers report a variety of challenges related to risk management, but the most common is a lack of clear ownership of risk throughout the product life cycle (35%) and not having access to the right information during design and development (34%).

Those who use design control and risk management software created for the medical device industry (versus those who use general-purpose tools) are much less likely to report a missing "feedback loop" of post-market processes and product risk. Nearly one-third of those who use general-purpose tools report there isn't a strong feedback loop of post-market processes into product risk, versus just 11% of those who use specialized design control and risk management software specific to the industry.

Overall, more than half say they cannot currently document closed-loop traceability and a surprising 14% say they have no plans to resolve this over the next 24 months — a troublesome finding given that closed-loop traceability is a regulatory requirement and regulatory bodies are placing a significant emphasis on it.

QUALITY METRICS

Given that just 2 in 10 say they use a QMS designed for the medical device industry, it's surprising that nearly 7 in 10 agree that "quality is woven into my company's culture"— a sign that some organizations are aspiring to a quality-first culture even when they may not have the best mix of tools to achieve it. A smaller share (45%) report that senior leadership at their organization sees quality management as a strategic asset rather than an area of control/compliance. As one survey taker shared,

> **"OUR COMPANY LEADERS DON'T APPRECIATE THAT QUALITY ISN'T JUST A BOX-TICKING EXERCISE."**

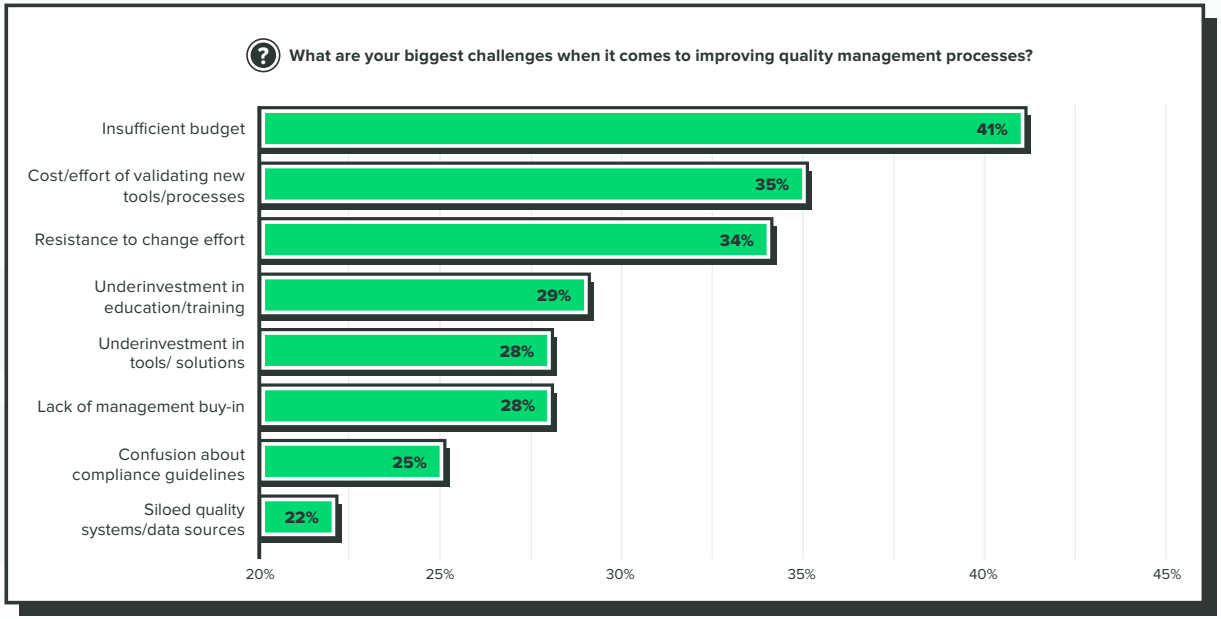
Another explained, "QMS [at my company] is just a hunt for signatures, even when they are aware that what has to be signed is not true. 'It's just for compliance and nobody will notice.' QMS is a circus to make the auditor happy. Of course, I have quit."

What are the biggest challenges in the area of quality management? Insufficient budget, the cost/effort of validating new tools or processes, and resistance to change efforts. This suggests that some who recognize that their organizations' tools and processes are inefficient are trapped by that inefficiency — unable to set aside time and resources to select and deploy better tools.

IMPROVING QUALITY MANAGEMENT

Cost, lack of time, and resistance to change all cited as top barriers to improving quality management.

Source: Greenlight Guru | 2020



Q: What are your biggest challenges when it comes to improving quality management processes?

MARKERS OF EFFICIENCY

This year, Greenlight Guru's survey focused specifically on markers of efficiency. Regardless of quality or total risk, how efficient are internal processes that oversee these?

The majority (59%) report their companies' processes are "efficient" or "very efficient" in bringing new devices to market. (Not surprisingly, investment in industry-specialized tools correlates with greater efficiency.)

Among the specific findings:

- On average, it takes **144 hours** to compile a design history file.
- Approximately **1 in 4** respondents say that documenting closed-loop traceability (CLT) requires "substantial effort." Just 28% say they can document CLT in real-time.
- **31%** say it takes 2 days or more to update a traceability matrix; only 13% can do so in less than one hour.

STRATEGIC INDICATORS

According to a large-scale study by McKinsey about the effects of the pandemic on business leadership and innovation, the pharma and medical products sector was the only one surveyed that increased its focus on innovation in 2020 compared to 2019[2] — a sign that some companies view the pandemic as an opportunity to eliminate complacency and focus on those factors that will drive growth and differentiation.

Greenlight Guru's survey looked at how companies view quality—whether as a requirement for compliance or a strategic asset that lends insights and improvements across the product development continuum. Roughly 1 in 3 respondents work for a company that values quality as a strategic asset, meaning quality is supported at every level of the organization and viewed as a competitive strength. An equal share (34%) say their organizations either value quality purely as a compliance activity or don't value quality at all. When asked whether quality data is used to make business decisions, just 1 in 4 said this is true.

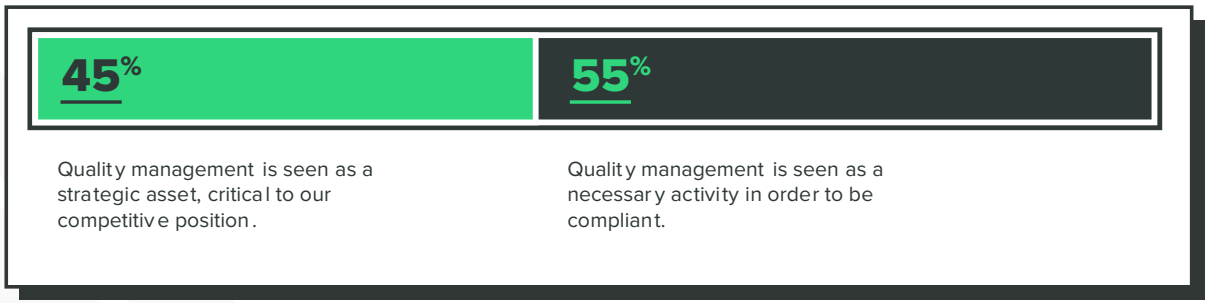
2 in 3 say quality is woven into their company culture.

> **SENIOR LEADERSHIP DOES NOT UNDERSTAND THEIR ROLE IN BRINGING IN A QMS. THEY DO NOT UNDERSTAND THAT THEY NEED TO OWN IT. THEY ONLY WANT TO BE TOLD WHAT TO DO TO BE BLACK-AND-WHITE TO A STANDARD.**
>
> – survey respondent

[2] "Innovation in a crisis: Why it is more critical than ever." McKinsey (June 2020)

QUALITY AS A STRATEGIC ASSET

Most still view quality as a compliance issue, not a strategic imperative.



Source: Greenlight Guru | 2020

Q: Does senior leadership within your company see quality management as a strategic asset or a necessary area of control/ compliance?

SIGNALS FROM MARKET LEADERS

In what ways do highly competitive companies outperform their peers?
The research uncovers what these best-in-class organizations do differently.

Of those surveyed, 40% report their organizations are highly competitive relative to market peers.[3] So, what separates these high-flyers from all the others?

Highly competitive companies are 4x more likely to forecast strong revenue growth in 2021 when compared to less competitive peers — though that level of out-performance is mostly expected. What else sets them apart?

Market-leading companies take a holistic approach to documenting design controls and risk. For example, 40% of high performers begin documenting design controls in a traceability matrix during concept and feasibility, compared to just 8% of lower performers, and 36% begin documenting risk during concept and feasibility, compared to just 14% of lower performers.

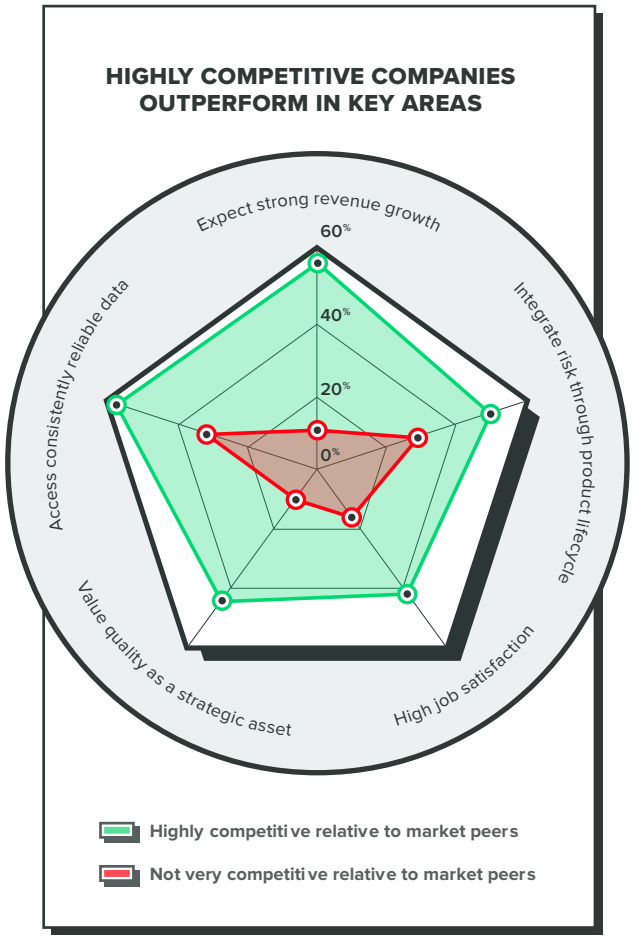
Half of high-performing companies say they fully integrate risk management into the QMS throughout the product life cycle, compared to 29% of lower performers.

High performing organizations are also 2x more likely to leverage traceability for impact analysis. When asked whether "engineers at my company spend more time on compliance paperwork than engineering," just 21% of high performers agreed with this statement, versus 50% of lower performers.

Perhaps not surprisingly, job satisfaction among professionals at high-performing companies is significantly higher: 81% of people working in high-performing companies report being "satisfied" or "very satisfied," versus 42% of those at lower-performing companies.

Finally, high-performing organizations view quality as a strategic asset; it's not a "checkbox" activity, but a key engine of competitive strength. Or, as one respondent phrased it,

> **"QUALITY MANAGEMENT IS THE GLUE FOR THE COMPANY; IT IS THE BUSINESS MANAGEMENT SYSTEM. WHEN VARIOUS PROCESSES ARE NOT IMPLEMENTED EFFECTIVELY, DEPARTMENTS WORK IN SILOS, AND IT RESULTS IN POOR OUTCOMES AND PERFORMANCE."**



Source: Greenlight Guru | 2020

[3] Survey-takers self-evaluated how competitive their organizations are relative to their peer group. They chose from the following answer choices: "highly competitive," "moderately competitive," and "not very competitive. This section compares "highly competitive" to "not very competitive" responses.

THE TECH ADVANTAGE

While technology is never curative, the right tools do give companies a significant advantage. The research points out the specific benefits that specialized technology for the medical device industry offers the companies that deploy it.

Roughly half of all respondents say their organizations still use general-purpose tools, both to support design control and risk management processes (53%) and quality management processes (49%).

We wondered: What advantages do companies that use technology specifically designed for the medical device industry have compared to those using general-purpose tools, in particular, a quality management system designed specifically for the medical device industry (MDQMS)?

MDQMS users are significantly more likely to project strong revenue growth in 2021 (50% say this, versus 31% of those using general-purpose tools). About 60% say the data generated by their quality system is consistently reliable, compared to 36% of those who use general-purpose tools. And those who use a specialized MDQMS are 1.7x more likely to be able to demonstrate closed-loop traceability and 1.7x more likely to say they are "very confident" the company can demonstrate product lifecycle traceability in the event of an unannounced audit.

Those using general-purpose tools may end up with good results, but they suffer due to the inefficiency of using tools not purpose-built. As one survey-taker noted,

> **"THE LEVEL OF DOCUMENTATION SUPPORT MY ROLE PROVIDES TO OPERATIONS AND DEVELOPMENT IS SIGNIFICANT AND NOT UNDERSTOOD BY SENIOR LEADERSHIP."**

Finally, those using purpose-built tools for the medical device industry are much more likely to say their MDQMS had a positive impact on securing funding — a finding that's particularly interesting given current conditions in capital markets. Some 69% of those using an MDQMS say their quality management system had a positive impact on securing funding, versus 40% of those using general-purpose tools.

UPSIDE OF PURPOSE-BUILT QMS TOOLS

Companies that use an MDQMS significantly outperform their peers in these key areas.

95% Feel confident they could pass an unannounced audit

50% Expect strong revenue growth in 2021 despite pandemic

70% Can currently demonstrate closed loop traceability

60% Have access to consistently reliable data

Q: What solution(s) does your company use to support quality management processes? [Answer choices: (a) general purpose tools (e.g. paper, Excel, Word, Sharepoint); (b) general purpose QMS or document control software tools (e.g. software that can be used for multiple industries); (c) QMS software designed for the medical device industry.]

Source: Greenlight Guru | 2020

BUILDING A QUALITY CULTURE

For organizations that aim to be top competitors in their niche, quality is seen as much more than a tactical advantage; quality is a mindset that influences best-in-class product development and product improvement.

Greenlight Guru asked respondents several questions about quality, including to what extent senior leaders see quality as an asset, versus seeing quality as a necessary aspect of compliance. What are the specific benefits that correlate to organizational leadership that values quality beyond a compliance requirement?

> **[MY COMPANY] DOESN'T UNDERSTAND THE CONCEPT OF CONTINUAL IMPROVEMENT APPLIED TO QMS PROCESSES. COMPLIANCE IS NOT THE END GOAL, IT SHOULD BE A MINIMUM EXPECTATION.**
>
> – survey respondent

Market strength: Companies that see quality as an asset are 2x more likely to say their organizations are "very competitive" relative to market peers than those that don't value quality the same way; they are also less likely to report experiencing the negative effects of the pandemic, such as loss of funding or slowed time to market.

Efficiency: Three in four (76%) quality-as-an asset companies say they are efficient in bringing new products to market, compared to 45% of all others. Quality companies are also 1.6x more likely to be able to demonstrate closed-loop traceability compared to those that don't prioritize quality, and they spend less time achieving traceability. Half of the companies that view quality as an asset can update their traceability matrix in four hours or less.

Risk management: Companies that treat quality as an asset are much more likely to integrate risk management throughout the product life cycle; 57% say they integrate risk throughout the life cycle, versus 34% of those that do not view quality as an asset. One survey taker explained the risk his/her company takes when it views compliance as a necessity, cut off from the overall health of the business: "The most influential members of senior leadership are not aware of the disparity between our current level of compliance and what is expected by many auditors. Maintaining the quality system does not always show immediate value, but when it becomes critical (audits, recalls, etc.) it is too late to fix things. Not prioritizing quality is a gamble."

Strategic point of view: Quality-focused companies are twice as likely to say the data from their quality management system is consistently reliable and twice as likely to report they often use quality system data to make business decisions. One survey taker explained that their company doesn't see the strategic value of quality, saying, "[My company] doesn't understand that quality is not about documentation for compliance, but how it contributes to the overall benefit for the company." Another complained, "Company leaders do not fully grasp the strength of a good interwoven quality system that feeds/covers every aspect of the firm."

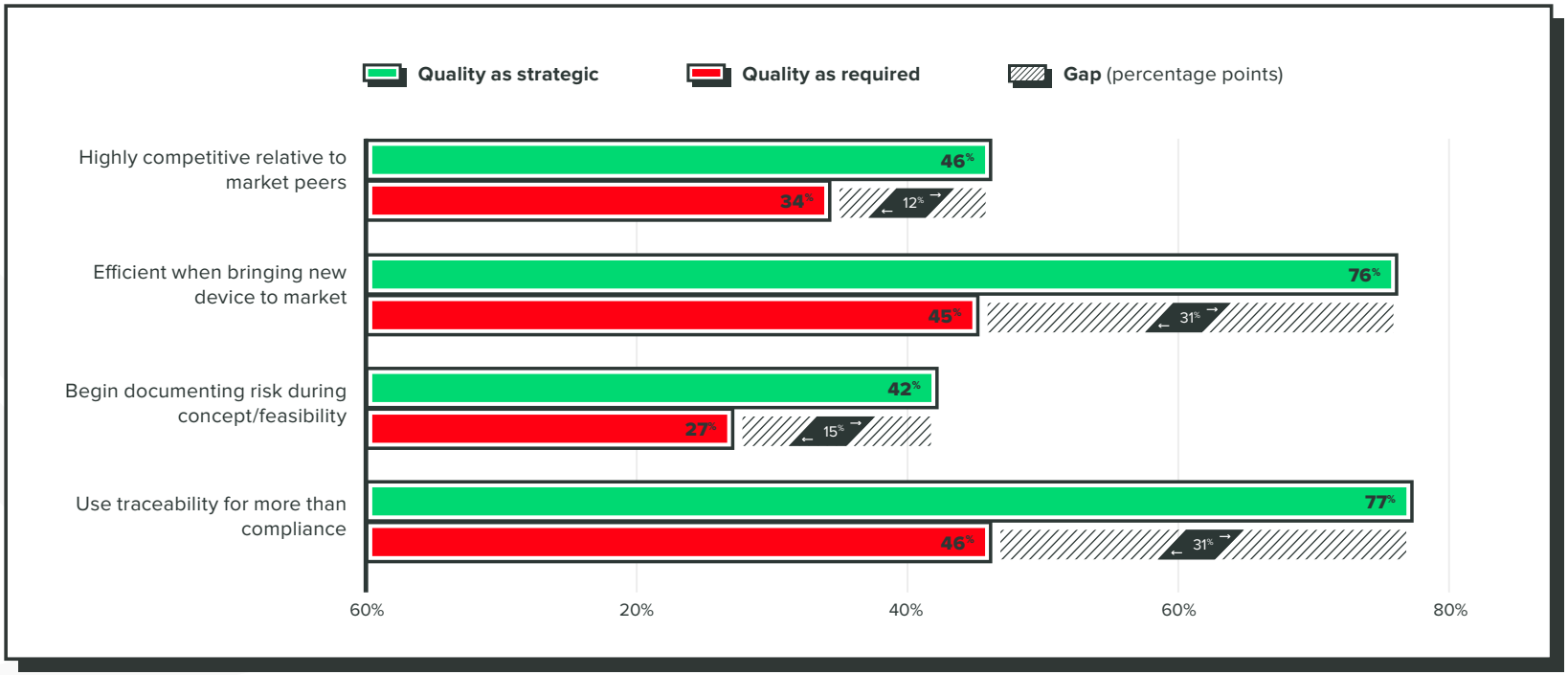
LEADERSHIP BUY-IN TO QUALITY CULTURE:

Organizations that prioritize quality tend to have leaders that support their efforts. For example, among companies that DO NOT prioritize quality, **50%** of employees say a lack of management buy-in is an obstacle to improving the product development process, compared to just **7%** of those who work for companies that view quality as a strategic asset.

Perhaps not surprising, people working at companies that prioritize quality are **4x** more likely to report feeling satisfied with their jobs. One survey taker shared what it feels like to work in an organization that doesn't value quality; he explained, "Quality is often painted as the bad guy who is forcing us to slow down to do work that doesn't matter."

QUALITY AS A STRATEGIC ASSET

When companies view quality as an asset rather than a compliance requirement, they tend to outperform in key areas.



Source: Greenlight Guru | 2020

Q: Does senior leadership within your company see quality management as a strategic asset or a necessary area of control/compliance?

LEADERSHIP MISALIGNMENT

Company leadership often has different focus and expectations vs. managers and individual contributors — and these differences can lead to additional risk, as well as affect job satisfaction.

The research shows that the way company leaders view opportunities and challenges differs greatly between management and what we call "contributors," or those on the ground completing the tactical work. This misalignment can not only lead to problems understanding and working toward shared goals; it can also breed resentment and job dissatisfaction.

What does each group view as the most painful tasks related to managing design controls? Executives are most concerned with ensuring traceability throughout the product life cycle, managers say documenting work throughout product development, and individual contributors are most focused on managing a "pile" of documents. Yet when it comes to the primary barriers in product development, all three groups agree: A shortage of resources.

When it comes to the biggest risk management challenges, there's a big divide between what executives say versus what managers say. Executives overwhelmingly choose "having enough information during the design and development process to assess product risk" (45% choose this), while managers point to "lack of clear ownership for risk throughout the product life cycle" (40%).

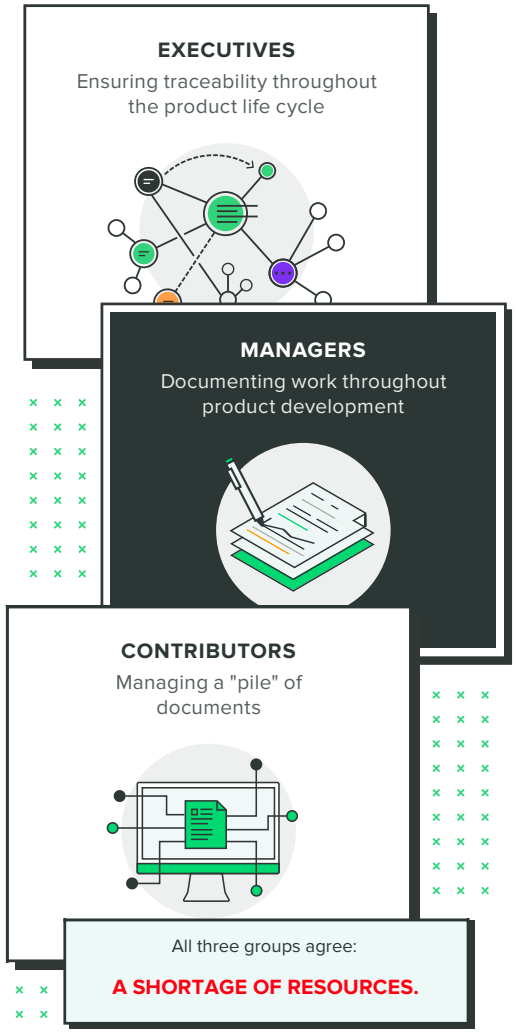
One survey taker described the way risk is treated at his/her company, and how little the function is appreciated:

> **"[COMPANY LEADERS] DON'T UNDERSTAND THAT RISK MANAGEMENT IS WOVEN THROUGHOUT THE ENTIRE LIFECYCLE OF THE PRODUCT AND THAT RISK-BASED APPROACH MUST BE PART OF OUR PROCESSES FROM START TO FINISH."**

Even more interesting, when asked whether their organization values quality as an asset, executives are much more likely to believe this is true. Some 46% of executives claim the company views quality as a strategic asset, versus 31% of managers and 34% of individual contributors. One survey taker explained:

> **"COMPLIANCE IS SEEN AS A NECESSITY/BURDEN AND IT IS HIGHLY SEPARATE FROM PRODUCT DEVELOPMENT, MY WORK IS OFTEN DISREGARDED AND SELDOM VALUED."**

PRIMARY BARRIERS IN PRODUCT DEVELOPMENT



Overall, executives tend to be more satisfied with the job. About 41% say they are “very satisfied” compared to 23% of managers and 30% of individual contributors. Understanding what drives these numbers is important. A few clues: Managers and contributors who work with purpose-built tools tend to be more satisfied than those who use general-purpose tools. And those who work at organizations that view quality as an asset are 2.5x more likely to be “very satisfied” compared to those who do not. One survey taker offered additional insight on this point:

> **[MANAGEMENT DOESN’T UNDERSTAND] THE HIGH-STRESS LEVELS CAUSED BY NONCOMPLIANCE.”**

POINT OF VIEW BY COMPANY ROLE

What are the key differences in point of view when comparing senior executives, management and individual contributors?

	Senior Executive	Management	Individual Contributor
"Shortage of resources" is a top barrier to improving product development process	44%	52%	57%
"Access to data" is a key challenge when assessing product risk	45%	32%	29%
Believe quality is woven into company culture	72%	67%	60%
Very satisfied in current role	41%	23%	30%

Source: Greenlight Guru | 2020

A PRESCRIPTION FOR 2021

What can organizations do to join the ranks of high-performing companies in the medical device industry?

Based on the research, we see four key areas for medical device companies to focus on in 2021 and beyond.

INVEST IN MOVING UP THE TECH MATURITY CONTINUUM

The research shows that those companies that invest in technology designed for the medical device industry gain efficiency and real-time insights, and they also tend to be more strategic in how they use risk and quality data to inform business decisions. Now more than ever, these companies are benefiting from process automation, more reliable data, and even AI-fueled insights to target failures or inefficiencies in the system. For best-in-class organizations, however, technology is not a solution to all that ails, but a "partner" in the journey to process improvement and efficiency, and quality management.

ADOPT A 'QUALITY CULTURE' APPROACH

Best-in-class organizations see quality not as a compliance requirement, but as a pathway to building value and fueling growth. A report from McKinsey found the direct cost of quality for medical device manufacturers to be approximately 6.8% to 9.4% of industry sales — and high-quality practices would reverse a large portion of these costs.[4] The path to high quality, says McKinsey, is in part about operational excellence (product and process controls, quality systems, etc.), but quality culture also plays a big role. The report's author explains,

> **"HIGH-PERFORMING SITES DO NOT LEAVE QUALITY TO THE QUALITY FUNCTION ALONE; INSTEAD, THEY EMBED QUALITY-RELATED ACTIVITIES INTO THE ROLES OF STAFF ACROSS THE ORGANIZATION."**

BUILD COHESION BETWEEN LEADERS, MANAGERS, AND CONTRIBUTORS

Companies should take steps to (a) diagnose the areas where leaders, managers, and on-the-ground contributors have differing perceptions of the organization's priorities and practices. Do these groups have shared values? Do managers and individual contributors feel understood and valued by leaders?

A big step in the right direction: addressing process inefficiencies and dysfunction. Too often the "cost" of new technology, more reliable data, and improved quality systems are much less than the cost of not doing these things — punitive expenses in the form of wasted labor hours, noncompliance, product development delays, and employee turnover.

[4] "Capturing the value of good quality in medical devices." McKinsey (February 2017)

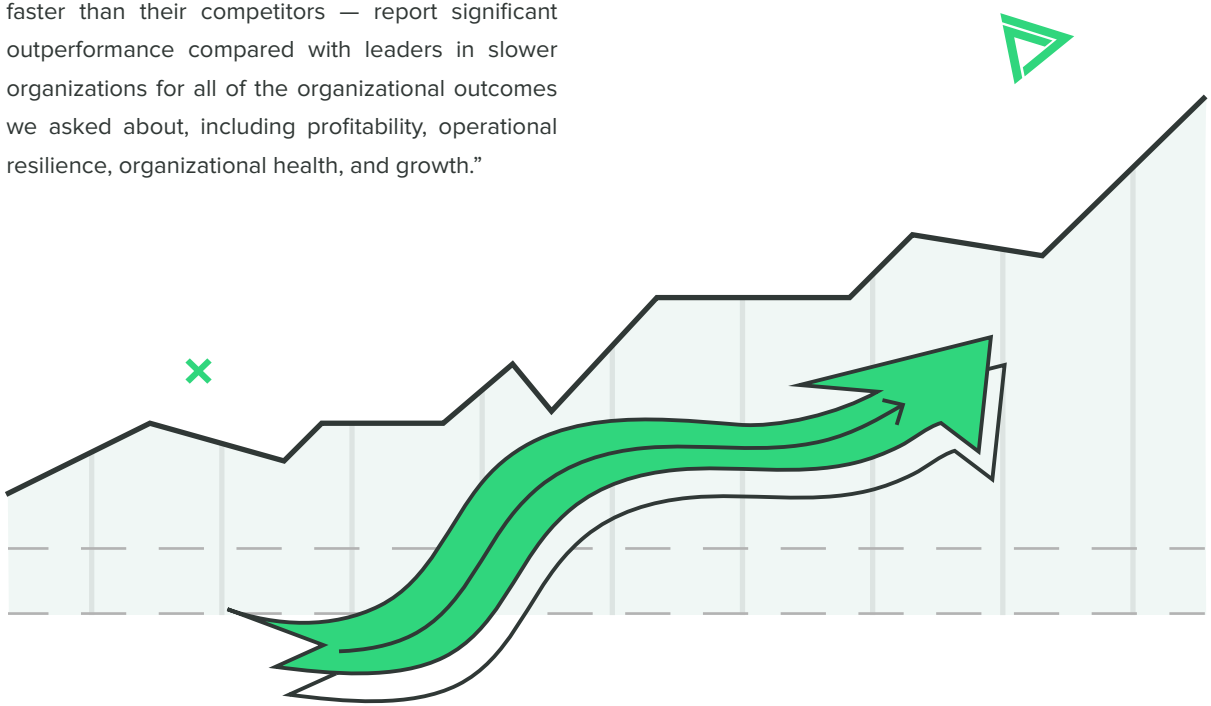
MEASURE BASELINE PERFORMANCE WITH AN EYE TOWARD INCREMENTAL IMPROVEMENTS

The pandemic has forced many businesses to rethink the pace of development, as well as the cost of pushing ahead with existing plans in the face of a radically different market environment. A report from RBC Capital Markets explains,

> **"IN [THE HEALTHCARE] SECTOR, THE NEXT PHASE OF COVID-19 WON'T BE A SLOWDOWN BUT AN ACCELERATION OF CHANGE AND INNOVATION, MANY OF WHICH WERE SIMMERING IN THE BACKGROUND BEFORE THE PANDEMIC."**[5]

Companies must define the specific metrics that will drive value, innovation, and growth even once the pandemic has passed. For example, what can organizations do to free engineers from "paper pushing" and redirect them to more valuable (and satisfying) activities? What would be the return on investment for technology upgrades? And where can leaders design efficiency and speed into the process?

In the COVID era, agility and speed are of particular concern. A McKinsey study analyzed changing priorities among business executives during the pandemic and "speed" was the top priority. The report explains, "Leaders at faster organizations — that is, those who say their organizations are significantly faster than their competitors — report significant outperformance compared with leaders in slower organizations for all of the organizational outcomes we asked about, including profitability, operational resilience, organizational health, and growth."

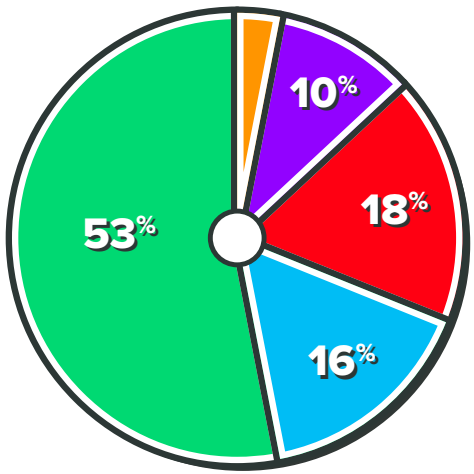


[5] "The impact of COVID-19: a catalyst for change, innovation and investment." RBC Capital Markets

METHODOLOGY

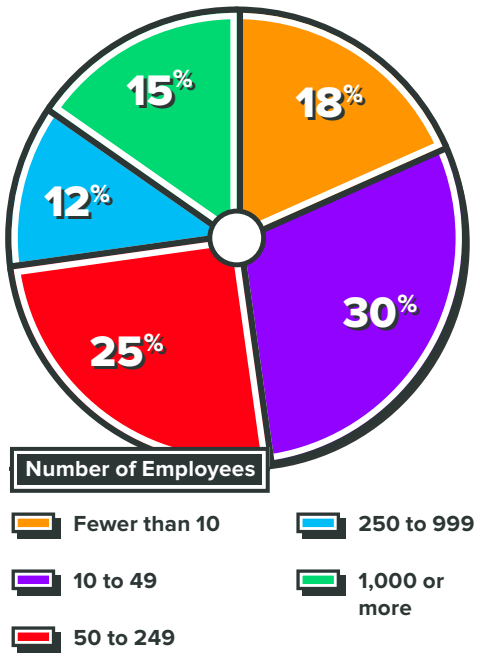
The results in this report are from an online survey that was fielded between October 6 and 20, 2020. It had 311 respondents, all of whom completed the survey. Key demographic variables are included below.

YEARS OF EXPERIENCE IN INDUSTRY



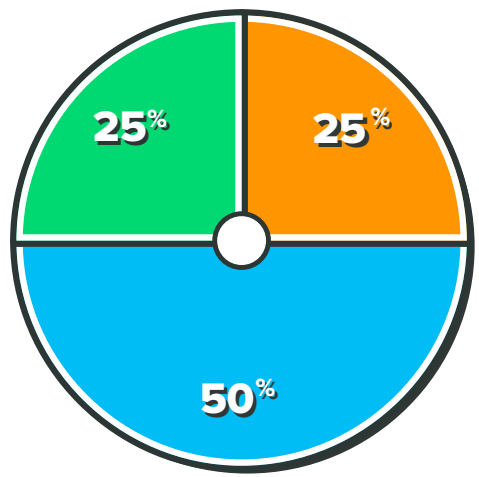
Source: Greenlight Guru | 2020

SIZE OF COMPANY



Source: Greenlight Guru | 2020

ROLE IN COMPANY



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