2020 INDUSTRY BENCHMARK

STATE OF MEDICAL DEVICE PRODUCT DEVELOPMENT & QUALITY MANAGEMENT

RESULTS FROM A SURVEY OF OVER 500 MEDICAL DEVICE PRODUCT DEVELOPMENT AND QUALITY PROFESSIONALS FROM AROUND THE GLOBE

greenlight guru

INTRODUCTION

Medical device companies, more specifically product development and quality teams, are expected to deliver innovative, life-changing medical device(s) at a rapid pace, all while maintaining compliance and achieving true quality – no pressure.

This balancing act of staying up-to-date with the ever-changing regulations and satisfying the need to work efficiently, while scaling processes, has made product developers' and quality professionals' heads hurt.

To help paint a picture of the strategies, tactics, and technologies today's medical device professionals are using to accelerate product development, ensure compliance, and promote quality, we are releasing the results of our first annual Medical Device Product Development and Quality Management Benchmark Survey.

We asked what it is that helps their teams or holds them back from becoming more efficient and nimble, while ultimately delivering better patient outcomes and positively influencing their company's competitiveness in increasingly crowded markets.

This report shares the results of hundreds of survey responses from medical device professionals across the globe. They shared helpful insights and critical information about how their companies are currently managing both their product development and quality activities. The size and stage of development for each company varies, yet we uncovered indicators of market leading companies and what it takes, or doesn't take, to get there in 2020 — without all the headaches.

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KEY CHALLENGES

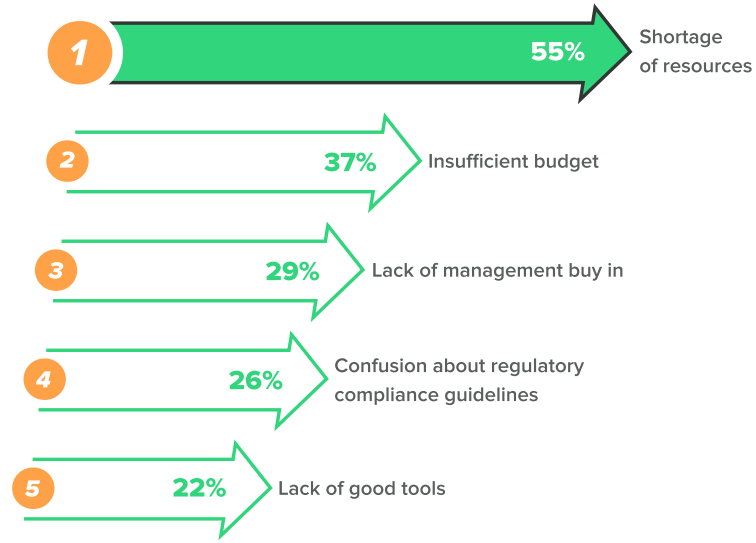
When challenges are brought about organically — through shifts in the market, new technologies, or simply a challenge outside one's reach — it's one thing. But when they're self-inflicted, it's quite another.

Misallocated resources, insufficient budgets, and misguided management priorities are all self-inflicted challenges that hold companies back from achieving maximum efficiency during the product development process.

> **Misallocated resources, insufficient budgets, and misaligned management priorities are self-inflicted challenges that hold organizations back.**

Survey-takers shared that the key barriers to improving the product development process are a shortage of resources (55%), and insufficient budget (37%). A lack of management buy-in was also a problem for more than 1 in 4.

Primary barriers for improving product development processes



Source: Greenlight Guru | 2019

KEY CHALLENGES

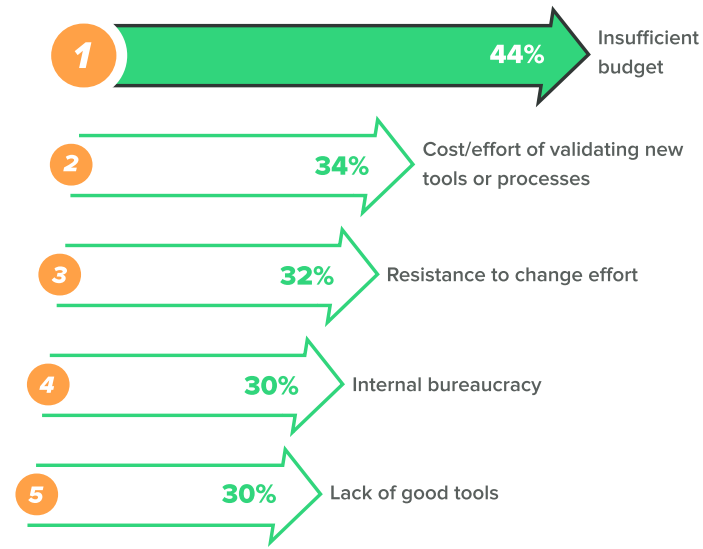
Barriers to best-in-class quality management were similar. Insufficient budget was the most-cited challenge (44%), followed by the cost of validating new tools (34%) and resistance to change efforts (32%).

“The company does not prioritize resources for QA[...] and sees the function of the department as required for compliance with the law only,” shared one survey respondent, employed by a medical device manufacturer in North America.

Technology Late-Adopters

Another area of critical concern: using legacy technology for complex processes and record-keeping.

Primary barriers for improving quality processes



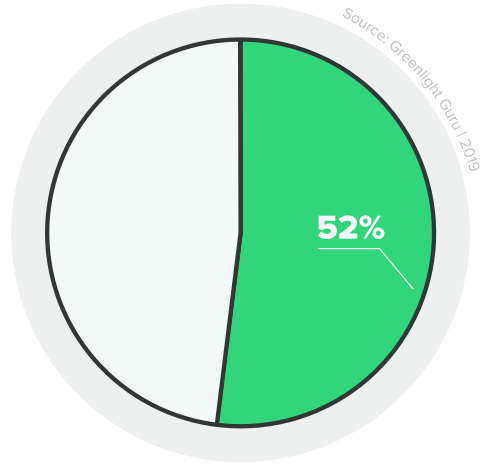
Source: Greenlight Guru | 2019

KEY CHALLENGES

Nearly 3 in 5 survey respondents say they are using legacy tools to support quality management processes, and more than half use legacy tools to support design controls and risk management processes. Legacy tools include off-the-shelf solutions like Microsoft Excel and Word, as well as paper-based record-keeping.

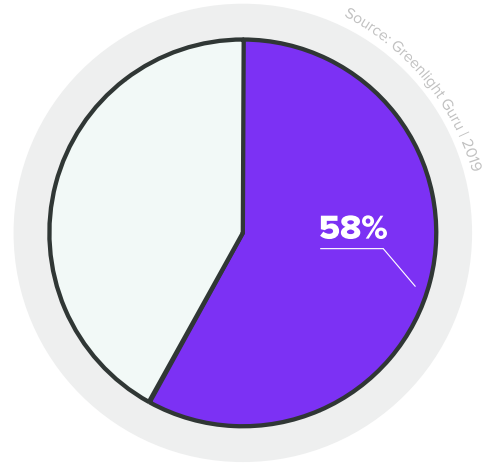
These generic tools create a ripple effect of inefficiencies felt throughout the organization — but, as long as profits continue to outweigh losses, many organizations will simply continue plugging along. “No need to change as long as there is enough profit,” said one respondent who works for a medical device manufacturing firm in the United States.

What companies are using to support their design controls and risk management processes



52% We use legacy tools that are not designed for the purpose for which we are using them (e.g. paper, Excel, Word).

What companies are using to support their quality management processes

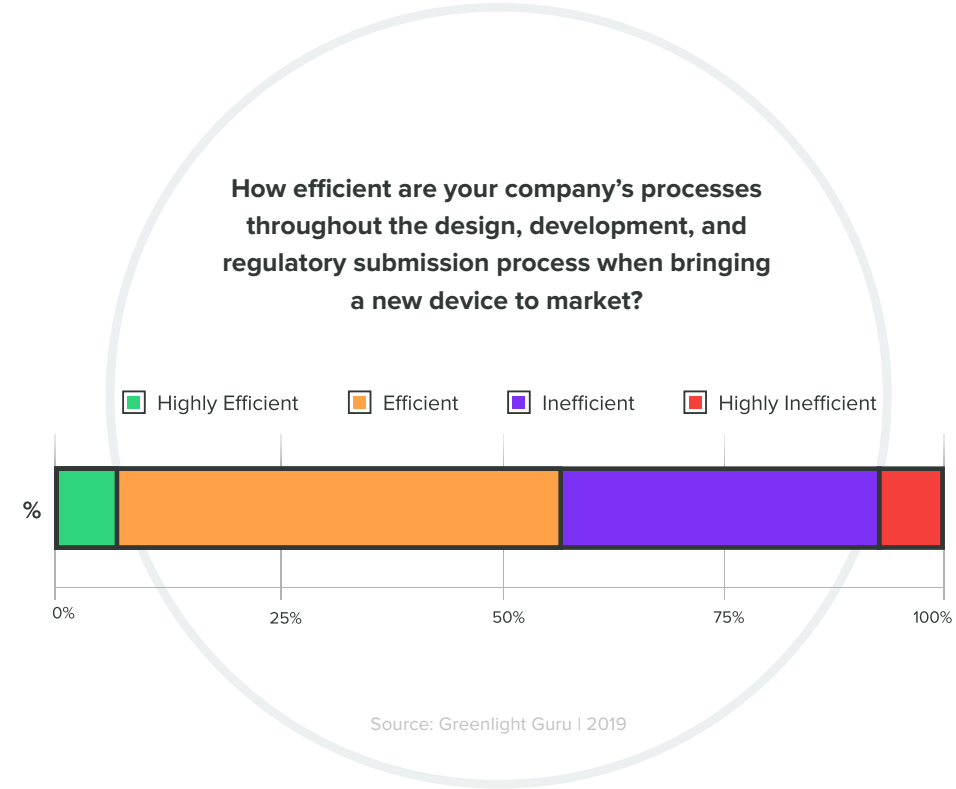


58% We use legacy quality management tools, including some paper-based systems (e.g. MS Office, Dropbox, etc)

KEY CHALLENGES

Inefficiency is a Widespread Concern

Nowhere in the organization is this resistance to change felt more strongly than in the realm of efficiency; of the 518 organizations surveyed, only 7% said that they consider themselves to be highly efficient throughout the process of bringing a new device to market.



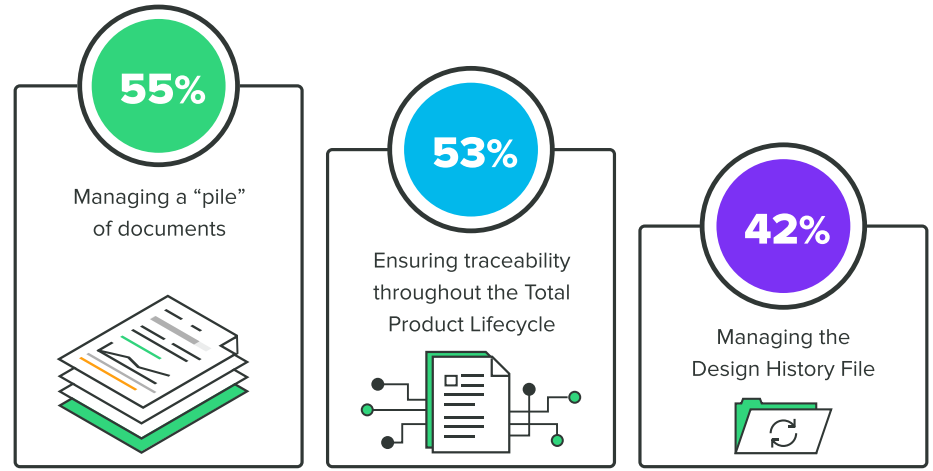
KEY CHALLENGES

A key example of this issue is the number of hours required to compile a design history file; the average response was **212 hours.** To put that in perspective, that comes out to five-and-a-half weeks of work hours for an employee. Of the organizations surveyed, **42% said that managing design history files was a major challenge.**

Echoing this, one survey respondent who works for a design and development firm in the Pacific northwest says that the most frustrating aspect of their job is the “level of manual operations in collecting quality data.”

Top 3 Pains of Design Controls

What are the specific pain points related to documenting and managing design controls?



Source: Greenlight Guru | 2019

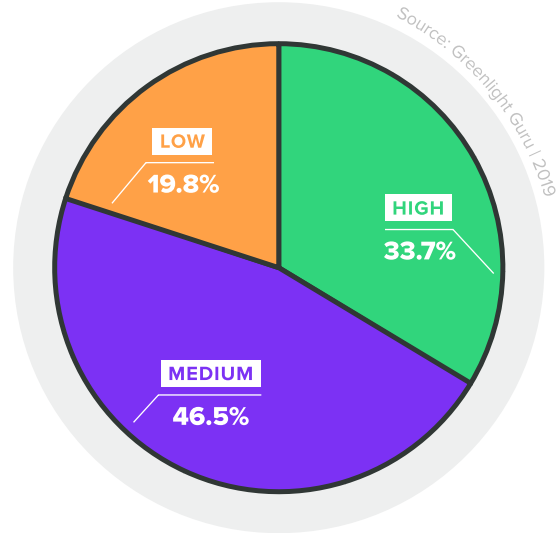
KEY CHALLENGES

Other challenges that chip away at efficiency when managing design activities include document management (cited as a challenge by 55% of survey-takers), ensuring traceability throughout the Total Product Lifecycle (53%), and managing the Design History File (42%).

When asked about his greatest challenges on the job, one respondent to the survey, an employee of a design and development firm located in the western United States said, “the amount of simple tasks that take time and distract from being proactive.”

Additionally, while closed-loop traceability (CLT) is revolutionizing aspects of product development the design, development, manufacturing, quality, and compliance activities, just under half (46%) of respondents agreed they can demonstrate CLT at this time. This finding is of especially high concern as we are mere months away from the deadline for EU MDR compliance (May 2020). The effort required to demonstrate CLT to Notified Bodies will cause tremendous inefficiencies for these organizations.

Effort required to document Closed-Loop Traceability



33.7%
Documenting closed-loop traceability requires substantial effort.

46.5%
We have not achieved real-time, documented traceability, but the effort required to document is modest.

19.8%
We document closed-loop traceability in real time.

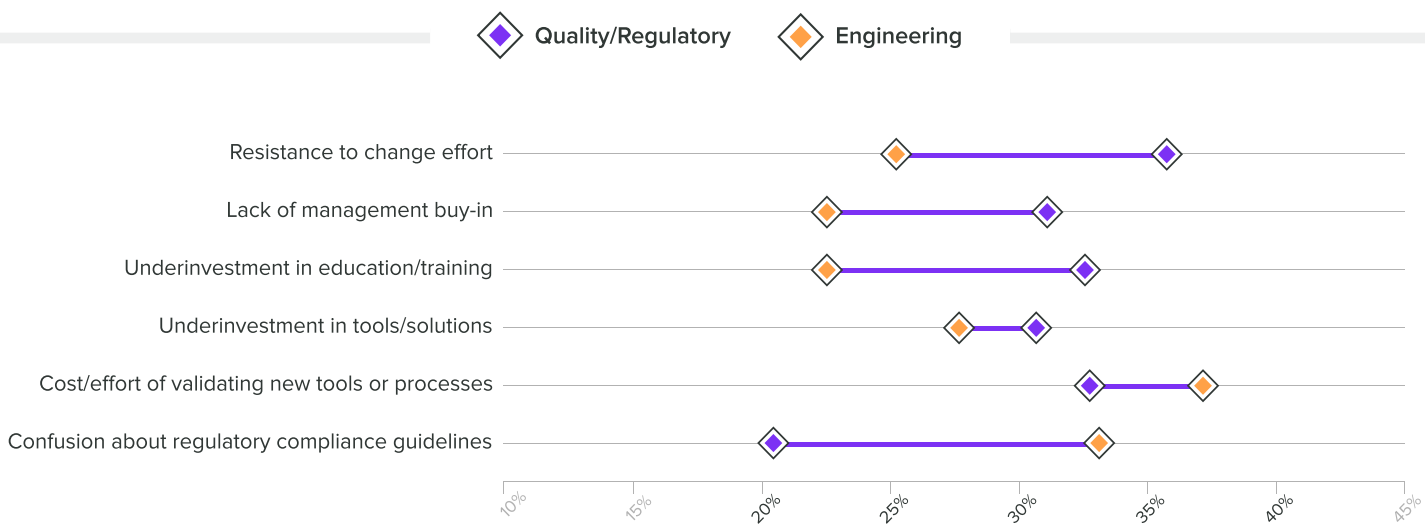
Definition of Closed Loop Traceability: The ability to connect people, processes and data seamlessly across the value chain. For example: product-related customer complaints or non-conformances can be traced back to specific design control elements.

A MATTER OF PERSPECTIVE

The unique challenges industry professionals experience vary by role, as do priorities. When we examine the perspectives of those working in quality versus those in product development, interesting differences emerge.

Listing the biggest challenges related to improving quality management, those in quality roles are most likely to cite “resistance to change” — and are 44% more likely to say so than those working in product development. And product developers are over 50% more likely than quality/regulatory professionals to cite “confusion about the regulatory environment.”

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



Source: Greenlight Guru | 2019

A MATTER OF PERSPECTIVE

Priorities change by role, too. When asked about their top quality management priorities in 2020, those in quality roles stress “updating compliance to a new standard or regulation” — cited it 50% more often than for those in product development (engineering and R&D). Those in product development are much more focused on “ensuring compliance to stay audit-ready.”

What are your top quality management priorities in 2020?

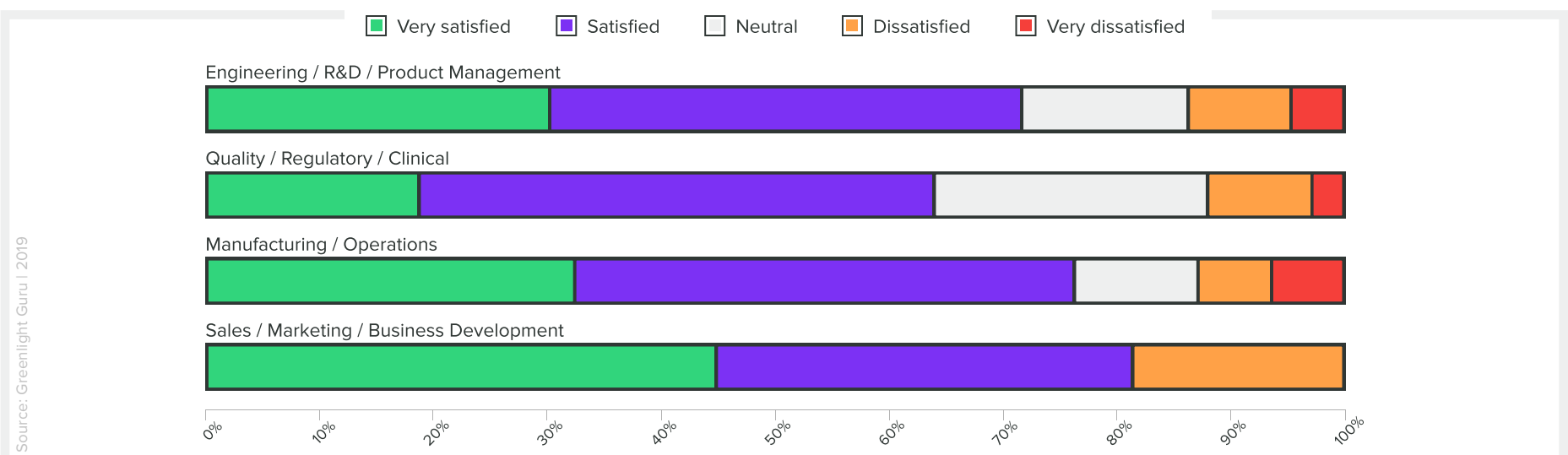
Source: Greenlight Guru | 2019

A MATTER OF PERSPECTIVE

Job satisfaction: Another interesting area of variance: the job satisfaction rates of different roles within the medical device industry. Overall, the roles surveyed report relatively high levels of satisfaction (68% of respondents were either “satisfied or very satisfied”). Nearly 1 in 3 of those in product development report being “very satisfied,” while just 19% of those in quality roles say the same thing. Those in sales and marketing have the highest levels of satisfaction; 45% reported being “very satisfied.”

One respondent who works for a design and development firm located in the Rocky Mountain states explains, “I feel like I spend my time being the bearer of bad news,” this person said. “As I dig in and learn more about compliance, senior management is less than enthused to hear what I have to propose.”

How satisfied are you in your current role?



QUALITY-AS-AN-ASSET

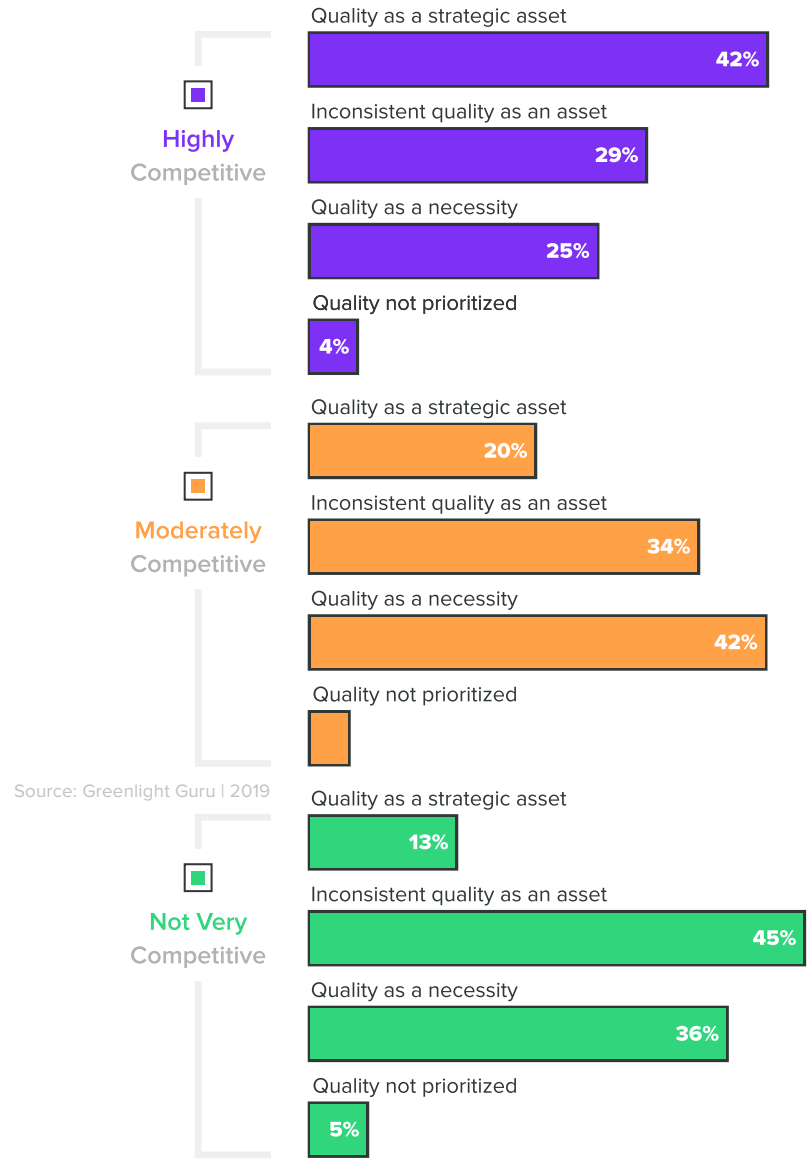
For the industry's top performers, quality isn't just a buzzword — it's a cultural value.

Our research found that companies considering themselves highly competitive were over 3x more likely to view quality as an asset compared to companies that didn't consider themselves to be very competitive. Indeed, organizations that see compliance only as a necessity are less likely to consider themselves competitive.

> **Companies considering themselves highly competitive were over 3x more likely to view quality as an asset.**

"QMS is seen as a quality department function and not a culture with responsibilities in most all areas of the business, such as change management, product and process controls, design controls, CAPA, procurement, etc...," said a respondent who works for a medical device manufacturer and supplier from the American south. While one would hope that most organizations are committed to quality, this respondent's views regarding management's priorities are fairly common within the field.

How Quality Culture Impacts Competitiveness



Source: Greenlight Guru | 2019

QUALITY-AS-AN-ASSET

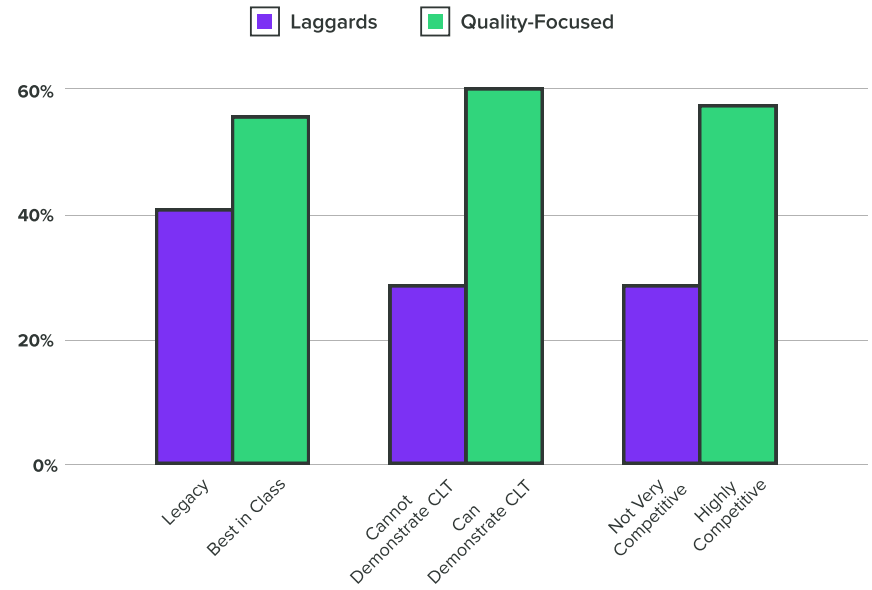
Another respondent from a design and development firm in Germany was even more harsh. “Regulatory aspects are more or less ignored in favor of fast but poor-quality results.”

“Quality-as-an-Asset” means building quality into every stage of the organization’s strategy and business processes — from device design and development to manufacturing, sales, and post-market surveillance once devices are being used by end-users. In order to reach this level of embeddedness, the organization must embrace this principal culturally, from the top down.

Of the organizations that say they use legacy tools such as Excel or paper, less than half (41%) agree that quality is woven into the organization’s culture (compared to 56% using best-in-class tools).

It’s also worth noting that 69% of the organizations surveyed reported using between 2 to 5 tech solutions to manage quality processes. It’s difficult to know whether that technology stack includes one or two best-in-class tools, but prior research suggests few are using all-in-one solutions that handle the majority or entirety of their quality management needs. In other words, many organizations’ quality management efforts are still fractured, siloed and disorganized.

When quality is woven into a company’s culture - it shows



Source: Greenlight Guru | 2019

QUALITY-AS-AN-ASSET

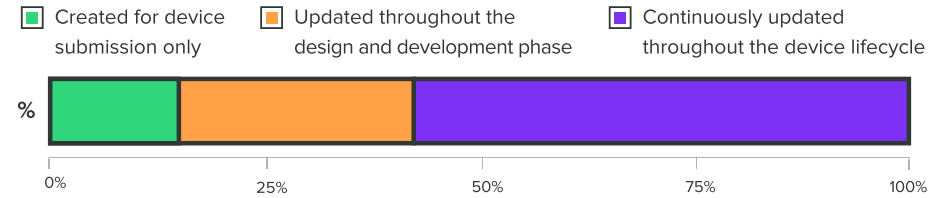
When it comes to design controls, 75% of respondents say they view design control activities as essential to the quality and safety of their devices, 13% say they view it as simply a necessary quality activity and 12% say they do it primarily for compliance. And, while the majority of respondents (57%) manage design controls and design history files continuously throughout each product's lifecycle, 27% indicate they only update them during the design and development stage, and another 15% compile them for device submission only.

Not all organizations that technically follow the rules and regulations for quality truly embrace them. When asked what they would most like to see, one respondent to the survey from an OEM firm in the Rocky Mountain region said, "Attention to detail in creating quality results rather than just checking off boxes for compliance's sake."

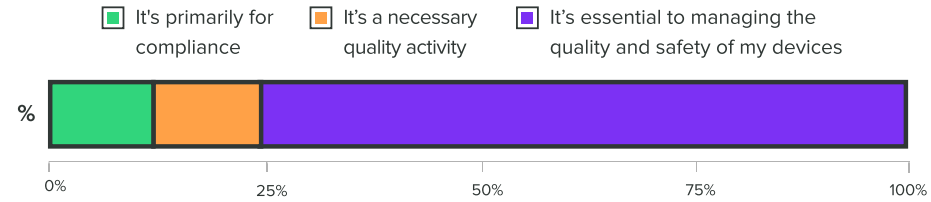
> **"Management would rather have a bad document in 10 minutes then an excellent document in two days."**

Design Controls Activites

What is your organization's approach to managing Design Controls and Design History Files (DHFs)?



How do you view design control activities?



Source: Greenlight Guru | 2019

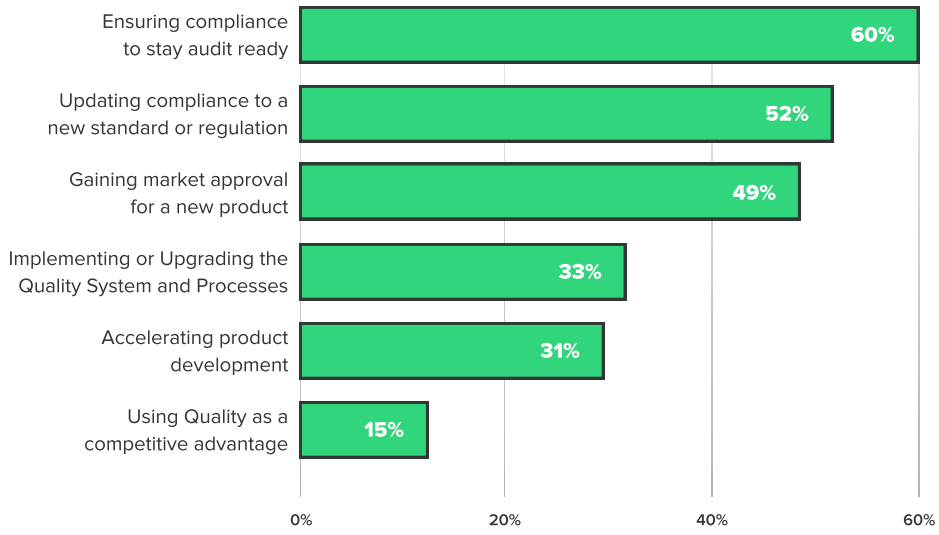
QUALITY-AS-AN-ASSET

Additionally, organizations that embed quality into their culture starting at the top — when the company's top leaders consider quality to be a priority — were 50% more likely than their peers to have risk management activities fully integrated into their QMS throughout the product lifecycle.

So, what's next for quality-focused leadership? Top quality management priorities for 2020 include ensuring compliance to stay audit-ready (60%), updating compliance to a new or standard regulation (52%), and gaining market approval for a new product (49%).

So, it's safe to say that the most productive and competitive organizations in this industry are looking forward to an active 2020.

What are your top quality management priorities in 2020?



Source: Greenlight Guru | 2019

THE RISK CONUNDRUM

When it comes to managing risk, leaders in quality and product development worry most about having access to enough information to assess product risk.

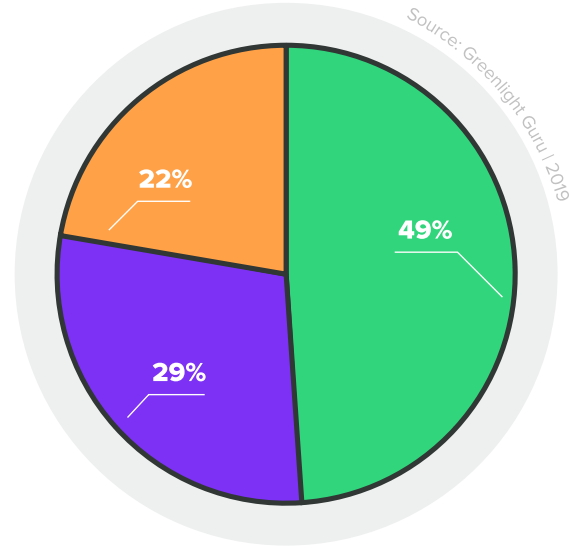
First, a quick look at what organizations do to manage risk: Almost half (49%) of respondents say that they fully integrate risk management into their quality management system throughout the device lifecycle; another 29% say they do not fully integrate risk management into the device lifecycle, but that documenting risk takes minimal effort. However, 22% of respondents — none of which integrate risk management into the quality management system — admit that risk documentation is a substantial effort for their organizations.

But here's a quick peek at what's missing: Sixty-five percent of very small businesses (VSBs) with under 25 employees admit they still use legacy systems — including paper-based systems — to support quality management processes. That's enough to put an auditor's teeth on edge.

And the statistic doesn't get much more positive when looking at small (25 - 249 employees) or mid-size (250 - 999 employees) organizations, either, which reported that 61% and 56% of their organizations also do this, respectively. The number drops off a bit for large companies with 1000 employees and above with 35% admitting to this practice, but the point is that many organizations could stand to modernize their quality management processes.

Integrating Risk Management

How would you describe the effort required to integrate risk management throughout the entire product lifecycle



49%
We fully integrate risk management into our quality management system throughout the product lifecycle.

29%
We do not fully integrate risk management into our quality management system, and documenting risk takes modest effort.

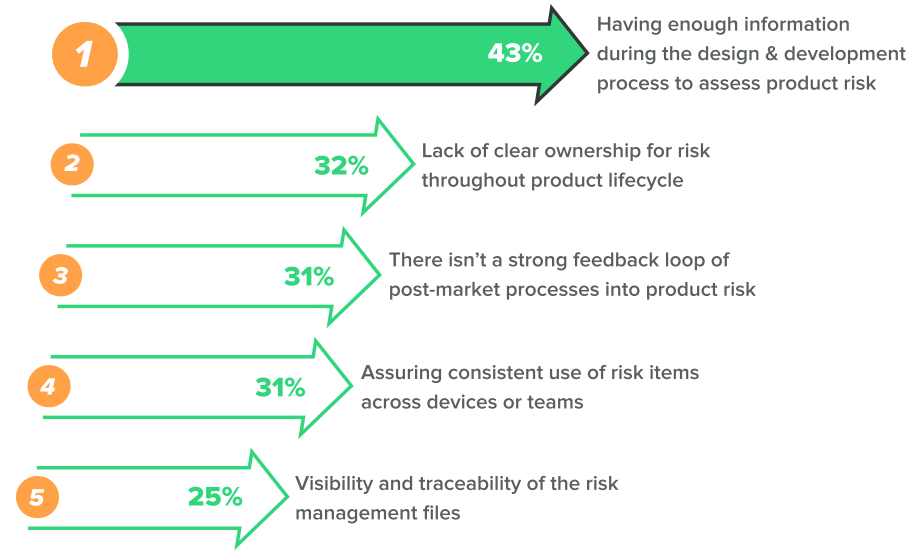
22%
We do not fully integrate risk management into our quality management system, and documenting risk takes substantial effort.

THE RISK CONUNDRUM

When it comes to managing device risks, the most common challenges cited include having enough information during the design and development process to assess product risk, which was cited by 43% of respondents, lack of clear ownership for risk throughout product lifecycle, cited by 32%, and, tied for third, lack of a strong feedback loop of post-market processes into product risk and the challenge of ensuring consistent use of risk items across devices or teams, both highlighted by 31% of respondents.

Indeed, the relationship between managing device risk and technology has only grown more intertwined as organizations increasingly depend on artificial intelligence for business intelligence, product development and quality management. If relying on AI, companies must be even more methodical about oversight; for example, ensuring accurate data, internal training, and adequate controls. Forty-two percent of respondents to our survey stated a desire for improved visibility into risk controls, a number which grew to 52% among organizations that consider themselves to not be very competitive compared to their peers.

Top 5 Challenges in Managing Risk



Source: Greenlight Guru | 2019

THE RISK CONUNDRUM

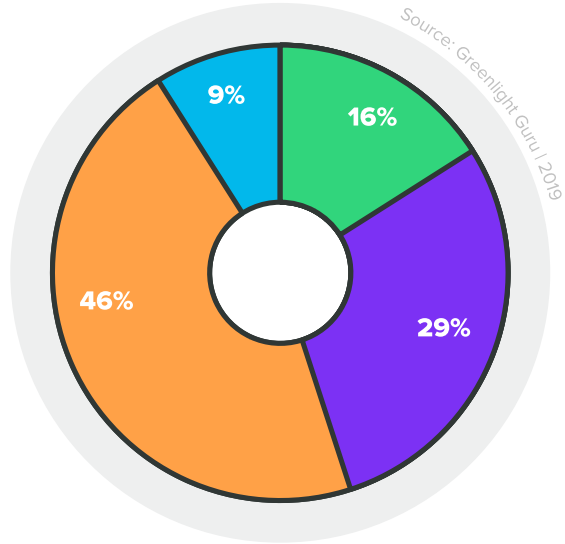
When it comes to closed-loop traceability (CLT), nearly half (45%) cannot demonstrate it today — though more than half of those have plans to fix this within two years.

> **Of those that can demonstrate CLT, 1 in 3 say it takes substantial effort to do so.**

As mentioned previously, it's troubling to see the large share of organizations that cannot demonstrate CLT today, as well as those that can, but do so inefficiently. With EU MDR compliance due by early next year, these organizations face tremendous headwinds in the year ahead.

Achieving Closed-Loop Traceability

Describe your company's current ability to achieve closed loop traceability



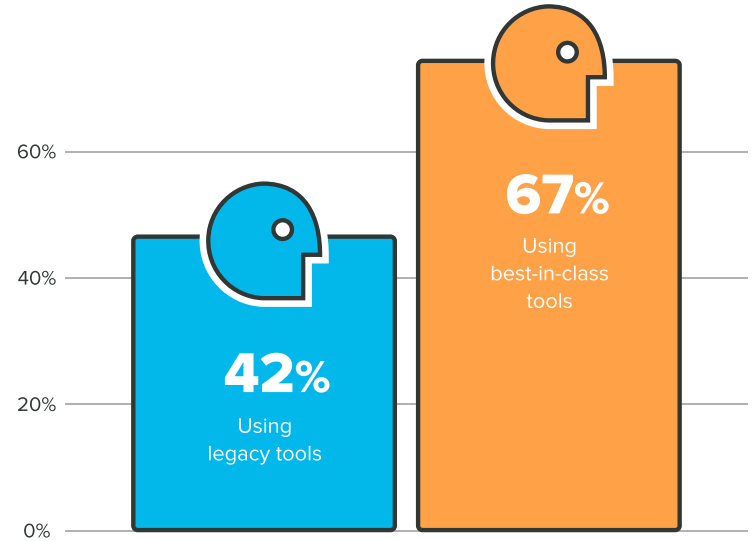
- **16%** We cannot demonstrate closed loop traceability consistently (and have no plans to change this in the next 2 years).
- **29%** We cannot demonstrate closed loop traceability, but have plans to do so in the next 2 years.
- **46%** We can currently demonstrate closed loop traceability.
- **9%** Unsure

THE RISK CONUNDRUM

Despite the link between risk management and the need for rigorous, technology-supported controls and documentation, 52 to 58% of organizations say they use legacy systems for quality management and risk management, respectively. Additionally, 1 in 3 say product level risk management is minimally or not at all integrated with post-market quality processes. Other than best-in-class organizations, the industry is still waking up to the benefits of integrating design, risk, and post-market quality activities over the course of the device lifecycle, rather than viewing this as merely a compliance activity.

Reaching fully integrated risk

Those who use either legacy tools or best in class tools were asked to describe the effort required to integrate risk management throughout the entire product lifecycle

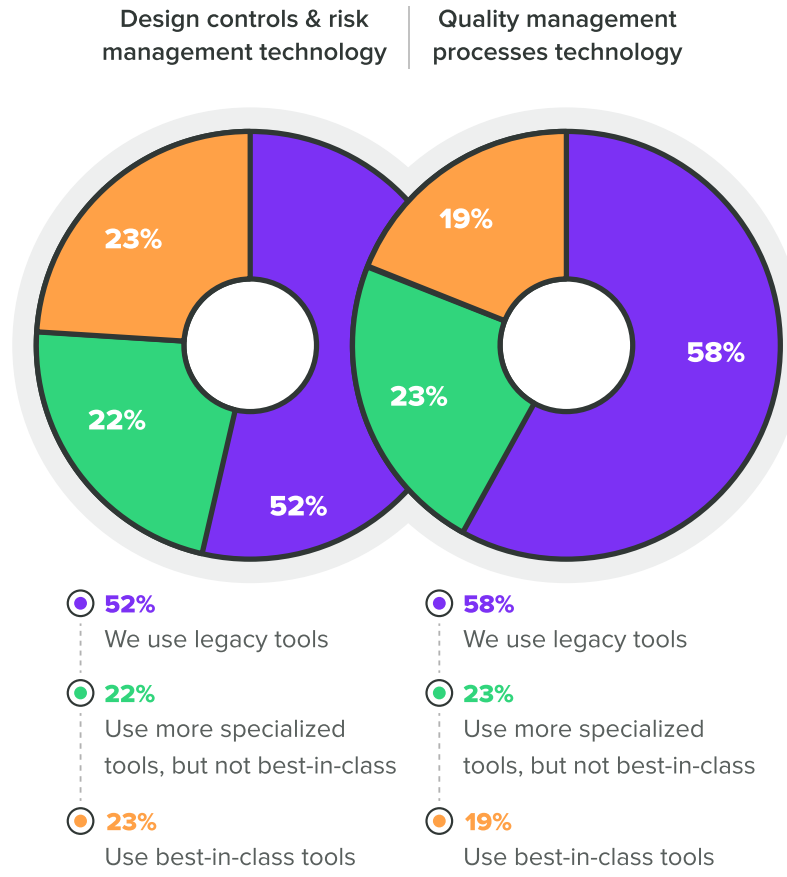


Risk is fully integrated into the entire product lifecycle

TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

For those with many years experience working in the medical device industry, it may come as no surprise that legacy tools still dominate the industry — across design assurance, risk, and quality management activities. The challenge is that while these solutions may save money short term, long term these ad-hoc systems create tremendous (and costly) inefficiencies, as well as introducing both patient and business risks.

The research shows that 52% of the organization surveyed use legacy systems for design controls and risk management, and 58% rely on legacy solutions for quality management.



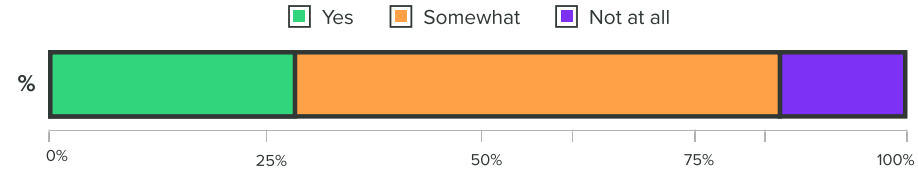
Source: Greenlight Guru | 2019

TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

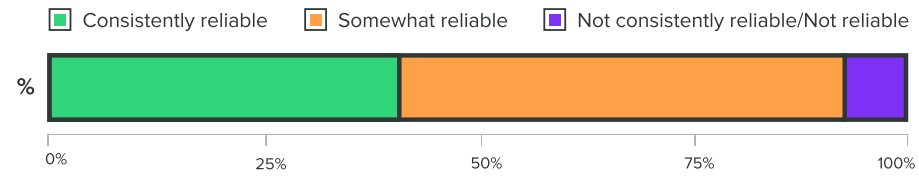
And the challenge is not only outdated technology; it's also poor/ineffective data collection and management. 71% report the data collected by their company's quality system is not easily accessible in real-time. And nearly 60% indicated the data generated by their quality system was not consistently reliable.

Data Access & Reliability

Is the data collected from your company's Quality System considered easily accessible in real time?



How reliable is the data being generated by the quality system?



Source: Greenlight Guru | 2019

TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

What about those that use modern, best-in-class systems? What specific benefits are associated with purpose-driven solutions when compared to those organizations using legacy systems?

THEY ARE

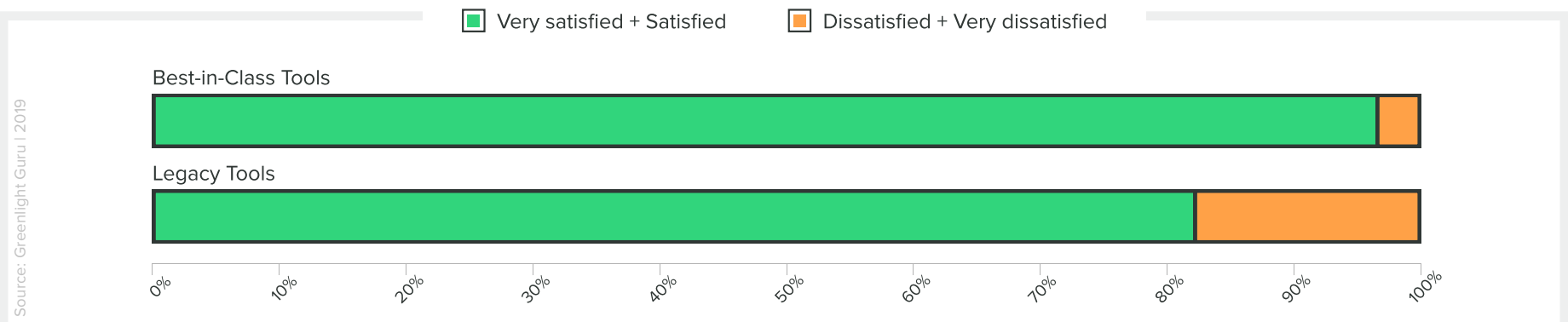
- **3x more likely** to call themselves *"highly efficient"* when bringing a device to market.
- **2x as likely** to say they are *"very confident"* about demonstrating total lifecycle traceability in the event of an unannounced audit
- ***Significantly* more likely** *to be EU MDR ready.* Roughly half of those using best-in-class tools are either "ready today: or confident they will be ready (compared to fewer than 1 in 3 inside organizations depending on legacy solutions).

TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

The effects of the legacy versus best-in-class conundrum even bleeds into the much-overlooked area of job satisfaction; 81% of respondents who work for companies that have adopted best-in-class design controls & risk management technologies to do their jobs say they are satisfied or very satisfied in their current roles, while just under two-thirds of workers at organizations that employ older technologies such as Excel or Word documents can say the same.

How do investments in technology affect job satisfaction?

Overall respondents reported they were satisfied at work, but those companies that invest in best-in-class tools are much more likely to have satisfied employees compared to that still use legacy tools...



"Very Satisfied" at Work? Workers at companies using best-in-class design control and risk management technology solutions are roughly 2x more likely to say they are "very satisfied" in their roles compared to those in companies that use legacy systems.

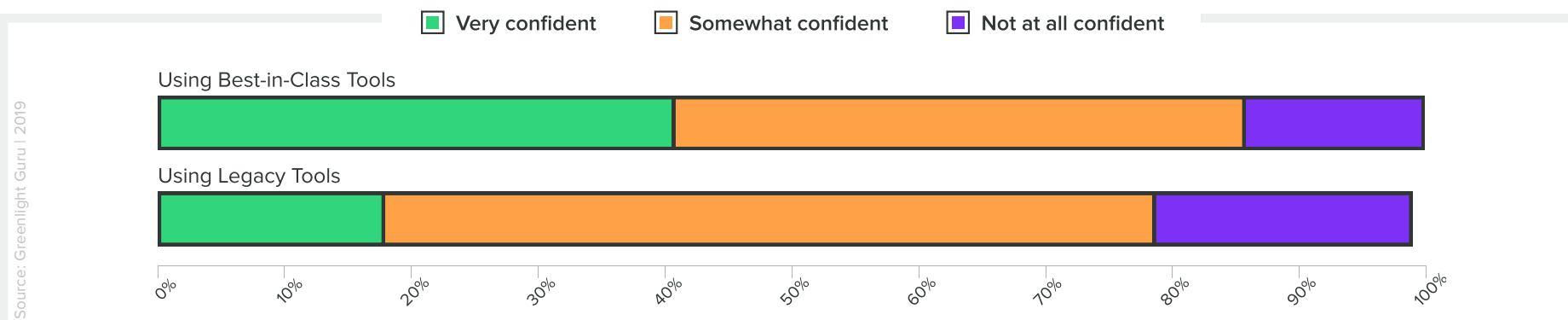
TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

Understandably, larger companies struggle more than smaller companies to move away from legacy technologies. While almost half of small companies (those with fewer than 25 employees) use best-in-class tools, only 15 to 17% of organizations with more than 1000 employees able to say the same.

However, one of the most dependable barometers of technological maturity was an organization's relationship to closed-loop traceability (CLT) — organizations that have embraced it have generally invested in all-around better tools specifically designed for medical product development or quality management that are best-in-class. These tools allow them to move away from time-consuming activities and focus their efforts on improving other processes, which allows them to improve the quality of their devices, their operations, and the state of their business.

Technology Investments Impact Audit Confidence

If a government agency or notified body showed up for an unannounced audit tomorrow, how confident are you that you could demonstrate total produce lifecycle traceability?



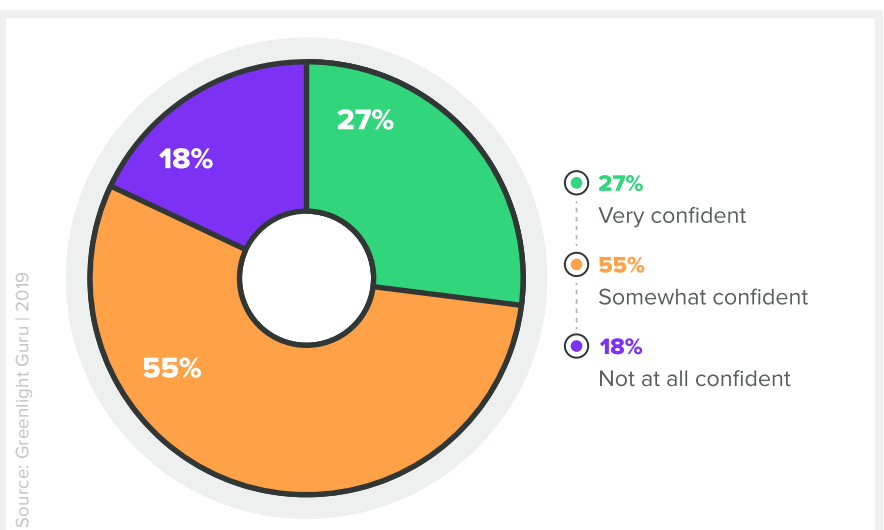
The Link Between Technology & Preparedness. Those with best-in-class tools are (not surprisingly) more prepared for an unannounced audit, which in turn has a trickle-down effect on efficiency and job satisfaction. Those with best-in-class tools are (not surprisingly) more prepared for an unannounced audit, which in turn has a trickle-down effect on efficiency and job satisfaction.

STATE OF (UN)PREPAREDNESS

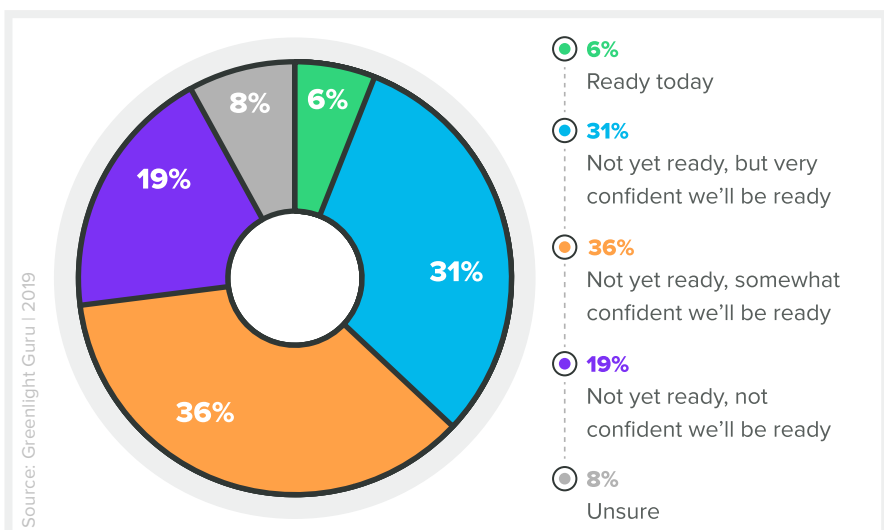
A key marker of operational excellence and efficiency is how well medical device companies are prepared to face unannounced audits and pending regulatory changes – and on this front, the research shows preparedness (or lack of preparedness) is a critical concern for many. Only 1 in 4 say they are "very confident" they could demonstrate total lifecycle traceability in the face of an unannounced audit. And even fewer (just 6%) are currently ready to meet EU MDR implementation (though 31% say they are confident they will be ready by May 2020). Put another way: more than half report they are not confident they'll be ready in time, despite a three-year transition period to meet EU MDR directives.

Readiness for EU MDR

If a government agency or notified body showed up for an unannounced audit tomorrow, how confident are you that you could demonstrate total produce lifecycle traceability?



Estimate your company's readiness to meet the EU MDR implementation date in May 2020:

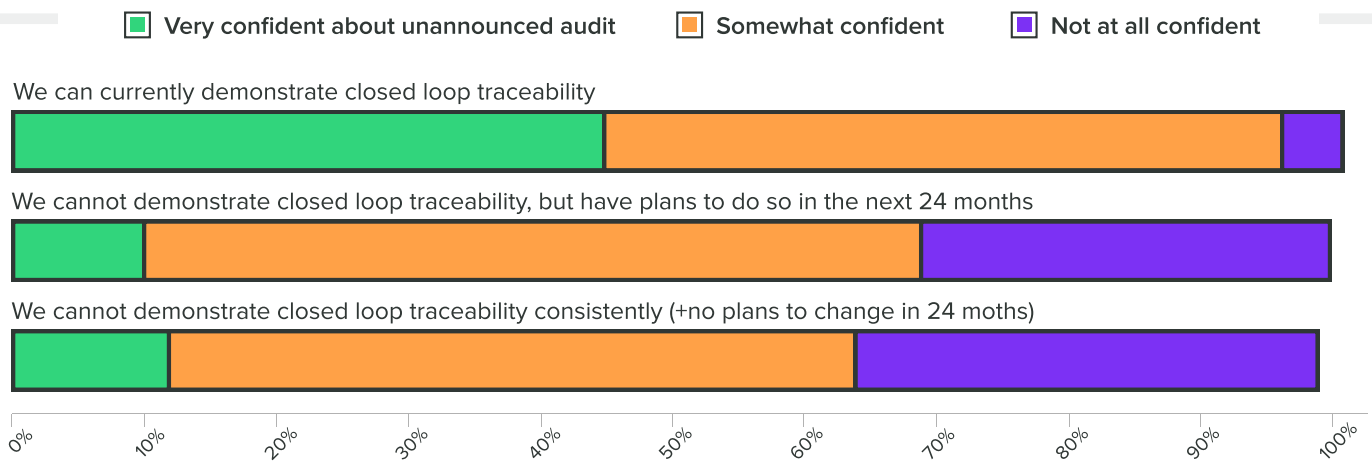


STATE OF (UN)PREPAREDNESS

A key part of being compliance-ready is being able to demonstrate closed-loop traceability, especially if a regulatory body or agency visits without notice. Almost half of organizations that can currently demonstrate closed-loop traceability say they would be confident they could pass an audit; almost half (48%) of organizations that consider themselves to be competitive in comparison to their peers can demonstrate closed-loop traceability. Additionally, 55% of organizations said they could demonstrate total product lifecycle traceability.

Audit Confidence and Closed Loop Traceability

If a government agency or notified body showed up for an unannounced audit tomorrow, how confident are you that you could demonstrate total produce lifecycle traceability?



Source: Greenlight Guru | 2019

STATE OF (UN)PREPAREDNESS

Large organizations with over 1000 employees were more likely than their smaller counterparts to be able to demonstrate CLT, with 58% of these organizations already having met this goal.

Of the most competitive companies, 14% say it would take them one day or less to prepare for an audit while an additional 41% say it would take them a week or less. Of organizations surveyed that say they are not very competitive, 7% say they could take less than a day to prepare for an audit; 31% say it would take less than a week.

Thirty-eight percent of organizations surveyed say they are either ready for EU MDR or are very confident they will be ready by the deadline. However, organizations shared that the areas of compliance they are most concerned with include clinical evidence (42%), availability of notified bodies (41%), and tech file revisions (36%).

Competitive organizations are 2x as likely to need less than a day to prepare for an audit

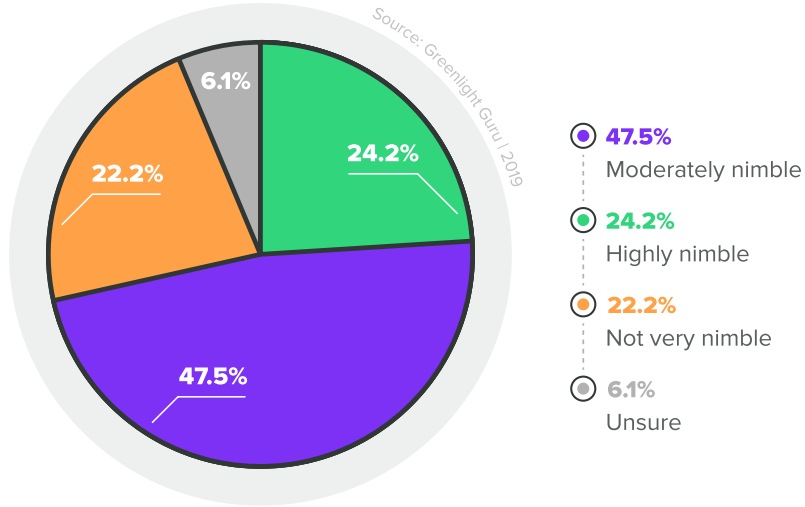
When it comes to medical device standards, principles, or regulations that organizations find the most difficult to interpret and implement, the most commonly cited were EU medical device regulations (38%), Risk Management Standard — ISO 14971 (23%), and computer system validation (22%).

THE PATH TO AGILITY

About half (47%) of the organizations we surveyed consider themselves moderately nimble; almost a quarter of respondents (24%) said they are highly nimble, and another 22% stated they were “not very nimble.” These results signal a growing awareness of the benefits of agility in the medical device industry.

When asked to what extent the organization’s quality management system contributes or detracts from being nimble, the largest share (41%) reported their QMS helps them to meet their agility goals.

How nimble is your company?



Source: Greenlight Guru | 2019

THE PATH TO AGILITY

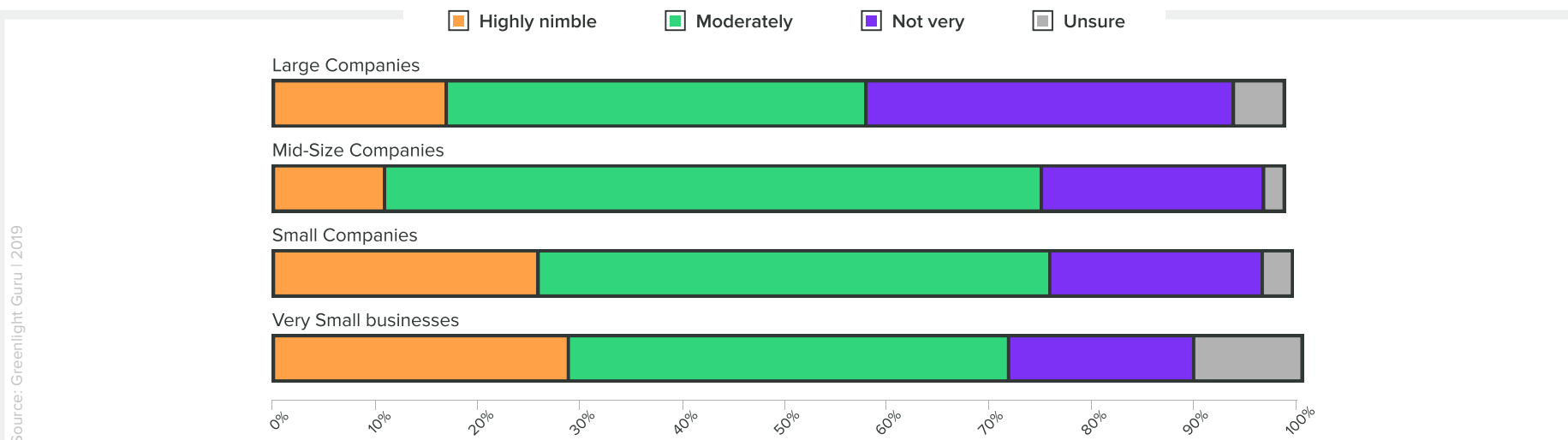
DAVID VS GOLIATH: ARE SMALLER COMPANIES MORE AGILE?

According to our survey, yes, smaller organizations have a slight edge when it comes to agility. Of the 519 organizations we surveyed, 29% from small companies say they are nimble, versus 17% of at large companies.

Despite bigger budgets, larger companies struggle to move away from legacy technologies, with only 19% of organizations with more than 1000 employees able to say they've adopted best-in-breed tech to support quality management processes.

How Nimble is Your Company?

Overall smaller companies are more nimble. Large companies struggle to be as agile their small-business competitors



THE 8 TRAITS OF MARKET LEADERS

In our research, we found that there are eight factors that indicate an organization is — or is about to be — a market leader.

AMONG THEM:

USING BEST-IN-CLASS TOOLS

Almost half (46%) of organizations that say they are highly competitive in the marketplace are investing in best-in-class tools (i.e., not using legacy tools).

LEADERS HAVE ACCESS TO RELIABLE DATA

Half of organizations that consider themselves to be highly competitive say their data is consistently reliable, with another 45% saying their data is somewhat reliable. This beats organizations that are not considered competitive, of which just over a third (28%) say their data is consistently reliable.

LEADERS EMBRACE CLT

While this point is related to trait #2, it deserves its own mention. Achieving Closed-Loop Traceability (CLT) is one of the best tactics when it comes to ensuring quality. Organizations that embrace CLT are far more likely than their competitors to consider themselves highly competitive. And these organizations run more efficiently, saving time and money, while boosting job satisfaction and employee morale.

QUALITY IS WOVEN INTO CULTURE

It's simple: Leaders view quality as an asset — an integral part of their culture. It's just part of who they are. Well over half (58%) of organizations that say they're highly competitive also agree that quality is woven into their culture; over half (just over 51%) of them also say that senior leadership within their company sees quality management as a strategic asset.

COMPANY LEADERS INVEST IN QUALITY

5

While many medical device companies are focused on running lean and trying to minimize costs, market-leading organizations invest in technology to get to the next level. The numbers back this up: Organizations that describe themselves as competitive are also the least likely to cite under-investment in technology as an obstacle, and over half of them (53%) say they anticipate spending more on technology next year.

QUALITY LEADERS ARE READY

No one likes visits from a regulatory body, but the most competitive organizations can handle the prospect of one better than their competitors. Over half of competitive organizations say it would take them less than a week to prepare for an inspection (a rate 45% higher than non-competitive companies).

When it comes to EU MDR compliance, market leaders also shine, with almost half (47%) saying they are either ready today or very confident they will be ready before the May 2020 deadline, as compared to an average of 31% of “not very competitive” companies.

LEADERS ARE NIMBLE

7

Running an agile business is key to success, with 36% of highly competitive organizations calling themselves “highly nimble,” in comparison to an average of 19% of not competitive companies. The ability to adopt new tools, adapt to new business conditions, and quickly change focus are all vital for businesses which want to remain or become competitive.

LEADERS LOVE WHAT THEY DO

Employee happiness is a clear indicator of an organization's overall health. Respondents who work for highly competitive organizations are generally highly satisfied with their jobs — just over 75% of these respondents said they were either "very satisfied" or "satisfied" with their current job; less than half (48%) of employees at organizations that are not competitive could say the same. In fact, while only 8% of employees of highly competitive organizations say they are "dissatisfied" or "very dissatisfied" with their jobs, over 26% of respondents who work for uncompetitive organizations say the same.

PRESCRIPTION FOR 2020:

5 THINGS TO FOCUS ON

The medical device industry now stands at a crossroads. On one path, there is the opportunity to accept the new ways of doing things and the advantages that they offer; on the other, there is the comfortable-yet-confining status quo.

Forward-thinking organizations don't just half-heartedly adopt technology — they embrace it and its capabilities.

HERE ARE A LIST OF THINGS ORGANIZATIONS SHOULD

CONSIDER DOING BETWEEN NOW & THE END OF THE YEAR:

GET THE RIGHT DATA

Market leaders know exactly what's going on in their company and never have to wonder if they have a clear view of the facts. In order to make good decisions quickly, accurate data is simply a must.

INVEST IN THE RIGHT TOOLS

This can be seen as an extension of the previous item, as the right tools will make finding the right data much easier. Best-in-class medical device product development and quality management tools have become a necessity, not a luxury. Yes, the investment of time and money is sizeable, but these are key ingredients to becoming a top performer. Spending more now for the right tools can lead to savings later.

CREATE A CULTURE OF QUALITY

A “culture of quality” doesn’t just mean not making errors; it means attention to quality is embedded in a company’s processes, technology, and training. The research shows this attention begins at the top: leadership must be fully invested, ready to support it through action.

GET AUDIT-READY

Being prepared for an unexpected visit from a regulatory agency or notified body isn't just a question of avoiding penalties or commercial delays due to compliance issues; it's being able to run the organization more efficiently, having confidence in data generated by quality and design systems, and improving organizational morale.

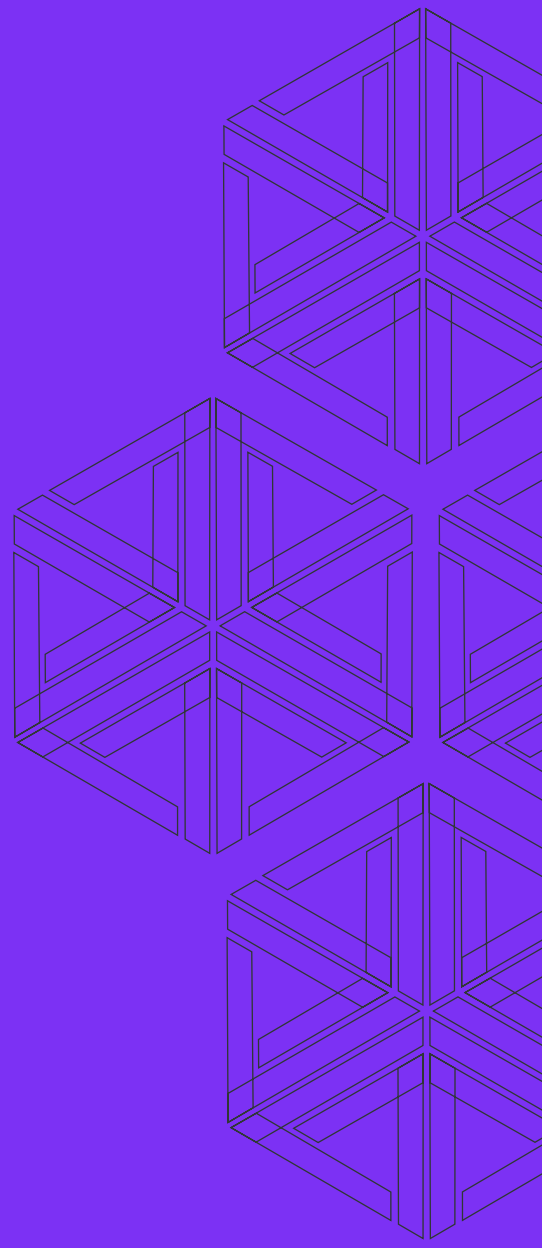
GET USED TO HEARING THINGS YOU DON'T WANT TO

An unfortunate side effect of access to good data is that sometimes, organizations learn things they didn't want to know. Access to real-time data may uncover new risks, hidden costs, underperforming processes, and other inefficiencies. The "underbelly" of a quality system that enables more reliable, timely information is a higher bar for efficiency and overall company performance.

The years ahead are difficult to predict, with new technologies, new regulations, new trade laws and countless surprises — both positive and negative – coming. But by valuing quality as a strategic asset, your organization and team can stay ahead of the curve, both in 2020 and beyond.

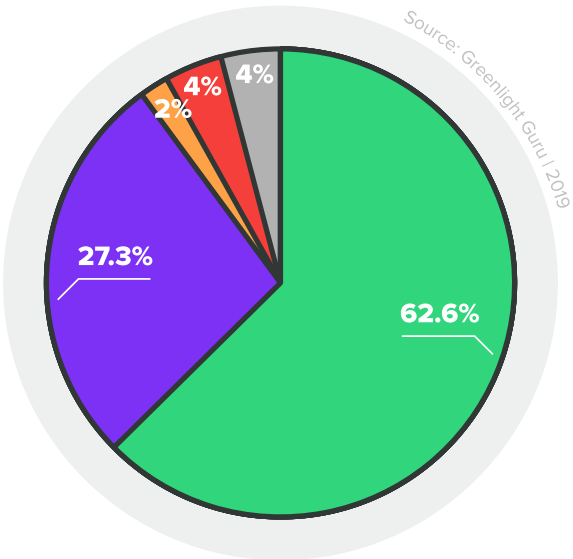
METHODOLOGY

The results in this report are from an online survey that was fielded between September 11 and 27, 2019. It had 524 respondents, all of whom completed the survey. The survey was not weighted.



METHODOLOGY

Role



62.6% Quality / Regulatory / Clinical

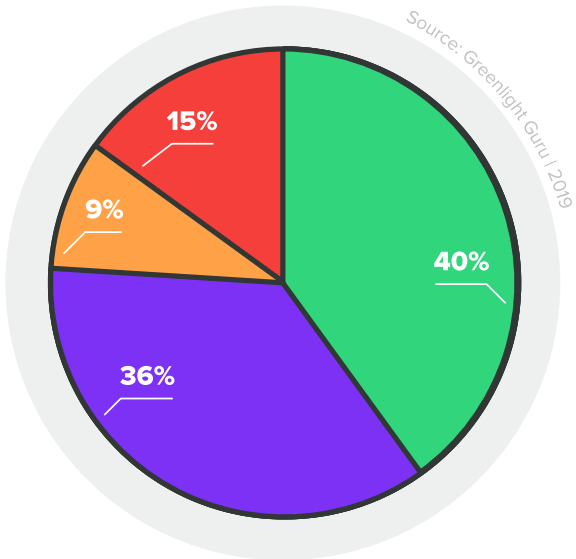
27.3% Engineering / R&D / Product Management

2% Sales / Marketing / Business Development

4% Manufacturing / Operations

4% Other

Company Size



40% Fewer than 25 employees

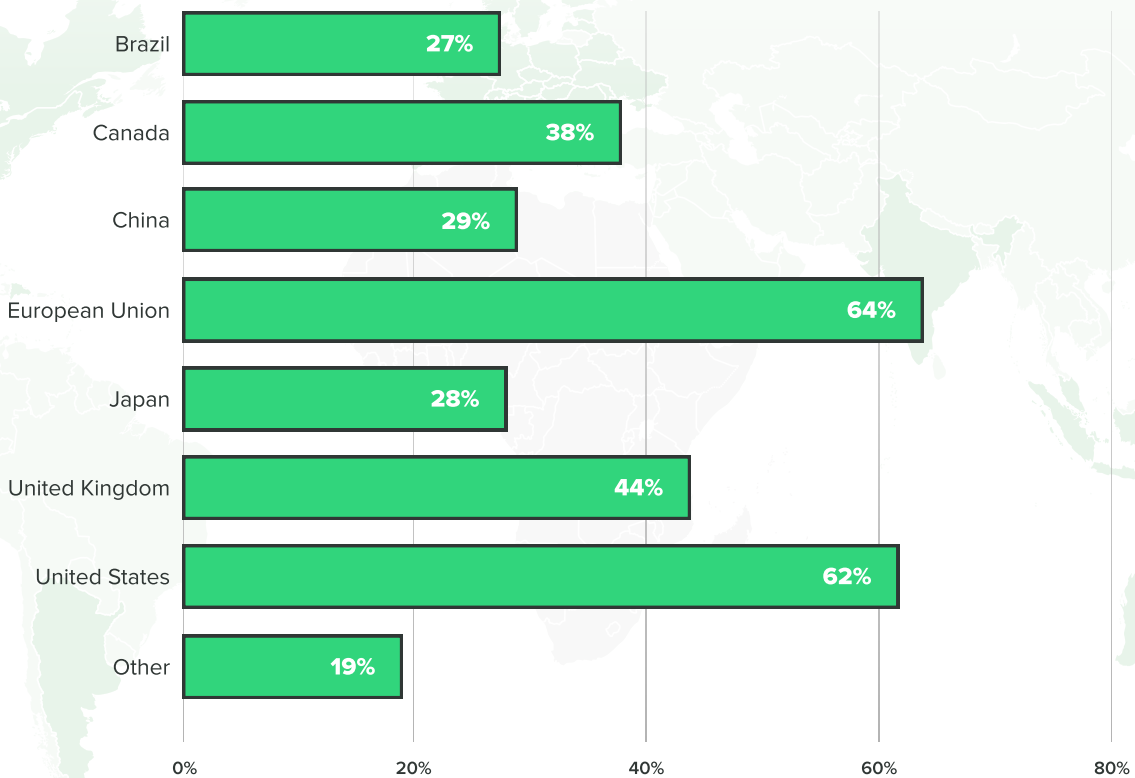
36% 25–249

9% 250–999

15% 1000 or more employees

Countries/regions

In which of the following countries/regions are you currently selling or distributing your device(s)?



Source: Greenlight Guru | 2019