greenlight guru

2024

State of the MedTech Industry Report

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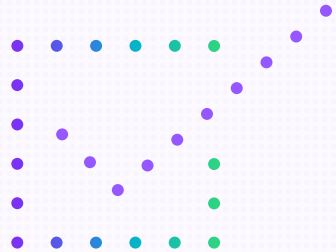
Methodology

Greenlight Guru surveyed 505 professionals working in quality, product development, clinical, and executive management positions. We fielded the survey to Greenlight Guru's customers and MedTech industry professionals in Q4 2023.



Area of responsibility	
Quality/Regulatory	61%
Product Development/Engineering/R&D	19%
Corporate Executive Office	8%
Clinical Operations	7%
Manufacturing/Operations	5%

Does your company have products for sale on the market?	
No products for sale on the market	28%
1–3	26%
4–6	10%
7–9	3%
10 or more products	33%

Role within organization	Senior Executive	23%
	Management	45%
	Individual Contributor	32%
Number of full-time employees	Less than 5 employees	9%
	5–10	12%
	11–25	16%
	26–100	24%
	101–500	20%
	501–1000	2%
	More than 1,000 employees	17%
Which class(es) of medical devices does your company produce?	Class I	41%
	Class II	66%
	Class III	24%
	Unsure	8%
	Not applicable	9%
What primary type of medical device classification does your company design/ manufacture?	Mechanical only	21%
	Mechanical + electromechanical	8%
	Mechanical + electromechanical + software	36%
	IVD	12%
	SaMD	8%

Outlook 2024: Key Benchmarks for the MedTech Industry

Results from Greenlight Guru's annual survey show the MedTech industry may be poised for positive development and growth in 2024.

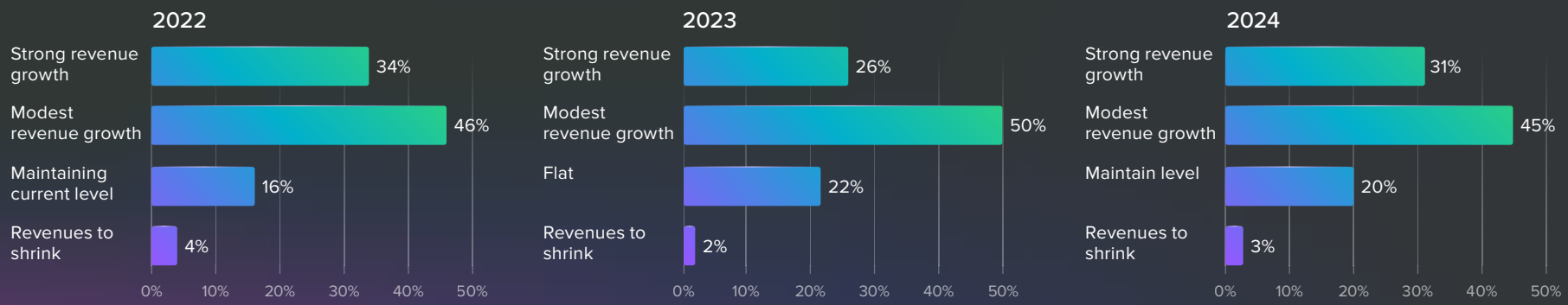
The overwhelming majority (86%) say they expect growth in 2024—roughly on par with 2023—but the share of those who are predicting "strong growth" is up 5 points.

Another positive signal: "Gaining market approval" moved from a #2 priority for 2023 to #1 for 2024. This comes as regulatory agencies grapple with how to speed up device approval times and simplify regulatory requirements.

And a focus on clinical investigations and trials moved up two points, to tie for #3 in 2024—not surprising given that 45% of professionals surveyed say they are launching new clinical activities in 2024.

Nearly 1 in 3 expect strong growth in 2024

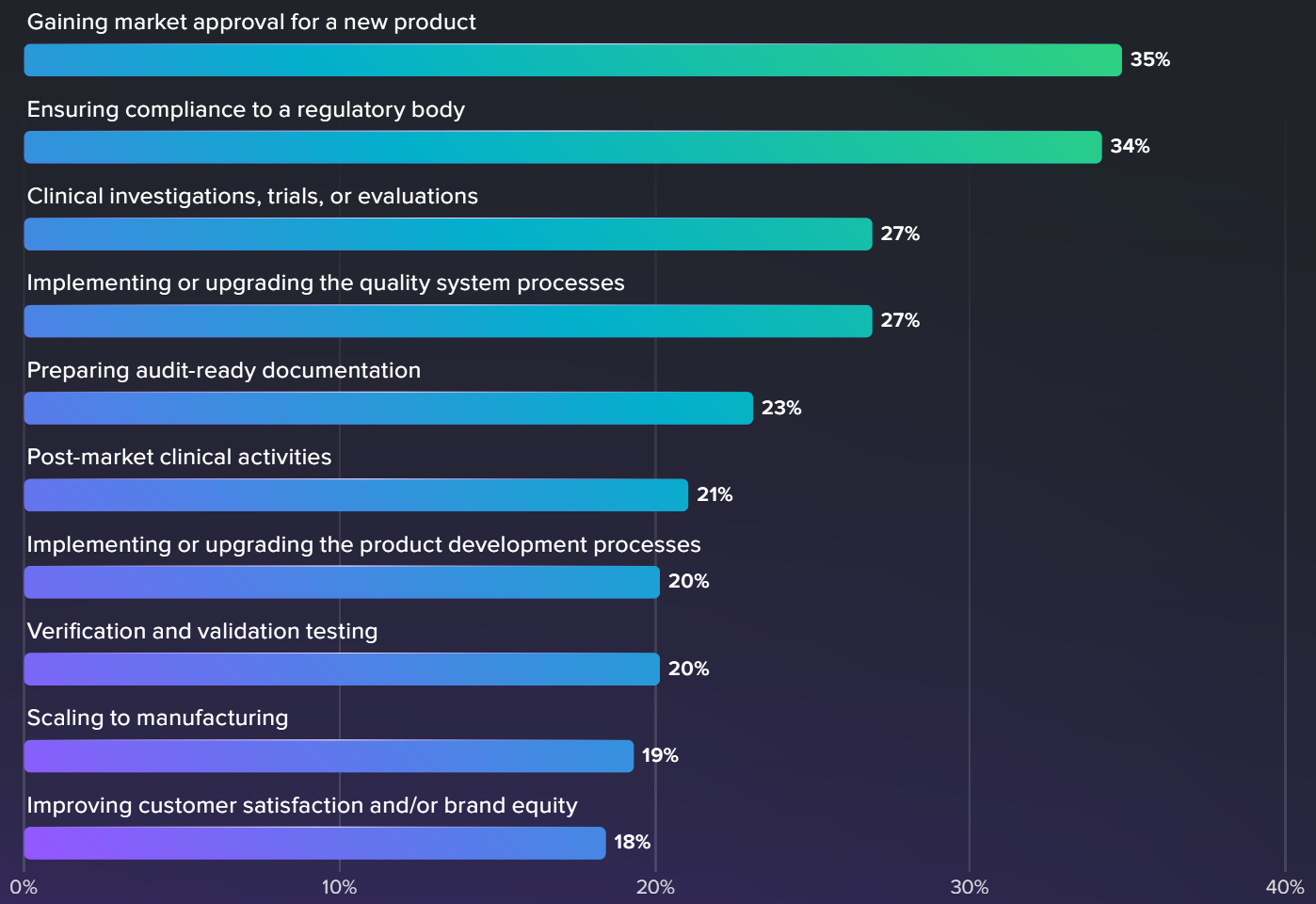
Q What is your company's revenue outlook for 2024?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Gaining market approval nabs top spot

Q What are your top objectives for 2024?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Despite strong predictions for growth, economic uncertainty continues to be a headwind for most (71%).

A significant number of those surveyed say uncertainty will delay product development (34%), halt new hiring (32%) and delay tech investments (28%).

Economic uncertainty still influencing strategy

Q How has recent economic uncertainty impacted your business?

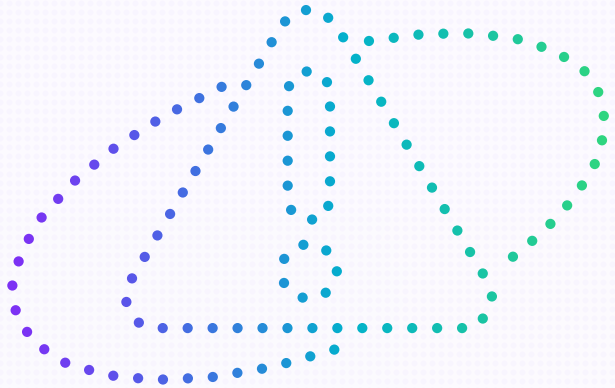
NUMBER OF EMPLOYEES	Under 10	11–100	101–1000	1000+
Reduced headcount	14%	20%	30%	49%
Halted new hiring	33%	29%	30%	44%
Delayed new product development	39%	29%	37%	38%
Delayed moves into new markets	24%	21%	32%	31%
Delayed new technology investments	30%	28%	28%	28%
Cut products from portfolio	4%	12%	18%	21%
None of the above	34%	32%	22%	15%

Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

The longer-term growth outlook for medical device companies is concerning due to the unsustainable rise in healthcare costs.

In essence, both investors and buyers are much more value-driven than before—so medical device companies are pressured to design innovative devices with strong patient outcomes at a lower cost. A report from KPMG highlights this pressure:

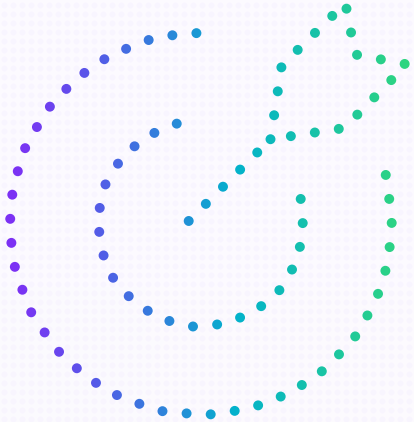
> "Despite [...] apparently attractive prospects, a shadow hangs over the sector in the form of a relentless downward pressure on pricing. Governments around the world are desperately trying to reduce the cost of healthcare—especially in the most expensive part of the system: hospitals. They want to pay less for medical devices and see proof of greater value in terms of better patient outcomes." [1]



The consulting firm correctly notes that players in the MedTech industry have traditionally focused on manufacturing and R&D, but with price pressures eroding margins, plus competitive threats from outside the industry, medical device companies must find new ways to unlock value, or "risk being stuck in the middle of the value chain, as mere commodity producers."

[1] https://kpmg.com/us/en/articles/2023/medical-devices-2030.html

Given all these pressures, successful device companies will be those that can manage twin mandates: R&D excellence and operational excellence. The latter is a new priority for many. No amount of development expertise or innovation can overcome the sand-in-the-gears friction imposed by subpar operations in this new climate—including underinvestment in technology and data management.



Operational excellence is now the foundation of high-performing medical device companies. McKinsey underlines this point in a recent MedTech Pulse report: "As companies grow bigger and devices become more complex, operations will be a differentiating factor for MedTech leaders. MedTech companies can improve their operations to become more reliable, robust, and profitable, ultimately delivering better patient care."[2]

The problem is, most medical device companies are far from achieving operational excellence. Among companies we surveyed, rates of "excellence" are particularly low related to operations, data, and tech. For example, 40% rate their organizations as "fair" or "poor" in how well they have integrated their systems.

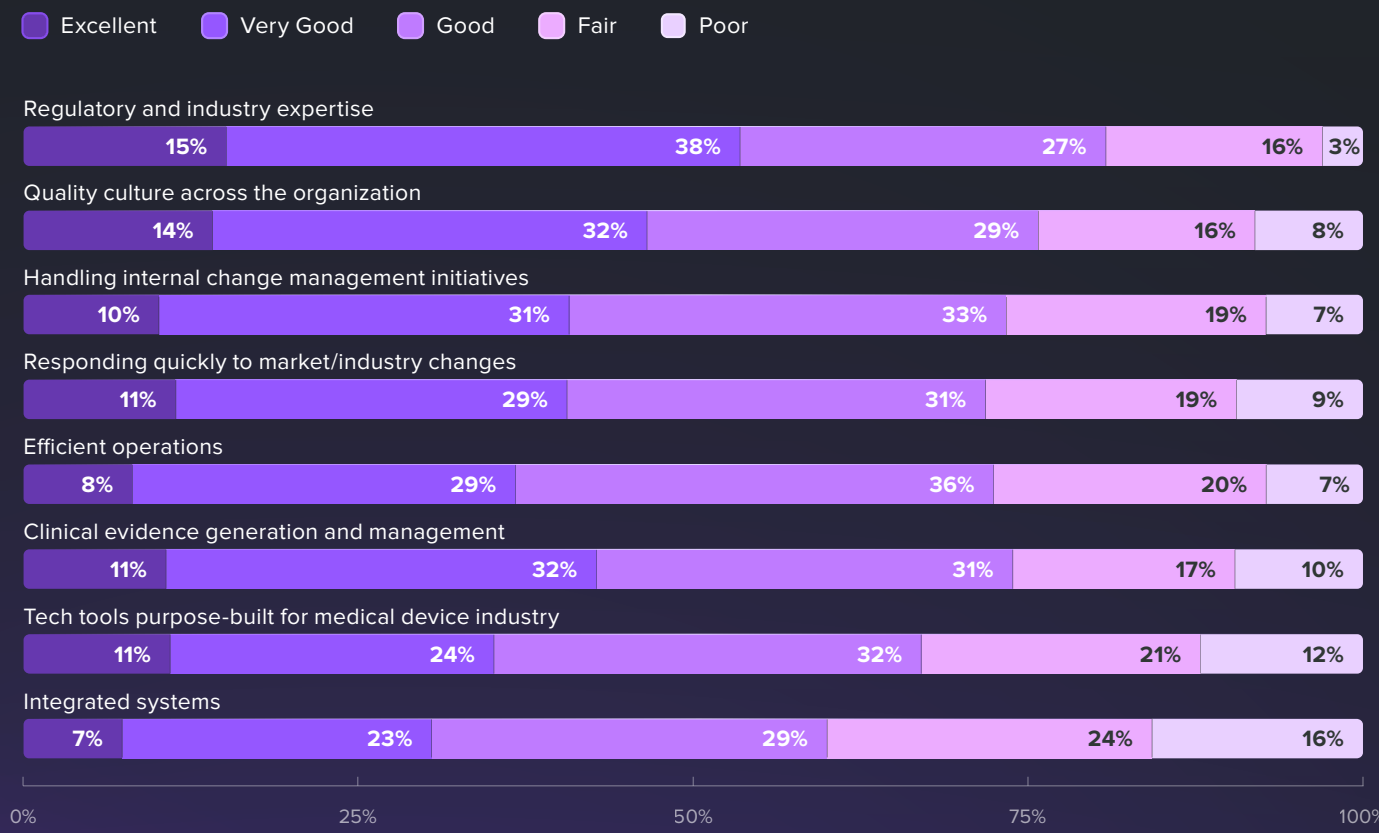
As one survey taker told us last year,

> "More than anything, I'd like a system that links everything—absolutely everything, like product documentation—together. It would transform my job."

[2] https://www.mckinsey.com/industries/life-sciences/our-insights/medtech-pulse-thriving-in-the-next-decade

Technology challenges undermine effectiveness

Q Please evaluate how well your organization performs across each of these areas.



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Digital modernization: a key step on the path to operational excellence

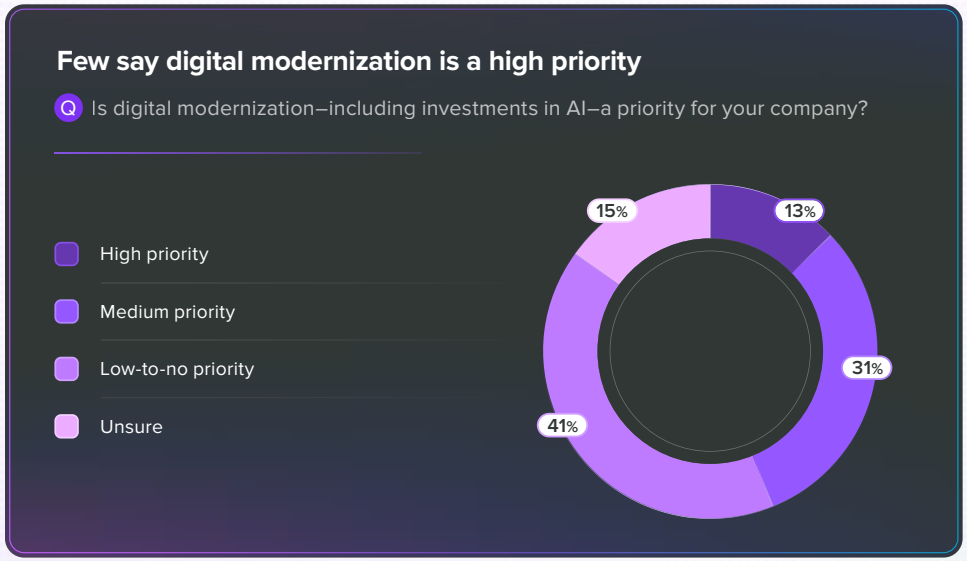
Greenlight Guru's research shows companies are still underinvesting in technology, though we see improvement year-over-year.

Here we are referring to R&D, manufacturing, and business technology—in other words, internal systems that power the organization, not device technology.

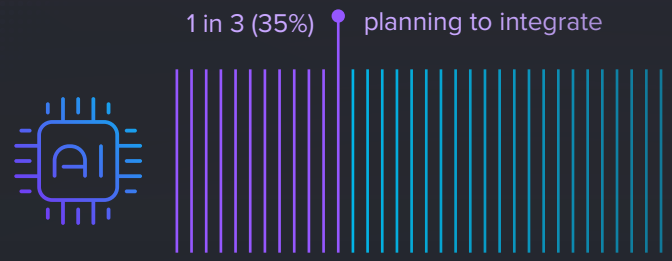
Investment in business solutions/tools is mostly staying level in 2024; just 36% say their budgets are increasing, while 43% report budgets are flat for technology. And overall, digital modernization is not yet a priority.

Keep in mind: Digital modernization is not just about investing in technology; it's also about boosting real-time access to data—which requires breaking down data and tech silos that stand in the way of greater digital maturity.

The research shows that "improving data integration and sharing" is the top productivity/efficiency measure companies say they are focused on for 2024. And investing in data management and access is particularly important now—at the dawn of the generative AI age. To leverage AI's potential, companies need data (i.e., "fuel") to train AI models and generate value.



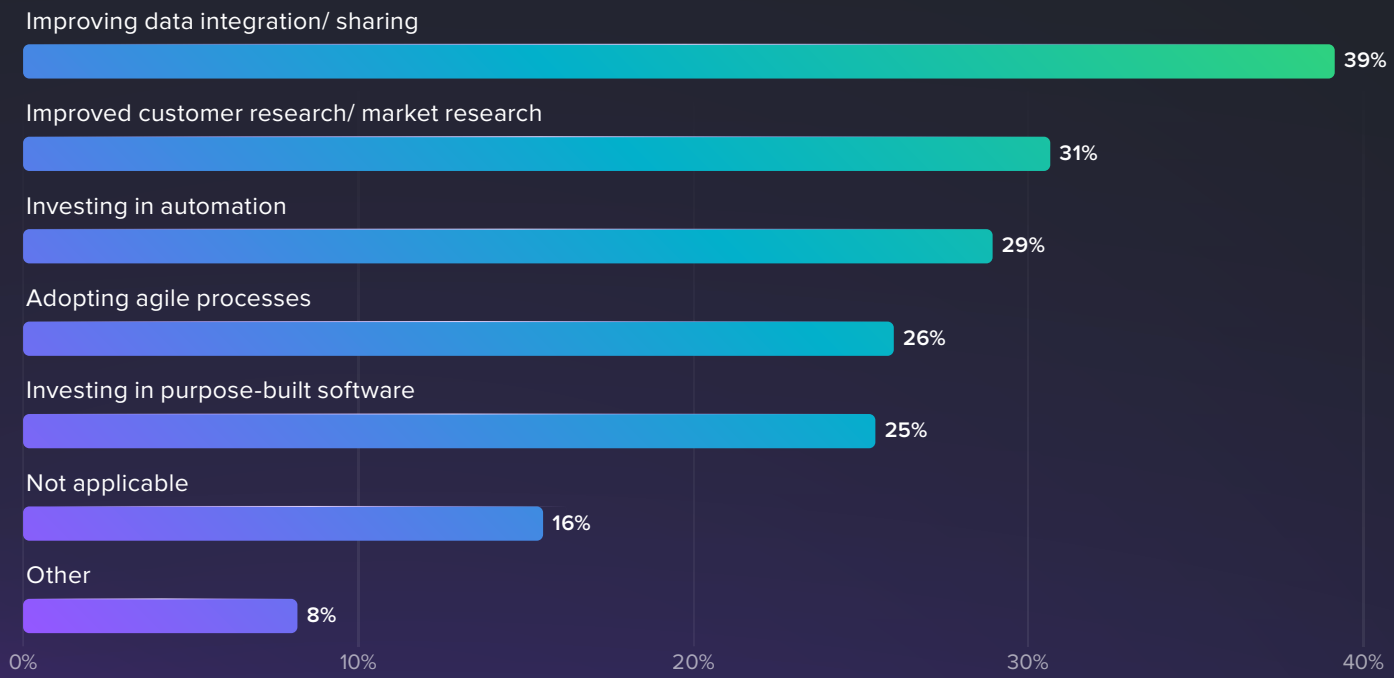
Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study



The share of companies using AI in devices—or part of a paid service connected to devices—is still relatively small (24%), though more than 1 in 3 (35%) have plans to integrate AI into their product(s). Greenlight Guru's research also delves into AI for operations—a topic we'll dive into in more detail on page 20.

To drive efficiency, organizations look to data integration

Q Which of these productivity/ efficiency actions, if any, do you expect to take in 2024?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Mandate for 2025: How Can Organizations Tame These Challenges to Prepare for the Future?

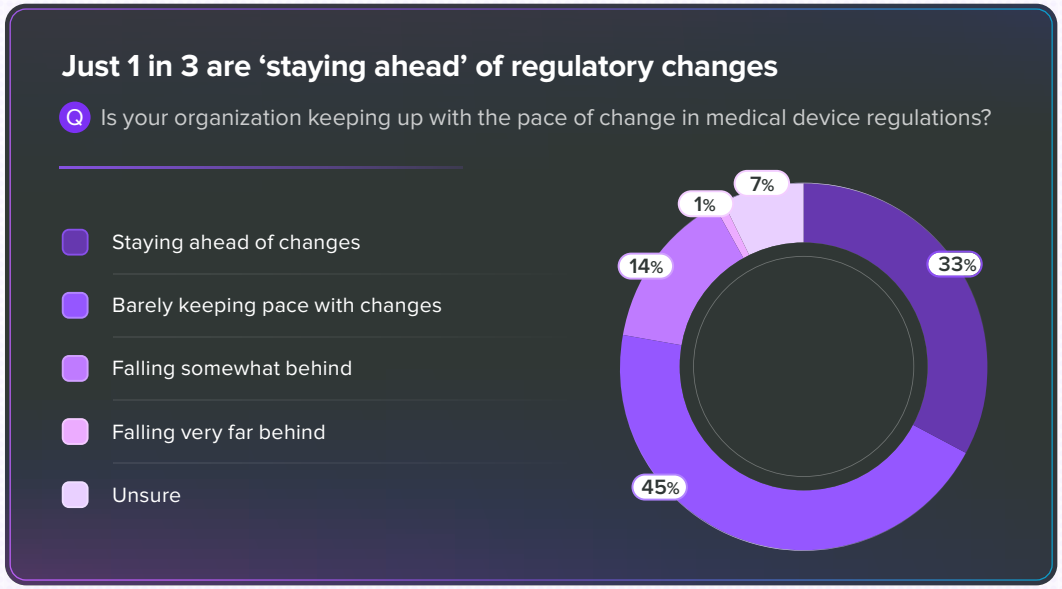
The mounting complexity of bringing a product to market and ensuring its safety can derail highly promising products and companies. How can organizations tame these challenges?

Industry insiders know that regulatory management and compliance is a source of tremendous frustration, and often it is a big driver of inefficiency.

Meeting the massive responsibility of regulatory requirements and keeping pace with changing directives—and doing all this while controlling costs and speeding time to market—is an overwhelming challenge.

Just 1 in 3 are 'staying ahead' of regulatory changes

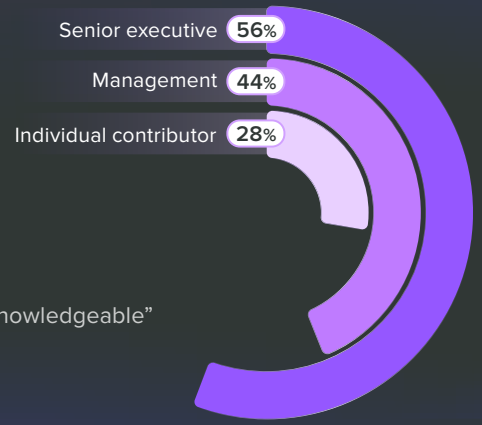
Q Is your organization keeping up with the pace of change in medical device regulations?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Regulatory know-how a challenge for many

Q How knowledgeable do you personally feel on industry and regulatory compliance information?



Graph indicates respondents who are "very knowledgeable"

Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Our research shows most are struggling to keep abreast of regulatory changes. Just 1 in 3 say they're "staying ahead," and 45% are "barely keeping pace."

Overall, fewer than half (42%) say they're "very knowledgeable" about industry and regulatory compliance information. Among quality professionals, that figure jumps to 49%—but is still less than half.

To be clear: This is not an indictment of the individual; instead, it speaks to the enormous complexity of regulatory compliance across country borders and across time.

In addition to surfacing knowledge gaps, the research also shows that regulatory compliance is too often low-value, highly manual work.

Professionals we surveyed say they spend at least 23 working hours per month on reactive remediation activities such as updating critical documentation and corrective action planning.

And they say they feel stressed over issues like learning new regulatory requirements, ensuring compliance, and preparing for audits.

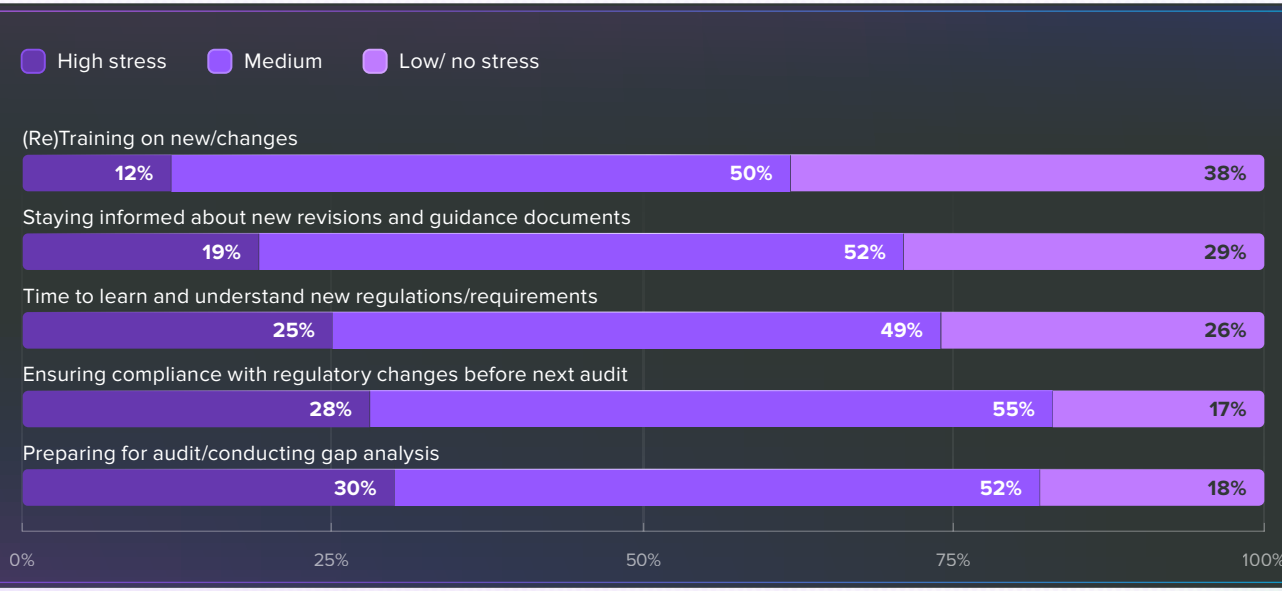
Despite these stressors, professionals in the industry report relatively high levels of professional satisfaction.

When asked what specifically brings them satisfaction, they shared details like, “working on products that are life-giving and life-changing,” “collaborating with brilliant people,” and “overcoming challenges others see as impossible.”

Individual contributors were significantly less likely to say they feel satisfied at work (66%) compared to executive leaders (81%)—a common finding in employee satisfaction surveys.

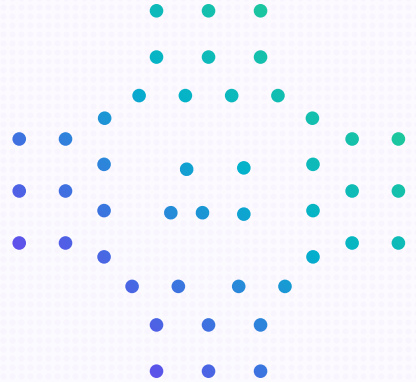
Regulatory complexity tied to stress

Q How stressful do you find these aspects of medical device regulation?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

To drive efficiency, listen to employees' workplace challenges



How can companies empower their employees to do more high-impact, high-meaning work and less of the mundane work? And how can they reduce the burden of complexity?

A first step may be to understand employee sentiments more accurately. As in previous years, our 2024 survey shows that frontline employees have notably different attitudes than executive leaders across a wide range of issues—including the root causes of inefficiency. For example, frontline employees are significantly more likely to identify tech and data silos, and point to these as serious bottlenecks. And leaders are much more likely to say they have high confidence that their current tech investments are sufficient to handle projected growth.

Perhaps most interesting of all: a stark difference in attitudes about how tech contributes to product innovation in MedTech. Nearly half of individual professionals (47%) say that better quality management technology and tools contribute to product innovation, compared to 35% of managers and 31% of leaders.

When it comes to taming regulatory complexity, the answer is not to simply learn more. As long as regulatory regimes remain as complex as they are today, there's little chance for individuals to feel confident about their knowledge levels—unless that is their sole job.

Instead, companies must find ways to leverage technology and AI to support their employees on the path to regulatory knowledge and compliance. With the right use of AI and automation, companies can process and analyze vast amounts of regulatory data more quickly and accurately. This not only simplifies regulatory and quality efforts but also enables a more proactive approach.

How AI Will Transform the MedTech Industry

Generative AI tools tuned to the MedTech industry can help companies drive operational efficiency and reduce risk. The potential upside is massive, but many organizations aren't positioned to leverage AI ... yet.

The Greenlight Guru study shows that fewer than 1 in 4 are using AI in devices today—though 35% say they plan to do this.

Aside from AI as part of devices, we wanted to understand to what degree companies are using AI to optimize R&D and manufacturing—what we call operational AI. As Alexander Murdoch, medical devices analyst at GlobalData explains, “AI has the capacity to improve medical device manufacturing efficiency and reduce risk through machine learning (ML). Computers can take in huge amounts of data and are able to learn errors along the way.”[3]

Most professionals we surveyed say they know AI and automation are useful (even critical) for operational excellence, but most still don’t use them in any meaningful way. In a survey Greenlight Guru conducted in August 2023, among professionals using AI tools like ChatGPT or Bard, 2 in 3 find them helpful to save time and drive up efficiency.[4]

The most common way organizations use AI for internal operations is to help with conducting research, though even that application is remarkably low at 17%. And though organizations largely do not use AI to analyze/summarize complex data, 30% plan to use it this way in the future. As one survey-taker working in R&D explained, “AI is good at finding data but not good at assessing it or using it to create or develop. In my experience, it will be a tool to gather information more quickly, but currently is very poor at assessing data to create actionable information."

55% **feel optimistic about the future impact of AI on the MedTech industry**

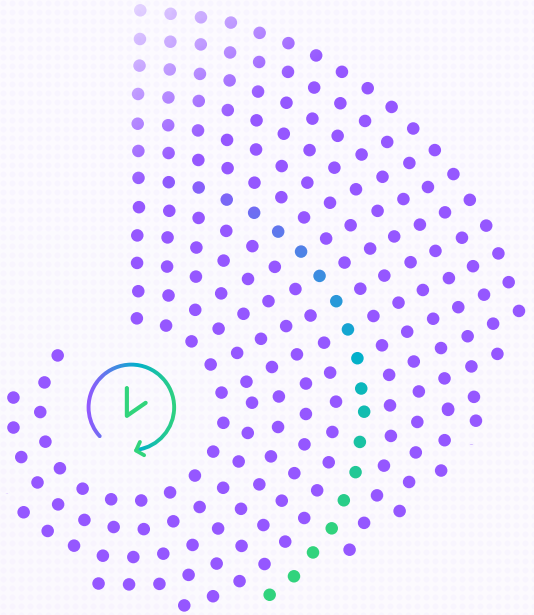
[3] https://www.medicaldevice-network.com/sponsored/reducing-medical-device-approval-times-in-2023/
[4] https://www.greenlight.guru/ai-medtech-trend-report

How will AI change the industry?

Most people we surveyed (71%) say they know companies will need to adopt AI to be competitive. They know it, but most have not yet taken significant steps to experiment with it or adopt it.

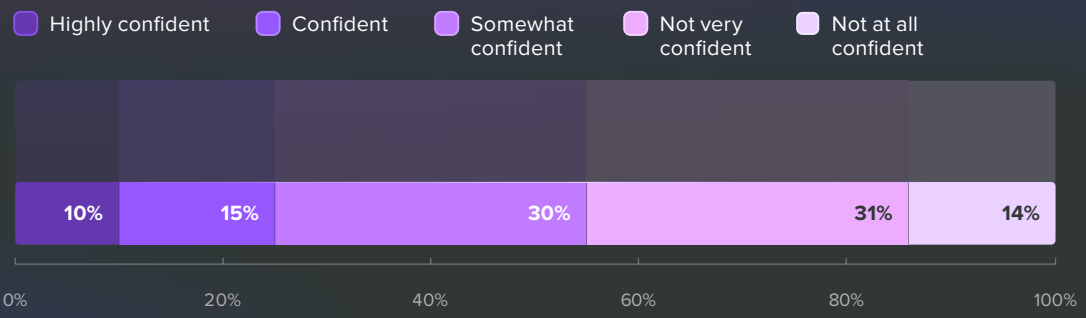
Many still think of AI solely in terms of clinical and product applications (e.g., interpreting diagnostic tests), but there is vast potential for AI to transform medical device manufacturing and operations—improving quality, reducing time to market, and driving innovation—and industry insiders overwhelmingly understand this.

AI will be tremendously useful to reduce the burden of regulatory complexity. Fully 76% say they believe AI will add value to gathering and analyzing market data, and 71% say it will be useful to analyze business system data. (Though few use it this way today.)



Use of AI to analyze quality data

Q AI tools can enhance understanding and interpretation of your business's quality data. How confident are you that your organization can use AI this way?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

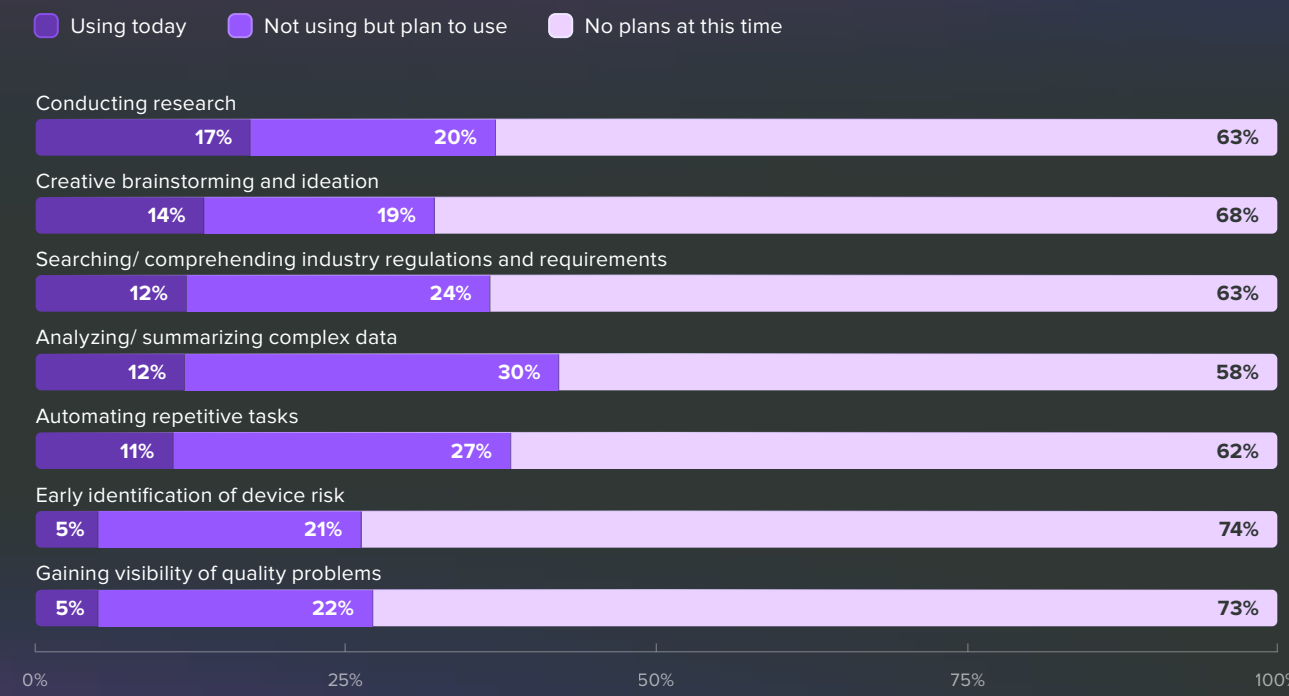
AI and automations are also useful for more rote—but still critical—tasks, such as tracking training progress and certification.

After all, 39% say they struggle to ensure staff training is completed, and 27% say managing training records and paperwork is a challenge.

One survey taker explained her optimism: "I am hopeful that AI can automate some of the more simple, mundane and routine tasks (like data collection and drafting simple summary reports), so that I can focus on tasks that truly require and utilize my expertise." Still others worry that AI adoption will have a human cost: "I feel like there is a probability that use of AI will devalue the knowledge and skills brought by the individuals to an organization."

AI optimism is high, but usage is still low

Q How is your company using AI?

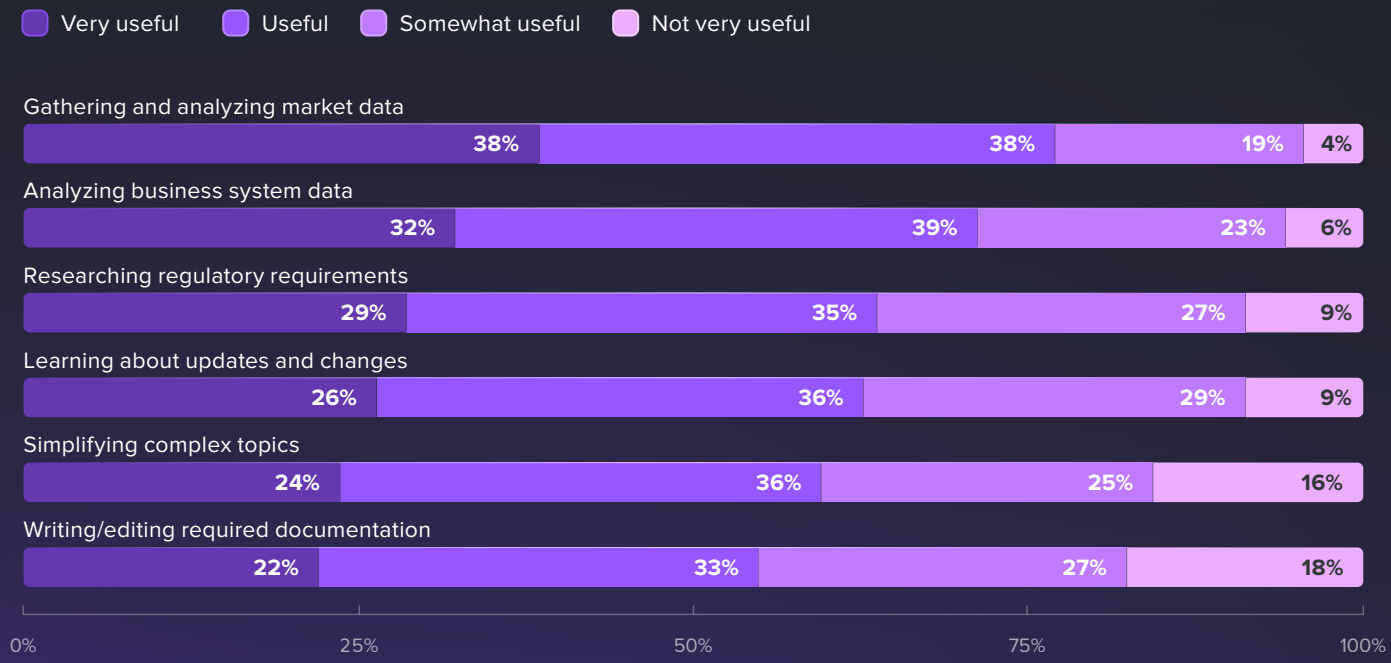


Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Despite some negative commentary, professionals we surveyed largely don't feel AI will threaten their careers in a meaningful way. The vast majority see either a positive impact (37%) or a net-neutral impact (47%) on their careers.

Many view AI as a tool to transform how they use data

Q How useful do you think AI/ automation will be for the following regulatory-related activities over the next two years?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

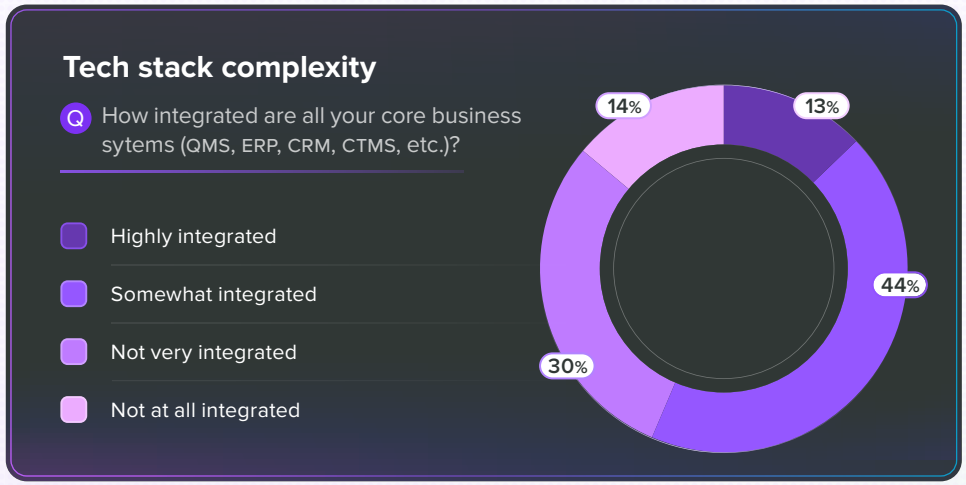
Purpose-Built Technology Elevates High-Performing Companies

Investing in purpose-built technology unlocks tremendous value—from real-time intelligence to time-saving automations.

Aside from AI investments, technology investments more broadly are largely flat for 2024. Just over 1 in 3 (36%) say they will invest more in 2024, while 43% say investments in tech will be the same as last year.

Lack of funds for tech upgrades is just one piece of the puzzle. Our research also shows a highly complex tech stack for many medical device companies. On average, organizations with at least one product on the market tell us they use 9 distinct platforms and tools—solutions for planning, quality, clinical, product development, supplier management, batch records, etc.

"Our research shows that just 12% of medical device companies have a highly integrated tech stack," says David DeRam, Greenlight Guru CEO. "When your core tech platforms don't speak with one another, it leads to hard-to-reverse data silos—and those data silos drag down visibility and efficiency. The time to dismantle data silos is *before* they become too onerous and complex." Or as one survey taker told us, "Tracking down information is half of my job, and it's a colossal waste of my time and experience."



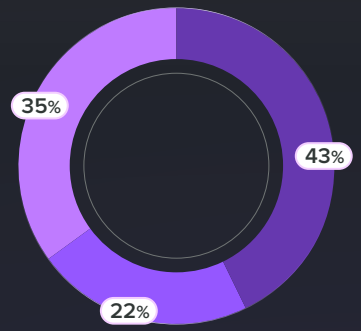
Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Under-investments in technology

Q What system/tool does your company use in each of these areas?

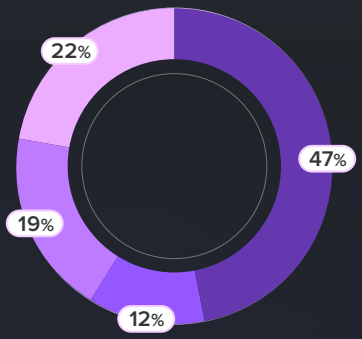
Quality Management

- General purpose tools (e.g., physical/ digital paper, Excel, Word)
- Tools designed for quality management only
- Medtech industry-specific tools designed for quality management



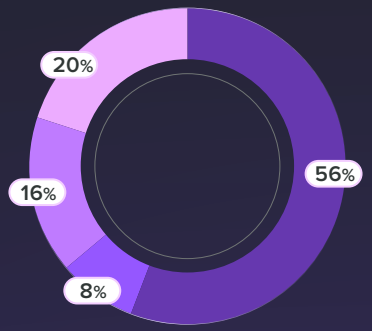
Design Controls

- General purpose tools (e.g., physical/ digital paper, Excel, Word)
- Tools designed for design controls only
- Medtech industry-specific tools designed for building design controls
- eQMS system



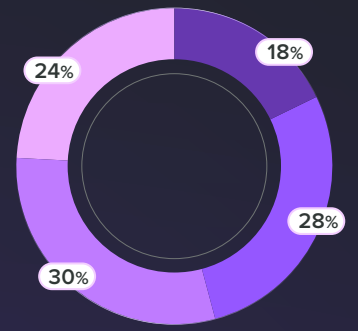
Risk Management

- General purpose tools (e.g., physical/ digital paper, Excel, Word)
- Tools designed for design controls only
- Medtech industry-specific tools designed for building design controls
- eQMS system



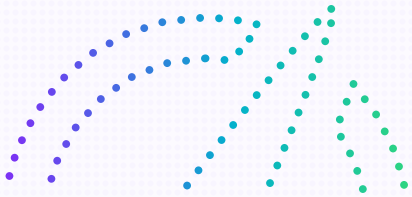
Clinical Data Collection

- Paper-based approach
- Non-validated general-purpose tools
- Validated tools designed for clinical data collection only
- Data collection managed by CRO/ consultant



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Companies that use purpose-built technology have a clear advantage over their peers. For example, companies that use tools purpose-built for quality management were 2x more likely to say they were equipped to meet their quality goals.



And those that use validated tools designed for clinical data collection were 4x more likely to say they are equipped to meet clinical objectives.

Yet our research shows there is still widespread use of general-purpose tools across many domains, including quality management, design controls, risk management, clinical data collection, and training management.

Viewing tech adoption solely as an expense is limiting. The alternative (using low-tech tools) has hidden costs: inefficiency, employee disengagement, and quality/reliability problems, among others.

Many companies forego purpose-built technology due to the cost of investment and rollout, but these investments often pay off—and begin generating a return—within two years.

A study of Greenlight Guru customers by Hobson and Company found that among pre-market companies that manage approximately 10 internal and 4 external audits per year, and 20 quality events per year, an investment in purpose-built technology paid off within 1.7 months, and generated an ROI of 446% in three years. (To view this study in-depth, visit our blog.)

The Building Blocks of High-Performing Organizations

What are the top challenges and opportunities for medical device companies? We explore key benchmarks related to quality, product development, and clinical activities.

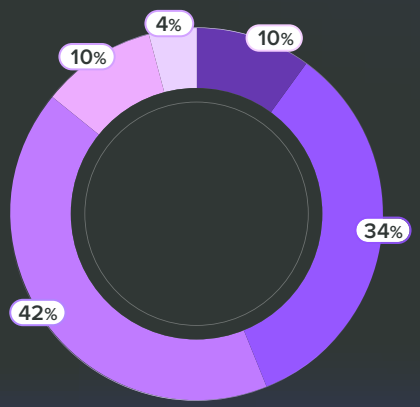
QUALITY

Professionals we surveyed report their biggest quality-related challenges are the cost/effort of validating new tools and processes (35%) as well as internal resistance to change efforts (35%).

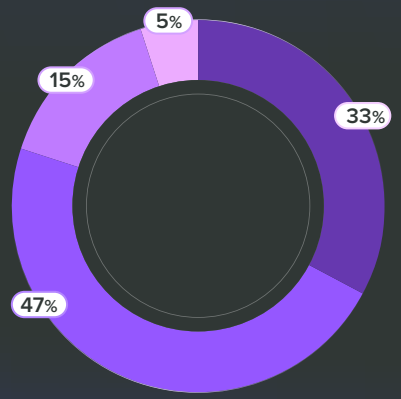
Resistance to change is particularly widespread inside enterprise companies–organizations with more than 1,000 employees–where 57% cite it as a challenge to quality.

And the stated effectiveness of quality measurement efforts is surprisingly low. Just 10% overall call their efforts “highly effective.” Among managers, that figure drops to 6%.

Q How effective is your company at measuring the results of quality initiatives/ activities?



Q How confident are you that your current quality system can handle your company's projected growth over the next 12 months?

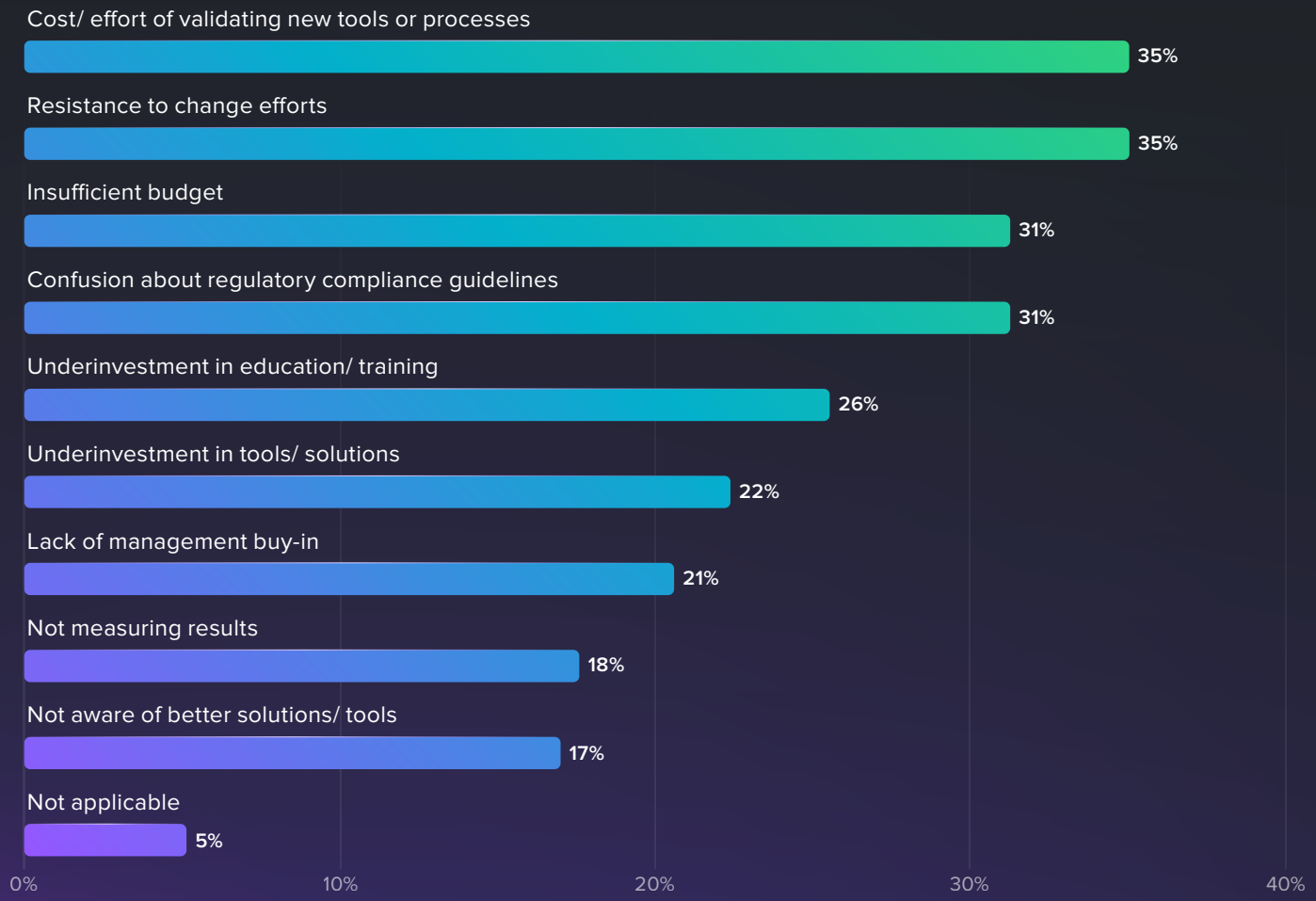


Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Inadequate investment in purpose-built technology may be part of the problem. Only 1 in 3 are highly confident their current quality system can handle the company's projected growth over the next 12 months. And just 36% are very confident they could demonstrate total product lifecycle traceability in the event of an unannounced audit.

Internal resistance to change undermines quality

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



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

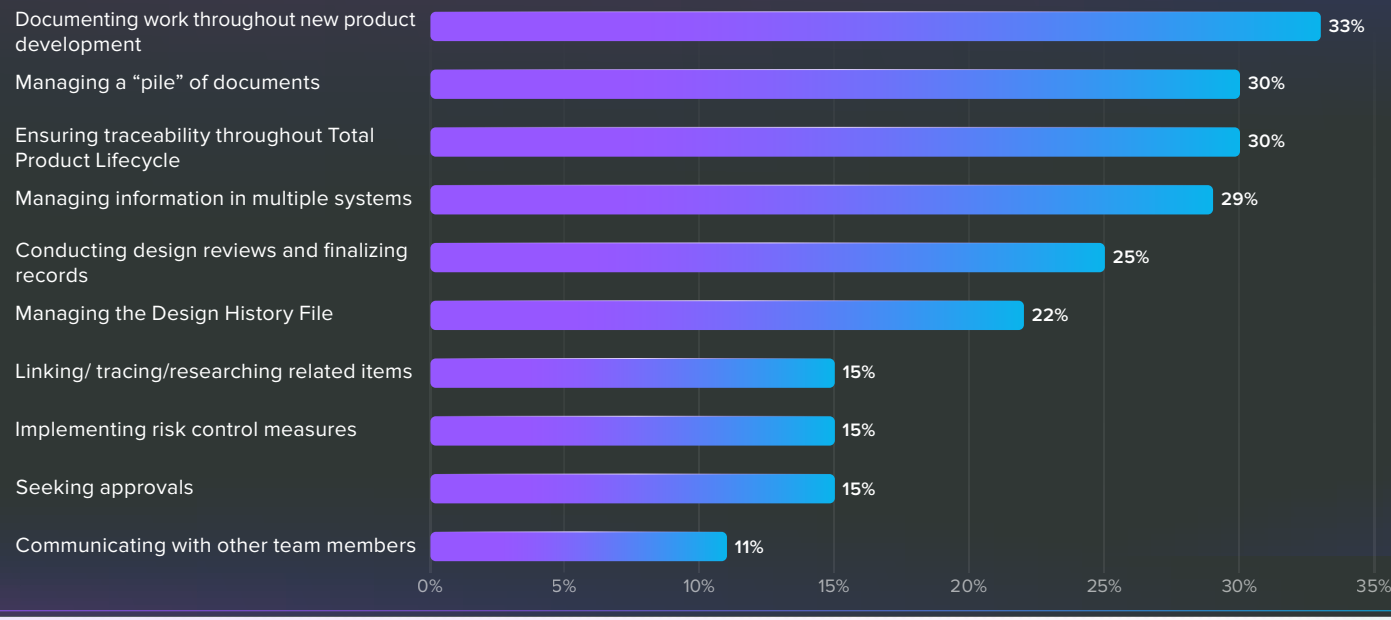
PRODUCT DEVELOPMENT

Supply chain logistics, maintaining product quality, and meeting timelines are all top concerns for product development professionals. New product development, on average, takes 3.5 years according to those we surveyed.

Product development professionals also report that when it comes to managing design controls, their most painful tasks are documenting their work (33%), managing documents (30%), and ensuring total product lifecycle traceability (30%).

Design controls

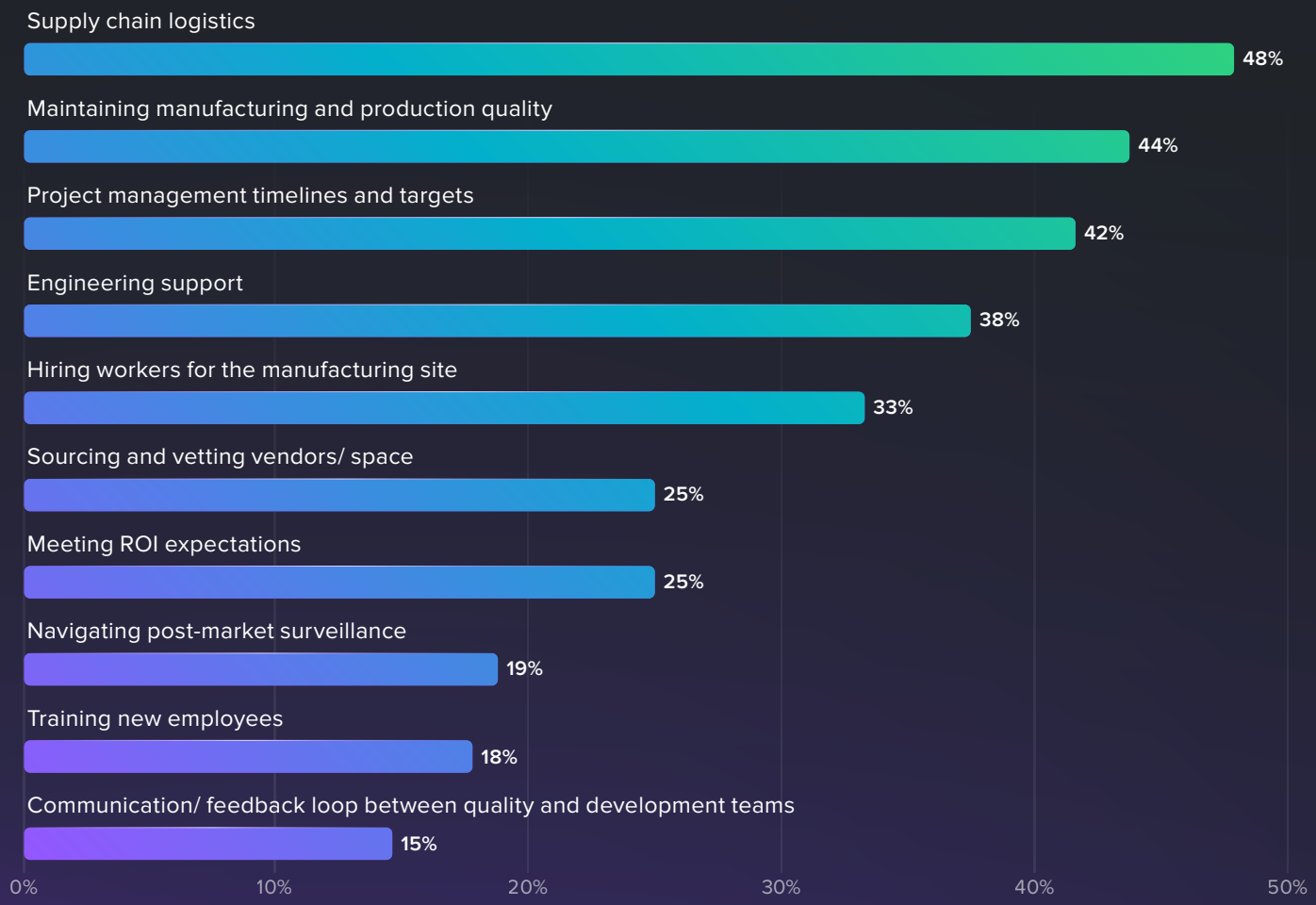
Q What are your most painful tasks related to managing design controls?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

Supply chain logistics is a top concern for product development

Q What are your biggest challenges related to scaling manufacturing as you launch your product in the market?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

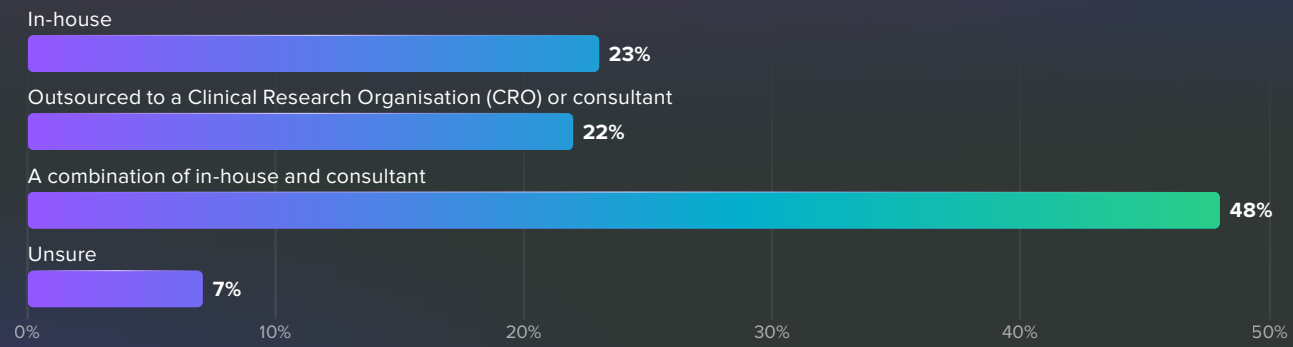
CLINICAL

Research from Vision Research Reports found the U.S. clinical trials market was expected to grow from US$23.83 billion in 2022 to US$35.1 billion by 2030—and organizations we surveyed support this trend.

The majority of professionals we surveyed told us they expect their clinical programs to grow over the next two years, and clinical investigations moved from a #5 priority to #3 for 2024 among organizations we surveyed.

Clinical activity outsourcing

Q How do you plan to run your clinical activities in 2024?

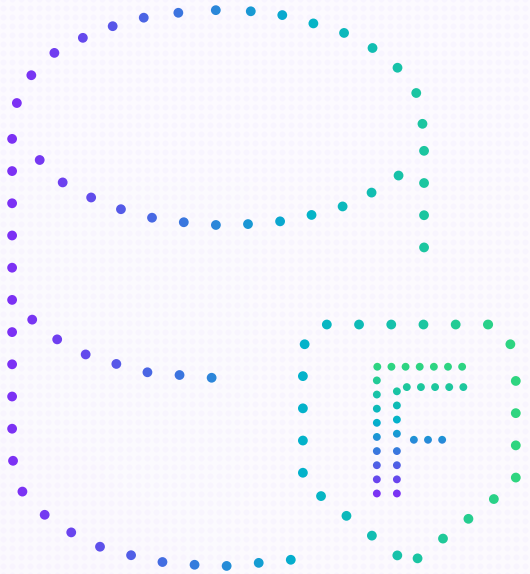


Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

This growth will come with growing pains, as most professionals we surveyed (59%) say regulatory agencies are requiring more clinical data than they did previously.

New guidance from the FDA in 2023 takes it even one step further: Not only do companies need to document clinical investigations/monitoring; they must also preserve data integrity by instituting clear methods for data collection, processing, and protection.[5]

Given that most organizations (70%) use outsourced clinical services—either wholly outsourced or in combination with internal clinical programs—companies need to ensure vendors are upholding the latest best practices and regulatory guidance.



[5] https://www.raps.org/News-and-Articles/News-Articles/2023/4/FDA-outlines-risk-based-approach-to-monitoring-cli

How Quality-Driven Organizations Achieve Operational Excellence

Research points to the knock-on effects of elevating a quality culture.

Each year we look at organizations that excel—whether due to high quality outcomes, competitive position, or even as organizations that attract top talent.

Knowing what makes these organizations different is a useful signal to medical device leaders as they make critical decisions about process, talent, and technology.

This year we focused on companies that tell us they are “very well equipped” to meet their quality objectives in 2024 and compared them to those that say they’re not well equipped to meet quality objectives. What sets these quality-first organizations apart from all others?

1. Best-in-class quality organizations are 2x more likely to prioritize **quality culture**. Market leaders understand that culture is fundamental—driving excellence across the organization and elevating performance.

2. **Measuring performance is critical**. Quality-driven organizations are 6x more likely to say they're measuring quality performance compared to others—whether that means individual metrics such as non-conformance and complaints, or KPIs that present an aggregate score of multiple, important variables.

3. High performers **value regulatory expertise and take an agile approach to managing regulatory changes**. They are 3x more likely to rate their organizational regulatory and industry expertise as “excellent” or “very good,” and they rely most often on publicly available regulatory databases/websites for information.

4 **They value data visibility and strong data management**. 38% of high-performing companies say they have a high level of visibility into quality problems—not a high score but significantly higher than lower performing companies, of which just 11% say the same. As medical devices grow more complex and regulatory bodies ask for even more documentation to win approval, companies will struggle under the weight of these requirements if they have little visibility into data and documentation.

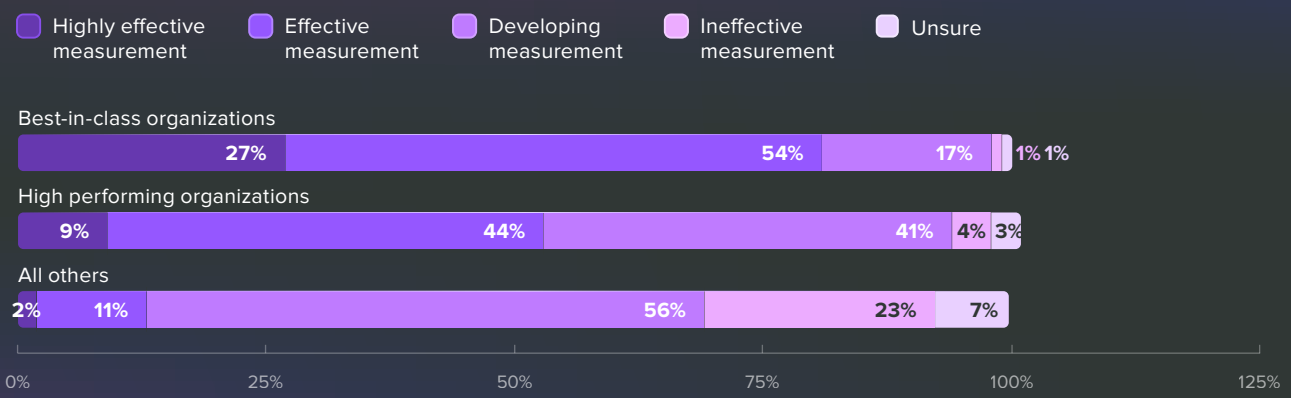
71% of high-performers say that if a government agency or notified body showed up for an unannounced audit, they are "very confident" they could demonstrate total product lifecycle traceability, compared to 13% of lower performers.

5 **They invest in purpose-built tools**. High-performing organizations are more likely to invest in purpose-built tools than are all others. For example, they're 4x more likely to use validated tools designed for clinical data collection compared to lower-performing organizations.

Yet even some high-performing organizations still use legacy, general-purpose tools. Nearly 1 in 3 (30%) best-in-class quality organizations we surveyed say they use general-purpose tools, compared to 51% of lower-performing companies.

Best in class organizations prioritize measurement

Q How effective is your company at measuring the results of quality initiatives/ activities?



Source: Greenlight Guru's 2024 MedTech Industry Benchmark Study

To learn more about how your organization can achieve operational excellence through optimizing processes, investing in purpose-built technology, and elevating data management, visit Greenlight Guru.

Our comprehensive suite of solutions and resources are specifically designed for the MedTech industry and can guide you in harnessing the full potential of modern technologies to bring high-quality medical devices to market, faster and with less risk.

Acknolwedgements:

We extend our gratitude to the professionals across the MedTech industry whose insights and expertise have been invaluable in shaping this benchmark report. A special 'thank you' to Reed Tech for their assistance in the promotion of the 2024 Benchmark Survey.

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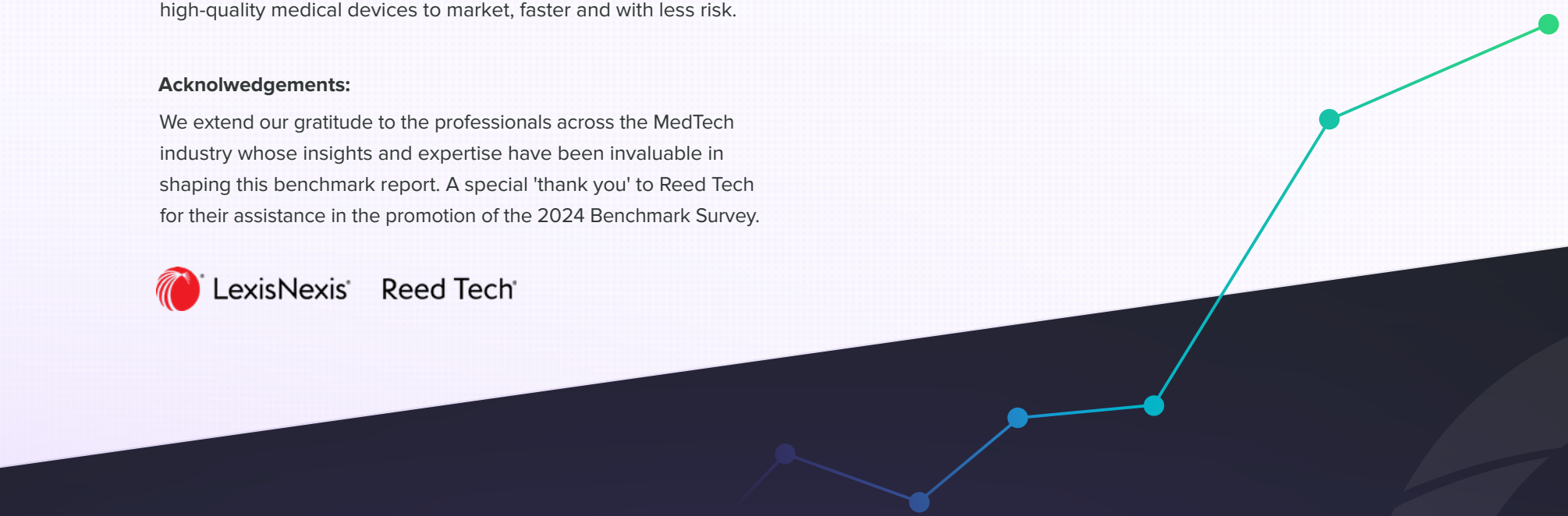

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Moving MedTech Forward