LIFE SCIENCES AND HEALTHCARE

PROACTIVE TOTAL QUALITY

Medical Device Companies' Imperative to Thrive

DASSAULT SYSTEMES

EXECUTIVE SUMMARY

What's more challenging than keeping up with the speed of business today for manufacturers? Keeping up with the pace of global healthcare is. The COVID-19 pandemic showed how quickly healthcare priorities can change globally and how responsive medical device companies need to be in the face of new realities.

Medical device manufacturers must continually innovate and deliver patient-tailored products faster than ever without compromising quality. They must maintain the trust they've earned with their customers and regulators, ensuring everyone has confidence in their company's ability to adapt. Proactive Total Quality provides a data-driven framework for innovation for these companies to thrive and deliver life-saving and -enhancing products as they always have.

MARKET CHALLENGES

The medical device industry is poised for steady growth. According to KPMG, global annual sales are forecast to rise by over five percent a year and reach nearly $800 billion by 2030. These projections reflect increasing demand for innovative new devices (like wearables) and services (like health data), lifestyle diseases becoming increasingly prevalent, and economic development unlocking the vast potential in emerging markets – particularly China and India.[1] The global pandemic added momentum to that opportunity.

Global medical device sales forecast

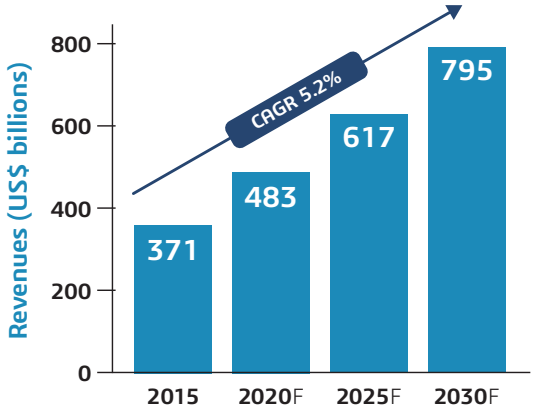


Image Source: KPMG [2]

Even before the pandemic, medical device companies faced daunting market realities.

- **Patient imperatives:** Patient needs, including care at home, create higher expectations for patient safety and experience and add pressure to manage larger portfolios of products.
- **Smart products:** Products are increasingly connected, creating a network of devices sharing data from the device to the cloud to the manufacturer and the hospital, all of which companies must manage safely and securely.
- **Ecosystem:** Medical device companies often rely on a complex network of suppliers, designers, universities, and other partners to get new and improved products to market and into patients' lives effectively. As the responsible party, the device OEM must effectively manage the ecosystem and ensure quality throughout each product's lifecycle.
- **Competition:** Stiff competition comes from known and also non-traditional competitors who can use contract designers and manufacturers to bring new products to market with a low barrier to entry, putting cost pressure on existing manufacturers. Medical device companies must leverage their deep expertise to fend off competition from high-tech and consumer companies as industry boundaries blur.

The challenges will only continue to mount and shift. Medical device companies must proactively address these challenges to thrive as the stakes continue to rise.

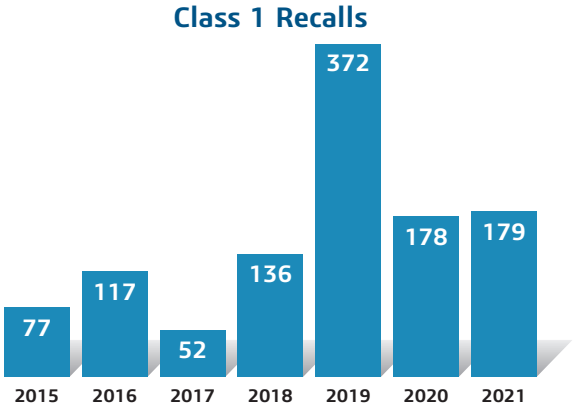
WHAT KEEPS CEOS AWAKE?

The old moniker is "change is the only constant in life." That can be hard to accept in a regulated industry like medical devices. Yet, change seems to be a constant companion for medical device companies. Patient needs change, regulations change, product portfolios grow, and markets change, sometimes in unpredictable ways.

COVID-19 has driven wild swings in demand for an array of device types. Resulting shortages in the supply of both end products and components have forced a need to find and certify new suppliers and materials. These companies may not have previously supplied to regulated customers and may need support to provide adequate visibility and assurance. And COVID-19 was just one disruptive event, albeit a powerful one. Disruptions will continue to occur, and medical device companies need to be more resilient to adapt to this level of disruptive change.

Mergers and acquisitions of small, innovative companies create ways for a company to address market needs. However, purchasing a company is easy compared to ensuring their processes and products meet quality and risk requirements as you bring it in and scale up to feed global channels. New norms for employee safety, plus virtual and remote work, magnify that risk. CEOs worry about ensuring quality and compliance in these new conditions that add risk for medical device companies.

These challenges create yet another nightmare: recalls. There are thousands of medical device recalls every year, most of which pose little or no chance of causing serious health problems. Class 1 recalls, however, represent a reasonable chance that the product will cause serious health problems or death. The FDA data in the image illustrates that the number of Class 1 medical device recalls issued during 2021 is higher than the total number of recalls issued during any of the previous seven years, except one.[3] Every medical device company wants to ensure they reverse the trend.



Data Source: US Food & Drug Administration Website [3]

How will companies ensure visibility into and control across these new and evolving distributed environments? Medical device companies know they need to respond quickly, with validated and compliant processes and products patients rely on for their health. Companies need to manage risk by building quality into all of their processes, not just their products.

Reliable risk management – the kind that allows leaders to sleep at night – starts at the beginning of design and development, continues through production and throughout the use of the device. It needs to be a continuous, data-driven process for spotting trends, identifying risks, and taking action before warning signs turn into product delays, rework, or recalls.

No matter how daunting, medical device companies must meet change head-on, without delay or sacrificing quality or compliance. Each company needs to manage the risk inherent in their response to market dynamics. The only way to do that is to build a foundation of data underpinning the processes. Once a company makes processes fully digital, they can simulate them and optimize them for the array of possibilities. Data-driven insights can shift decisions from reactive to proactive, even predicting quality issues before they happen and minimizing findings, complaints, and non-conformance events. These are just a few examples of how a strategy for Proactive Total Quality can be a reliable framework for innovation.

MOVING BEYOND COMPLIANCE

Compliance, once a target or business driver for medical device companies, is now table stakes, and assumed. Medical device companies need to build operational and business capabilities to meet and retain regulatory approvals. For business health, companies must also move beyond the compliance baseline, even as these regulations change.

Regulatory requirements continue to evolve rapidly and include full traceability plus a risk-based approach to quality. The FDA's Unique Device Identifier (UDI) focuses on post-market traceability from manufacturing to distribution and patient use. Regulators aim to improve medical device safety, traceability, and post-approval accountability with the European Medical Device Regulations (EU MDR) and ISO 13485. These both move beyond pre-approval, taking a lifecycle approach to promote transparency, rapid response, and adaptation to customer complaints and operative incidents.

Proactive Total Quality enables such a lifecycle approach. As regulators look to unleash innovation and allow more freedom and flexibility earlier in the medical device product's lifecycle, it places a dependency on having visibility, responsiveness, and control throughout the entire lifecycle of each product. Proactive Total Quality is the logical evolution of GxP (Good Manufacturing/Clinical/ Laboratory Practices) and Quality Management Systems, the general concept of which is now relatively harmonized internationally.

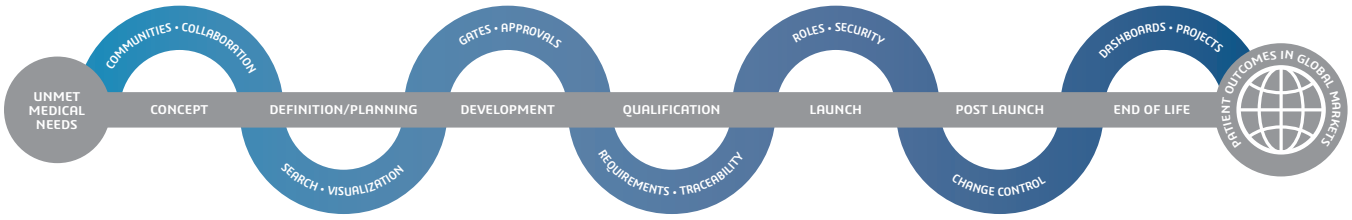
This discussion on data and digital solutions involves transformation. Beyond evolving existing and proven industry approaches, achieving Proactive Total Quality requires a far-reaching **digital** strategy. Digital solutions and the data that underpin them are pillars to meeting regulatory requirements, ensuring traceability of components, and executing risk-based approaches. Transformation is only possible with a digital infrastructure to inform the entire business and ecosystem.

Medical device supply is less and less unique; the supply chain is becoming globalized and multi-industry. Many medical devices are high-tech and use the same suppliers and materials as a car or aircraft. Companies able to benefit from this shared-value network are most efficient in design, procurement, and production. All of these industries share a requirement for perfect quality and reliability to protect human lives. Some others have been working toward digitalization and proactive and predictive quality for years. Regardless of their effort and progress, each supplier's quality is the medical device company's responsibility. The burden is on the medical device provider to ensure quality and regulatory compliance throughout their global supply chain, a challenge too daunting to tackle without a digital/data-driven approach for ensuring end-to-end traceability.

QUALITY FROM CONCEPT TO PATIENT USE

Proactive Total Quality is a comprehensive approach to ensure medical device companies can meet patient needs reliably, delivering in the face of the global challenges and pressures highlighted above. The graphic below illustrates how this approach connects data, information, and people across a medical device company's ecosystem, making quality both a goal and an asset in every phase of the product's lifecycle.

Simplified view of a medical device lifecycle with its phases and supporting processes



This Proactive Total Quality approach reaches across disciplines, companies, and the lifecycle of a product. It uses integrated software to create data integrity and digital continuity. Note that there is power when medical device companies start their quality-related efforts early. Moving these efforts left on the gray timeline allows a company to be more proactive and responsive to patients' needs. By building in quality from the concept stage, it can also lead to more profitable outcomes.

In addition to addressing quality early, the Proactive Total Quality concept also involves ensuring that each group gets the information they need in a useable way. Today, our smartphones and other consumer devices set expectations for a streamlined process and user interface. Employees in every department expect to gain access to the information and services they need comfortably and quickly. In this way, quality is no longer a burden. Consistent, coherent data flows across the enterprise and ecosystem support it naturally. Now, quality can become an opportunity to innovate more effectively and serve new markets more profitably and with superior patient outcomes. But it all rests on information flows.

Similarly, medical device companies are using real-world data (RWD) and real-world evidence (RWE) to support clinical trial designs and observational studies to generate innovative, new treatment approaches[4]. Capturing real-world evidence expands the datasets of medical device companies beyond what is planned and expected for their products into the real world for proof of their safety, quality, and effectiveness. These datasets must meld seamlessly with all the other device data, a task which is impossible without a comprehensive digital framework.

DATA-DRIVEN: BEYOND DIGITAL TO GAIN FLOWS FOR SPEED & CERTAINTY

Being proactive is easiest when employees have confidence that all information they need is accurate and readily available to guide their decisions and activities. Companies must move to a data-driven quality approach, away from document-focused systems.

Information rests on data, but is more; information is data in full context. Complete, accessible information running throughout an organization is typically called a digital thread. Contrast that digital thread to today's typical situation where system users wait for synchronization, authorization, DMZ Cloud access, and other hurdles. In short, today, people spend up to half of their time looking for information or digging it out of documents and independent systems and interpreting its meaning[5]. World-class companies build a foundation of clean, trustworthy data upon which to extract insights and knowledge quickly.

For example, current project management might use a Gantt chart and calendar, with relevant data for each aspect distributed and disconnected. With a data-driven approach, program management can flow easily and with deliverables that point to each other and items that appear on the project plan.

According to recent research from Tech-Clarity, over three-quarters of medical device manufacturers view the Digital Thread as either important or critical to achieving their business strategy.[6] This research points to data, design, design control, and reliability prediction issues medical device companies need to address.

The virtual or digital world can improve quality in the real world of products, processes, and quality events. Companies commonly use virtual product models during product design. Yet, most do not have a virtual world that spans the entire lifecycle of the product from concept to clinical, to manufacturing, and out in physician and patient use. Those few that do can simulate situations and get to a risk-based approach more effectively.

The relationship of real to virtual for every phase of the medical device lifecycle

Leveraging a data-driven framework for innovation puts the contextualized information where you need it when you need it to make informed decisions with speed and certainty. Consider the productivity improvements for your teams. Rather than spending time collecting data and searching for information, they can, instead get what they need quickly and confidently. A unified platform enables everyone to leverage program management techniques based on deliverables across all processes in a product's lifecycle.

- **Risk-driven Project Management**
  Govern projects and programs with a data-driven portfolio view that leverages tasks and deliverables to find and mitigate risk.
- **Design Controls & Development**

  Device Master Record (DMR): Automate and effectively manage the compilation of records containing procedures and specifications required to manufacture the finished device to help ensure compliance with FDA regulations, EU MDR, and ISO quality standards into a single, centralized, secure repository.

  Design History File (DHF): Manage new product development design projects, activities, and content to automate the creation of the Device design History File (DHF) to satisfy regulatory standards and good manufacturing practices for design control.

  Requirements: Create a fully visible, traceable, and collaborative environment for gathering customer needs and creating requirements to ensure product safety and minimize overhead of regulatory compliance.
- **Material Compliance Management**
  Provide materials compliance monitoring and analysis functionality to managers and design engineers for better decision making.
- **Regulatory Information Management**
  Manage comprehensive regulatory information, including submissions, forms, regulatory communications, and adverse event recording data with the ability to communicate to other quality processes the platform supports.
- **Quality Management**
  Manage complaints, CAPAs, non-conformance reports (NCRs) with a practical, consolidated, global approach.
- **Change & Configuration Management**
  Automate and effectively manage the enterprise change management, review release, training, and approved document distribution.

A Proactive Total Quality approach that spans all these functions provides a digital continuum. A company can set and reach quality objectives in each area with that foundation, creating a comprehensive, optimized, lean quality management process. It enables best practices to turn into objectives and standard procedures. Taking a comprehensive approach changes the game on quality, making it proactive and empowering for employees versus obligating them to play their part.

Proactive quality also supports the transition to risk-based management to optimize the processes, as evidenced by the FDA's Case for Quality program launched in 2011 that put risk-based management at the center of device validation. The Case for Quality program is intended to help the FDA identify device manufacturers that consistently produce high-quality devices based on good, compliant manufacturing practices. The Case for Quality also identifies successful manufacturing practices to help other device manufacturers raise their manufacturing quality level[7].

TOTAL QUALITY MEANS EVERYONE

The vision of Total Quality has always espoused that quality is everyone's responsibility, and we are now moving into an era where that can be a reality. Visibility into timely, accurate information - delivered in the appropriate context for every decision-maker - can transform a medical device company from reactive to proactive and responsive. It can also shift quality responsibility from the quality department to everyone, every department, partner, and healthcare provider, physician, and patient.

The company can learn from its past and update its design and risk assumptions to ensure it avoids duplicating errors and mistakes. Decisions are quicker - and better informed. A company with digital data flows across the enterprise and ecosystem can constantly communicate changes and monitor performance. Data from the entire lifespan and environment enables a medical device company to go beyond rear-looking reporting and analysis to forward-looking predictive capabilities.

The data-driven approach is essential for modern analytics systems such as artificial intelligence (AI) and machine learning (ML). Such advanced analytics and systems anticipate future events and quality results even from weak signals detected anywhere in their environment. If a system is learning by itself with ML, it and its users can be intelligent and proactive participants in quality.

Proactive Total Quality enables new working paradigms and new ways of working for all, as the list of activities in the previous section suggests. Every department gets what it needs and can collaborate efficiently and reliably with others, from individual contributors and hourly employees to supervisors, leaders, and executives.

Rather than be kept awake at night, with Proactive Total Quality, the CEO also gets appropriate information. Insights from across departments and the ecosystem show how to adapt and drive the business with that quality information. It's the promise of the Information Age delivered: data-driven decision making to improve quality, meet compliance requirements, and make informed business decisions to transform the business into a responsive, nimble competitor.

CONCLUSION

The stakes in healthcare today are higher than ever before, and the pace of change will not slow down - nor will the pressures from it subside. Patients' needs continue to evolve. There is no end to changes in regulations. Competition continues to emerge strong.

Medical device companies must master traceability and risk-based approaches to comply with regulations efficiently. The data you need to comply is overwhelming and can lead to poor profitability and results if not available through a digital platform approach. In short, digitalization is imperative.

Proactive Total Quality takes this even further – to use the data from across the entire lifecycle and ecosystem to seize control and direct activity for ever-improving quality with superior efficiency. The result is better patient outcomes and a responsive, thriving medical device company.

CEOs need to mandate a digitalization effort as the foundation of all other initiatives to sleep better at night. A platform of digital systems where data flows where and as required is the only approach likely to support companies in navigating the constant changes, competitive threats, need to evolve, and profit expectations.

With IT, R&D, Clinical, Operations, and Customer Care all leveraging a single source of information, they can play their roles alongside the Quality and Regulatory teams. The entire company can embrace Proactive Total Quality.

Leaders are building a data-driven innovation framework. This foundation aims for not only quality and compliance, but also innovation and efficiency to flow throughout the organization and every product's lifecycle. The health of the planet relies on this transformation.

CITATIONS

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