

A CULTURE OF QUALITY IMPROVES PATIENT CARE



The healthcare industry is undergoing an accelerated pace of change. Medical innovation is unleashing new possibilities and, in turn, spurring a need for providers and payers to deliver quality patient care that improves clinical and economic outcomes. In this environment, health system leaders will rely heavily on medical technology companies to provide the highest quality products and therapies in a cost-efficient way.

Each year, innovative medical technologies save, extend, and improve the lives of hundreds of millions of people around the world.

While medical device technologies are carefully well-designed, manufactured, and tested, they are complex and carry potential risks. For this reason, quality and safety surpass even innovation as the healthcare industry's top priority.

As medical technology has evolved, so too has the definition and scope of quality. Regulatory compliance and data-driven control systems continue to dictate the baseline for quality assurance. However, industrywide momentum is building for medical technology companies to adopt a culture of quality awareness among employees — an area where Medtronic is leading with best practices. According to McKinsey & Company, sound product and process controls, stronger operational maturity relating to

people and assets, and mature quality systems — along with a robust quality culture and practices — correlate with good quality outcomes.

“Building a culture of quality is the greatest commitment we can make to our customers, clinicians, and patients,” says Omar Ishrak, Medtronic chairman and CEO. “Without it, everything else — from innovative product and therapy development to market expansion — becomes near impossible to achieve. Together with the medical technology community, we must make it our priority to not only meet quality standards, but also to advance those standards by fostering a culture of quality and leading by example.”

GLOBAL QUALITY STRATEGY

At Medtronic, a commitment to quality products and the highest standards of reliability has remained steadfast since 1960, when co-founder Earl Bakken wrote product quality and reliability into the DNA of our company as cornerstones of the Mission statement. Nearly six decades later, the Medtronic global quality strategy continues to ensure that quality and a commitment to patient safety are evident in every aspect of the company's work. It informs the Medtronic business strategy in therapy innovation, globalization, and economic value, and guides global teams when they interact with customers, collaborators, regulators, and one another.

MEDTRONIC MISSION TENET 3

To strive without reserve for the greatest possible **reliability and quality** in our products; to be the unsurpassed standard of comparison; and to be recognized as a company of dedication, honesty, integrity, and service.

(written by co-founder Earl Bakken in 1960)

Medtronic
Further, Together

The Medtronic global quality strategy, aligned with industry standards set by the U.S. Food and Drug Administration (FDA) and regulatory agencies around the world, is organized around three basic imperatives:

1. Drive a mindset of excellence through a culture of quality
2. Ensure product superiority
3. Advance effective and efficient compliance with global regulations

“Our quality strategy is first and foremost rooted in patient safety,” says Noel Colón, Medtronic senior vice president and chief quality and regulatory affairs officer. “When employees and our partners uphold a culture of quality and put the patient first, we can successfully execute on processes and protocols that ensure quality, reliability, and regulatory compliance — from development and manufacturing to distribution and patient use.”



TOP TRAITS OF A CULTURE OF QUALITY

Leadership Support: CEO and other leaders live the company’s commitment to quality through their words and actions.

Employee Engagement: Programs, events, and reward systems recognize and incentivize employees whose commitment to the company and its mission is making a difference.

Internal Communications Program: Multi-channel internal communications emphasize key company products, therapies, and achievements, and their significance to employees, outside stakeholders, and the industry.

Employee Feedback: Widely communicated feedback systems identify departments and locations where quality improvement areas have been identified and provide opportunities for further raising the culture-of-quality bar.

Driving a culture of quality

Quality Begins with Me (QBWM) fosters a mindset of excellence across Medtronic, extending to company sites and the supply chain around the globe. Through QBWM, employees and senior leaders understand the behaviors that drive quality and ensure that everyone takes personal responsibility for quality outcomes.

“To have the broadest impact on patient safety, we must instill a culture of learning. To become a learning organization, we need to create a culture where employees feel comfortable sharing mistakes with the intent that those mistakes are not repeated by others,” says Vipul Sheth, Medtronic vice president of corporate quality.

“It’s also critical to provide opportunities where successes and best practices are shared with an intent to adopt them across the organization. To have the broadest impact on patient safety, we must expand the reach of what we’re learning and the protocols we see working well. This level of collaboration is critical in advancing best-in-class quality practices.”

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QBWM extends far beyond functions that have direct contact with products and therapies. All Medtronic employees are measured on and recognized for key QBWM behaviors:

- **Courageous:** Employees speak up in a blame-free environment when they notice something wrong.
- **Preventive:** Employees share and implement ideas to prevent quality issues from arising.

FIVE BENEFITS OF A CULTURE OF QUALITY

1. Greater patient health and safety.
2. Accountable and empowered employees.
3. Heightened credibility with regulators, as well as hospitals, physicians, and other healthcare providers.
4. Innovation culture.
5. Stronger cost efficiencies.

- **Accountable:** Employees do what they say they will do, and hold each other accountable.
- **Patient Focused:** Employees understand how their actions affect patients, and they put the patient first.

"The Quality Begins with Me concept strikes a chord that connects to the hearts and minds of employees," comments Prakash Patwardhan, Medtronic quality and regulatory affairs program director. "It reinforces a way of thinking focused on how employees can be a force for meaningful improvement as part of their everyday duties, and how their contributions can positively influence the patient experience."

A QBWM leadership toolkit helps senior management understand their responsibilities as leaders, including how to model expected behaviors to their employees. Additionally, QBWM assessments, which are conducted at every manufacturing site, identify opportunities for enhancing a culture of quality and entrenching quality in employees' daily responsibilities through:

- **Recognition of QBWM Behaviors:** Leadership-to-management, manager-to-employee, and peer-to-peer recognition
- **Visual Management:** Clearly defined and transparent quality metrics, customer feedback bulletins and signage, and additional measurement efforts
- **Continuous Quality Improvements:** Forums to share feedback and "lessons learned," as well as quality- and compliance-awareness training
- **Product Awareness:** Employee understanding of product and therapy use and the patient experience
- **Communications:** Formal and informal employee communications about quality expectations and performance

"A culture of quality is the foundation of everything we do at Medtronic, yet it can be hard to measure and quantify," explains Patwardhan. "Since Quality Begins with Me was introduced, we have seen sustained increases in the number of employees willing to practice a 'see something, say something' mindset and proactively prevent potential escapes (defective product leaving the site). Establishing, nurturing, and sustaining a culture of quality is a journey and a shared responsibility that requires perseverance, patience, and passion."

EXTENDING A CULTURE OF QUALITY TO SUPPLIERS

Medtronic works with suppliers and other firms around the world that play a significant role in ensuring that company products and therapies reach patients. All interactions that

FIVE WAYS MEDTRONIC BUILDS SUPPLIER PARTNERSHIPS

1. Quality Begins with Me can be used to design a quality program customized to suppliers' needs and culture, or as part of their education and training initiatives.
2. Supplier Quality Excellence Manual addresses key issues, such as the parties' roles, responsibilities, and expectations.
3. Annual Supplier Conference is a forum where approximately 1,500 leaders of top Medtronic suppliers learn more about the Quality Begins with Me Program and the importance of CEO engagement.
4. Supplier Optimization and Risk Reduction (SOAR) Program serves as a risk-reduction framework for suppliers.
5. Performance monitoring, such as quality audits, inspections, and monthly or quarterly management reviews, ensures the effectiveness of suppliers' quality systems and compliance with agreements.

occur at the supplier facility have a profound effect on product and therapy quality, making suppliers a critical partner in the Medtronic supply chain.

“Our partnerships with suppliers, coupled with the company’s close sourcing and quality team relationships, allow Medtronic to infuse quality into every supplier interaction,” says Ann Sheldon, Medtronic vice president of global supplier quality. “Suppliers understand the importance of transparency and accountability, which further strengthen the partnership dynamic.”

Supplier quality excellence has delivered improvements, ranging from the ability to better meet ongoing marketplace demands to reductions in product costs.

Ensuring product superiority

Every step in the Medtronic design and development process is intended to deliver products and therapies of the highest quality and reliability.

MEDTRONIC OPERATING SYSTEM (MOS)

The Medtronic Operating System (MOS) is a common framework and set of practices to get work done efficiently and effectively. It improves quality performance by taking workflows through a systematic process, transforming them from “unstable” to “stable” to “high maturity”. The framework implemented to achieve “high maturity” is the Cell Operating System (COS). When workflows are at high maturity, the result is significantly higher quality performance and far fewer issues in the field (10-times improvement over processes classified as “unstable”, and four to five times improvement over “stable” processes). Other frameworks to improve product quality include Design, Reliability and Manufacturability (DRM) and First Time Quality (FTQ).

DESIGN, RELIABILITY, AND MANUFACTURABILITY

The Medtronic DRM program uses predictive engineering practices and methods that drive continuous improvement in device design, reliability, and manufacturability. DRM is also widely used throughout the technology, aerospace, and automotive industries, to improve device performance, decrease product development time, and meet cost targets by identifying, minimizing, and preventing risk at the earliest stage possible.

“Design has a tremendous impact on the predictability of a product or therapy launch and marketplace acceptance,” says Nina Kohnen, Medtronic senior director of Design, Reliability, and Manufacturability, New Product Development. “It’s mission-critical for medical technology companies to instill a cross-company quality mindset at the beginning of a product’s or therapy’s life cycle.”

Support from Quality, Operations, and Research & Development leadership ensures DRM methodologies and principles are applied broadly across the company. Required training for all employees, including leaders, helps ensure DRM is embedded in the company’s product development program.

30-80%

REDUCED POTENTIAL FOR HUMAN ERROR

after launching First Time Quality protocol

Three practices are key to advancing DRM at Medtronic:

1. **Voice of the Customer (VOC)** sessions provide rich insights into clinician needs and fuel innovation and development processes.
2. **Concept Engineering** is designed to break through biases and the status quo and help identify promising solutions that address healthcare challenges.
3. **Predictive Engineering** actively manages technical risk during the development cycle, to bring products and therapies to market with rigorously proven performance and reliability.

A group of surgeons from Japan, China, and Australia attended a VOC Lab and Concept Engineering workshop hosted by the Medtronic Technology Center in Shanghai. Attendees tested surgical-tool prototypes, first on a desktop, then in a lab with simulated-use environments. They provided feedback on ergonomics, grip strength, reach, knob shapes, button size and location, and the force required to activate the device, among other product elements.

“Feedback from our customers is essential to provide products that meet their needs,” explains Brad Steinhoff, Medtronic senior program manager, Technical Fellow, and DRM Council member. “VOC uncovers customers’ insights and all aspects of customers’ experience, including understanding their unmet needs. It also helps project teams focus on what matters most to our customers.”

FIRST TIME QUALITY

First Time Quality (FTQ) is a protocol founded on an error-proofing methodology. The protocol is applied up front, during equipment and process design, as well as later, to existing manufacturing lines. The goal is to accelerate product and therapy improvements. It also ensures that the company does not make, ship, or receive defective materials or products at any process step. Employees trained in FTQ learn how to detect potential errors at the beginning of the product or therapy life cycle, develop robust controls, and identify improvement areas that can have the strongest impact on quality.

FTQ was created using best practices from within Medtronic and across the industry, culminating in the publication of an FTQ Playbook, which has been deployed to all Medtronic manufacturing sites. The protocol’s most

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– Patrick Joyce, vice president of Global Information Technology and chief information security officer

dramatic result has been the reduced potential for human error. Sites have experienced a 30 to 80 percent reduction in costs related to poor quality.

PRODUCT AND DEVICE SECURITY

The Medtronic Global Security program aims to protect Medtronic products, solutions, systems, information, and, most importantly, the privacy and safety of patients and healthcare systems. These expectations also extend to our vendors and business partners. Medtronic works closely with government agencies, industry partners, peers, expert security firms, and security researchers to enhance security efforts across the medical device and healthcare industry, as well as to shape guidance and regulations in the following areas:

- **Product Security.** Medtronic is focused on building secure products for life, from planning and design through device retirement. The Medtronic product security program involves security and medical device experts from inside and outside the company as well as rigorous development processes and practices that enable security and usability. The company is committed to delivering safe and effective devices that address patients' therapeutic conditions.
- **Information and Systems Security.** A number of Medtronic implantable devices are designed to capture and report data that can provide key insights to clinicians and patients, helping to improve outcomes. Measures to address data security are deployed as products and therapies are developed, leave company manufacturing facilities, and are used by healthcare providers and patients. Additionally, Medtronic has dedicated resources and processes that help prevent, detect, and respond to cyber threats. The company monitors system security and takes action to address vulnerabilities.

“Today, the cybersecurity landscape is constantly evolving,” says Patrick Joyce, vice president of Global Information Technology and chief information security officer.

“Throughout the full life cycle of a medical device, we continuously monitor for vulnerabilities and security risks. We assess and test for vulnerabilities based on global standards and best practices, and we engage regulators

MEDTRONIC INVESTED
\$2.3 BILLION
IN RESEARCH &
DEVELOPMENT
IN FY2018 WITH
320 ACTIVE
COMPANY-
SPONSORED
CLINICAL STUDIES

and communicate appropriate risk mitigation steps to key stakeholders.”

[Learn more about the Medtronic commitment to product and device security.](#)

Advancing compliance and working with global regulators

The Medtronic commitment to patient safety — combined with adherence to standards required by global regulators — is reinforced at all company levels through [corporate governance](#) initiatives focused on compliance, ethics, and integrity. These programs are designed to foster a culture of compliance and commitment to the laws and ethical standards in every country where Medtronic operates. The company invests in robust training programs for employees and partners around the world about their responsibilities under regulatory policies.

In the United States, the FDA is recognized for its gold-standard approach to regulating medical technology. Pre-market requirements are organized around three classes of risk: low, moderate, and high. Post-market requirements address quality systems, registration and listing, device reporting, and recalls. Medical technology manufacturers and regulators outside the United States follow similar requirements, and the FDA works closely with them to drive consistency in global regulations.

PRE-MARKET TESTING AND CLINICAL TRIALS

In 2018, Medtronic invested \$2.3 billion in developing and testing new products and therapies, with 320 active company-sponsored clinical studies. Every product and therapy advancement the company makes is subject to extensive testing, evaluation, and approval by regulators before being introduced to markets around the world. These regulatory authorities examine the results of all studies, as well as other data, before clearing or approving products and therapies for use by physicians and patients.

POST-MARKET SURVEILLANCE AND RESPONSIBLE PROMOTION AND MARKETING

A commitment to patient safety continues long after a product or therapy enters the market. Global regulators ensure post-market safety through complaint investigation and reporting procedures, corrective and preventive action, and recalls and removals — even when no actual harm has occurred. Medtronic upholds a [continual commitment to safety after product or therapy introduction](#), monitoring safety and performance through a rigorous post-market surveillance process.

Medtronic places integrity at the core of its sales practices and recognizes the importance of [responsible marketing and promotion](#). The company educates its direct sales force in appropriate communications and compliance programs that ensure any product or therapy promotion or sale is consistent with labeling, as well as all applicable laws and regulations pertaining to relationships with government and private customers. An extensive training program ensures employees understand industry risks, and honest and transparent product and therapy promotion.

BUILDING MOMENTUM FOR INDUSTRY COLLABORATION

The Medtronic business model is based on achieving better health outcomes by partnering with physicians, healthcare innovators, and patients. It also demands close collaboration with global regulators and medical technology industry partners.

While the footprint of the Medtronic culture of quality has expanded internally, the Medtronic QBWM program has garnered the attention of the FDA, [AdvaMed](#), and the [Medical Device Innovation Consortium \(MDIC\)](#). In 2019, AdvaMed launched a [Quality Culture Playbook](#), which draws upon the Medtronic QBWM effort and features elements of the Medtronic QBWM curriculum. It serves as an industry best practices resource.

Similarly, the FDA, recognizing that a singular focus on compliance does not result in a corresponding increase in device quality, launched its [Case for Quality](#) in 2011. The FDA collaborated with healthcare professionals, patients,

and medical technology leaders — including Medtronic — to create the program. The program showcases manufacturers that consistently produce high-quality medical technologies and provides best practices and additional resources to help other manufacturers raise their quality levels.

The FDA continues to work closely with the industry on its Case for Quality 2020 Strategic Plan. The plan's initiatives include a Maturity Model and data analytics as well as four initiatives devoted exclusively to creating and maintaining a quality culture.

A FUTURE GROUNDED IN QUALITY

Change is among the most powerful influences in today's healthcare industry. Amidst ground-breaking technologies that restore health and transform lives and new regulatory standards that raise the bar on patient safety, a steadfast commitment to quality must prevail. Through ongoing collaboration with industry members and global regulators, we believe medical technology companies will continue to create products and therapies that help improve clinical and economic outcomes for generations to come.

[Learn more about our commitment to transforming healthcare.](#)

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