HOW WE APPROACH QUALITY

BACKGROUND AND CORE VALUES

When we innovate beyond the status quo with breakthrough, safe and high-quality products, we can transform patient lives. In accordance with our core values of meaningful innovation and high performance to benefit patients and clinicians, our highest priority is to ensure that our products are safe and reliable. Boston Scientific fosters an environment where our people shape science and new ideas into medical solutions. Quality is embedded in all aspects of our business and all employees share responsibility for product quality and patient safety.

INVESTING IN OUR QUALITY MISSION

Health care providers and patients rely on us to design and develop medical devices they can trust. Our teams take pride in delivering the highest level of quality in all our products and we invest to ensure our people have the resources and infrastructure they need to deliver on our mission.

Our global quality and safety efforts are supported by:

- Mandatory quality training for all employees
- A global quality system that integrates customer feedback and regulatory requirements
- The Boston Scientific Best4 strategy

OUR QUALITY STRATEGY: BEST4

The Boston Scientific Best4 strategy centers on patient safety as our top priority. This proactive, preventive approach to quality begins with product design and continues throughout each product’s lifecycle. Our Best4 strategic framework enables us to uphold cohesive quality across our global supply chain. Its key drivers are culture, agility, performance and compliance.

- **Culture** fosters an environment that makes our quality policy real for every employee.
- **Agility** reduces complexity, removes obstacles and quickly adapts to changing business needs while adding efficiency.
- **Performance** delivers the best products, services, and solutions for patients and customers with robust produce performance.
- **Compliance** upholds all global laws and regulations with one Global Quality System while driving a patient-centric quality culture.
OUR ALL-EMPLOYEE QUALITY APPROACH

The Boston Scientific quality process is central to our culture. It is posted in all workspaces, on employee ID cards and on digital display, intranet and other device screens throughout the business. All employees play a role in continually raising the bar for product quality and patient safety, and every manufacturing and distribution site relies on a shared set of metrics to ensure the highest quality standards are met consistently in all our operations.

A unified, patient-centric framework enables us to be vigilant about our quality results as we continually evaluate the efficacy of our processes and systems. Oversight of this work includes governance by the company’s Board of Directors and its Risk Committee. The board’s Executive Compensation and Human Resources Committee assesses quality performance and applies a quality metrics modifier to our annual bonus plan, which helps to reinforce accountability across the company.

IMPLEMENTING OUR STRATEGY AND MAKING CONTINUOUS PROGRESS

At all stages of quality product development, we are focused on the unmet needs of patients who will benefit from our products.

Comprehensive systems and processes
The company’s Global Quality and Safety teams manage the processes and system for everything we do – from research, development and design to product building, supply chain operations and distribution. This includes all processes for the end-to-end life cycle of our products, from design and risk assessment to in-depth usability engineering. A vital aspect of this work is the selection of quality materials. Our teams carefully assess component and device materials and consider a range of factors, from efficiency and availability to worldwide medical and environmental requirements and regulations.
Ongoing process improvements

We facilitate ongoing quality progress through process improvements. For example, our practice of conducting limited market releases for key products demonstrates how we are adapting processes to further support the responsible development and expansion of new markets. Additionally, we engage in extensive post-market surveillance activities across our product portfolio to collect empirical and anecdotal evidence on the use of our devices. We also participate in routine auditing activities involving the U.S. Food and Drug Administration, European Union-notified bodies and country-specific regulators. In the event we detect an issue, we take immediate action in the best interest of patients and publicly post product advisories.

A focus on preventing quality issues

We invest heavily in systems, training and processes focused on preventative action at every stage of product development. Our Quality teams proactively identify measures we can take to prevent product quality or safety issues before they arise.

Programming to reinforce our commitment

Our global award program, Recognize Success, honors teams and leaders for their contributions to improved quality and patient care. We recognize employees companywide across a number of business units and functions. We also launched a quality award category reinforcing our focus on prevention, which received more than 200 nominations in 2023.

Our Quality Catch recognition program for product builders at all manufacturing sites provides incentives for people to raise system or process concerns. Employees who identify ways to integrate quality improvements are recognized by supervisors and peers for contributions such as “Eagle Eye” and “Raise Your Hand” catches.

In addition, each year our sites around the globe host Everyone Makes an Impact events to reaffirm our commitment to quality and highlight inspiring patient stories. Thousands of employees attend the events either virtually or in person to hear patients talk about how their lives were changed after being treated with Boston Scientific solutions. People from all parts of the business see for themselves the real impact of our work.

A one-company effort

We thoughtfully embed quality processes and initiatives throughout the business, including:

- Comprehensive pre-clinical science processes for in-vitro and in-vivo pre-clinical research, as well as evaluations of medical devices in the development phase
- Rigorous clinical trial standards and procedures for highly regulated clinical trials that generate publicly reported efficacy data
- Research and development (R&D) supported by 10 global R&D Centers of Excellence that specialize in key areas of new product performance and identify best practices for product design
- Close monitoring of ongoing product performance

For updates on our latest development efforts and our performance, see our 2023 Performance Report. To learn more about the results of our work at Boston Scientific, visit our website.