



HOW WE APPROACH QUALITY

BACKGROUND AND CORE VALUES

Meaningful innovation is one of our [core values](#). When we innovate beyond the status quo with breakthrough, safe and high-quality products, we can transform patient lives. Boston Scientific fosters an environment of creativity where our people shape science and new ideas into medical solutions that create value for patients, customers and employees.

INVESTING IN OUR QUALITY MISSION

Health care providers and their patients rely on us to design and develop medical devices they can trust. This expectation underpins every innovation we pursue and develop with care. 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:

- A single global quality system
- Quality systems training for all employees
- A quality master plan that prioritizes quality improvement projects, leading to higher quality products and better patient outcomes
- Companywide quality practices for integrating customer feedback and regulatory requirements into our processes
- The Boston Scientific Best⁴ strategy

OUR QUALITY STRATEGY: BEST⁴

The Boston Scientific Best⁴ strategy centers on patient safety as our top priority. This proactive, preventative approach to quality begins with product design and continues throughout each product's life cycle. 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** – foster a culture that makes our quality policy real for every employee
- ▶ **Agility** – reduce complexity, remove obstacles and quickly adapt to changing business needs
- ▶ **Performance** – deliver the best products, services and solutions for patients and customers
- ▶ **Compliance** – uphold all global laws and regulations as we adhere to our single quality system



Best⁴ Quality

culture + agility + performance + compliance

OUR ALL-EMPLOYEE QUALITY APPROACH

The Boston Scientific quality process is central to our culture. It is posted in all workspaces, on every employee ID card 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 systems 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 lifecycle 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.

Boston Scientific Quality Policy

- **“I improve”** reflects the individual commitment and accountability of every employee in an atmosphere of improvement and innovation.
- **“Quality”** embodies the mission to ensure our products, processes and services meet or exceed all applicable regulations, standards and customer expectations.
- **“Patient care”** incorporates our patient first mindset, reinforcing who is most important in our work.
- **“All things Boston Scientific”** means all employees incorporate our quality imperative in everything we do, every day.

I
improve
the Quality of
Patient Care and
all things Boston Scientific.

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, EU 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](#).

Programming to reinforce our commitment

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, our annual “Everyone Makes an Impact” events for employees around the world bring our quality policy to life by featuring people who share how they benefitted from our devices as patients.

A one-company effort

All of our quality processes and initiatives are supported by practices that prioritize a quality focus 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 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; and
- Close monitoring of ongoing product performance.

For updates on our latest development efforts and our performance, see our most recent [2022 Performance Report](#). To learn more about the results of our work at Boston Scientific, visit our [website](#).