Investments for Patient Safety and Our Future Growth

Our Quality and Regulatory Transformation Project *Elevate*

Elevate is a multi-year program focused on the strengthening of our quality management capabilities and the achievement of four core goals. We plan to invest approximately ¥80 billion over the three years from fiscal year 2024 through fiscal year 2026. We believe that we have completed 96% of our commitments to the U.S. Food and Drug Administration (FDA). As a global MedTech company, we want to be recognized for the high quality, value, and innovation that our products, services, and people bring to society every day, while continuously working to strengthen our quality management.

Our key long-term goals are

1. Strengthening our patient safety focus and product quality culture
2. Embedding sustainable, repeatable processes and compliance
3. Fostering constructive relationships with health authorities
4. Leveraging quality as a competitive advantage

Elevate initially began with 20 workstreams, driven by a strong team selected globally from each function. The four pillars of "Design & Development," "Manufacturing & Supplier Management," "Supply Chain, Market & Post-Market," and "End-to-End (E2E) Quality Processes" will drive our efforts to meet our regulatory commitments, create organizational capabilities, establish global quality system standards, and strengthen the foundation of our quality culture.

Key Workstreams

Recent Enhancements to Strengthen Quality Assurance and Regulatory Affairs (QA&RA)

Jan. 2019	Announced *Transform Olympus*, corporate transformation plan
May 2021	Added "QA&RA transformation" to key priorities of *Transform Olympus*; focused on capability development, skill-set enhancement, and the global integration of quality assurance organizations and processes
Nov. 2022–Mar. 2023	Received three FDA warning letters for Aizu Factory, Hinode Plant, and Olympus Medical Systems (Hachioji site)
May 2023	Announced our company strategy, focused on further QA&RA strengthening that prioritized addressing the issues identified in the FDA warning letters **Integrate remediation activities in response to FDA warning letters and "QA&RA transformation" initiative into a company-wide program.**
Nov. 2023	Launched *Elevate*, our quality and regulatory transformation project **Execute 20 workstreams to fulfill our commitments to regulatory authorities and to strengthen the foundation of our quality system, organization and culture for the future** (Please refer to the following pages for the key priorities.)
June 2025	FDA issued Import Alerts for certain medical devices manufactured by Aizu Factory.
Sep. 2025	96% of FDA commitments completed

Committed to fulfill our commitments made to the FDA with urgency and aims to complete Project *Elevate* by the end of FY2026

Key Priorities for *Elevate*: 1
Establishing a Global Quality Management System

What is a global quality management system?

The system consists of comprehensive global standards and procedures relating to quality management. At Olympus, we have established our Global Quality Policy, Global Quality Manual, quality standards and global standard operating procedures (SOPs) that must be observed on a global basis.

We also clearly define elements and other factors that can be improved at a local level (at each subsidiary or factory) while adhering to global standards.

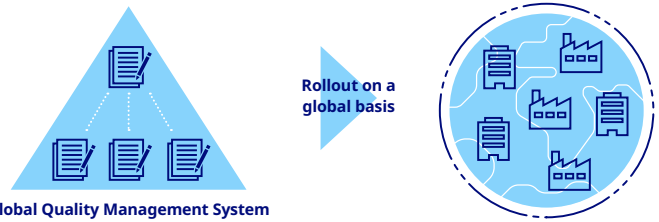
Measures taken

In response to issues raised in the warning letters from the FDA, we recognize the importance of developing globally harmonized systems. To address this, we have been building a global quality management system focused on 20 high-priority workstreams. We are aiming to ensure consistency, efficiency, and compliance with international standards across all operations and business entities. We have also set a shared goal of improving patient health and safety.

In fiscal year 2025, we completed the development and implementation of a global quality management system for seven of these workstreams and commenced operations.

Before — Independent structure and design of the local procedures were established for each region / facility

After
- Established and implemented globally standardized and harmonized processes for key elements of Quality System
- Significantly enhanced governance, while clarifying goal setting and the prioritization of initiatives



Key Priorities for *Elevate*: 2
Design Control and Process Control

What is design control?

Design control is the structured process of objectively evaluating and verifying to assure that devices meet user needs, intended uses, and specified requirements.

Measures taken

- ☑ Revised product design validation process and requirements across Japan sites
- ☑ Completed design validation in accordance with the revised rules for products manufactured at the site (Aizu Factory*1) that had received a warning letter from the FDA
- ☑ Assessed the results of the reevaluation and updated relevant product records*2
- ☑ Implemented training for engineers regarding the content of the revised design validation

What is process control?

Process control is a systematic approach to managing the manufacturing process so that products consistently meet quality standards. It involves monitoring procedures, inspecting equipment, and verifying product quality to maintain consistency and prevent deviations.

Measures taken

- ☑ Established a companywide governance system and built teams at each site to drive implementation
- ☑ Completed missing process validations in manufacturing processes
- ☑ Revised the manufacturing records template*3 to objectively prove that the manufacturing process is being properly monitored
- ☑ Established and revised SOPs and deployed globally to ensure consistent implementation of the process validation process

*1 Only Aizu Factory received a warning letter from FDA regarding design validation.
*2 The documented information that provides evidence of how a product is designed, developed, and verified to meet its design and quality requirements
*3 The documented information related to product manufacturing, such as raw materials, manufacturing processes, manufacturing date and time, and the personnel involved

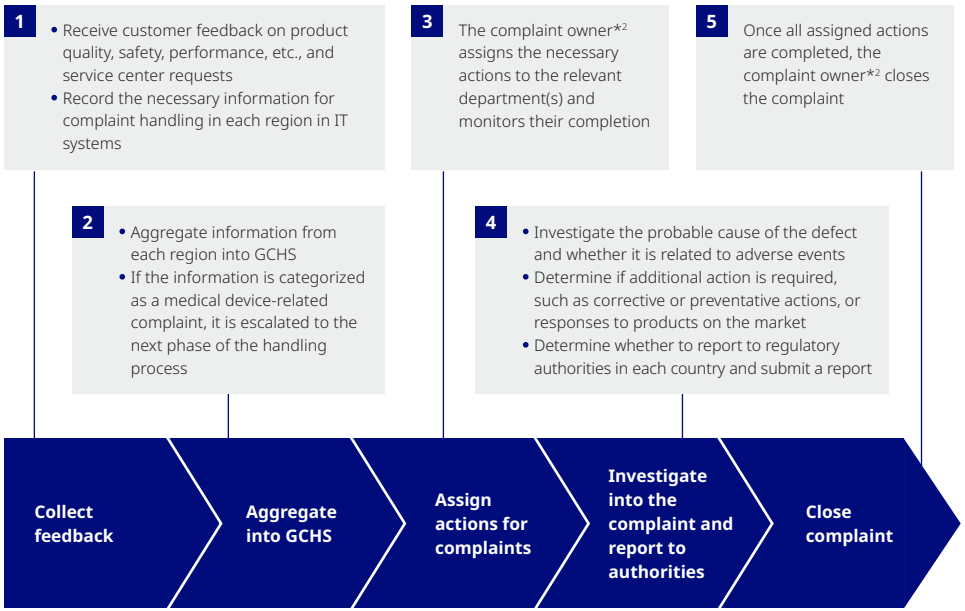
Key Priorities for *Elevate*: 3
Global Complaint Handling System

What is the Global Complaint Handling System (GCHS)?

The GCHS is a global IT system that centrally manages the handling of complaints*1 from each country. Complaints related to product malfunctions and injuries must be reported to the regulatory authorities within a certain timeframe as needed.

Measures taken

Previously, each country operated its own complaint handling system. In October 2024, we introduced GCHS in the United States, Europe, and Japan, followed by China and other Asian countries in November. This globally integrated process has enabled us to rapidly and reliably collect and centrally manage information. Additionally, we have created a global, centrally managed post market surveillance organization to ensure consistency in decisions and execution across all facilities.



Process of Complaint Handling

*1 Information from the market related to the quality, durability, reliability, usability, safety, and performance of medical devices
*2 A specialist in the Quality Assurance and Regulatory Affairs (QA&RA) Division who is responsible for managing the complaint handling from receipt through to closure

Effects of *Elevate*

Elevate will be an important enabler for innovation, growth, and improved profitability through sustainable benefits such as improved lifecycle management and digitally enabled processes to reduce costs, improve effectiveness, and shorten the time to develop, clear, and launch products.

Measures taken

Enhance Governance Associated with Standardization of Business Processes

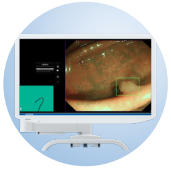
Our governance has been significantly enhanced by promoting the standardization and documentation of operations from a global perspective. Furthermore, we have established product development and manufacturing processes supported by data and documentation by advancing the *Elevate* initiatives.

Improve Product Lifecycle Management

We believe that the introduction of GCHS will enable us to analyze trends in globally aggregated and centrally managed information, detect signs of potential quality problems, and appropriately consider measures for products on the market. Utilizing this information in new product development will contribute to patient safety and lead to improvements in product quality and innovation.

Accelerate the Clearance/Approval Process for Products

Elevate has accelerated the clearance and approval process for several strategically important products. Most recently, we successfully obtained approvals or clearances for the following products.



CAD/AI (ODIN VISION)
U.S. FDA Clearance (July 2024)
EU MDR Approval (August 2024)

EDOF Scopes
U.S. FDA Clearance (May 2025)
China NMPA Approval (August 2025)

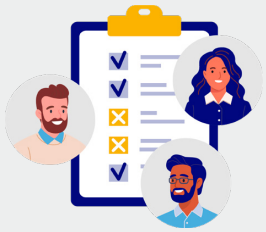
EU-ME3
U.S. FDA Clearance (January 2025)

VISERA S OTV-S500
EU MDR Approval (July 2024)*3
U.S. FDA Clearance (July 2024)

*3 OTV-S500 is classified as a Class I device in Europe. The necessary documentation was signed in July 2024.
Note: Products or devices presented include future technology which may be pending regional regulatory approval and are not available for sale in all regions.

TOPIC

Patient Focus Survey



Over 17,000 employees participated in the Patient Focus Survey in August 2024, providing valuable insights that highlighted our key strengths and identified areas for improvement. This survey was designed to provide a benchmark of our current organizational status, enabling us to regularly track progress over time.
This survey is a core component of our Patient Safety & Quality initiatives, designed to measure the progress and impact of our culture development program.

Patient Safety & Quality Mindset (Page 49)

We're pleased to report that 12 out of 15 questions received predominantly positive responses, reflecting our collective commitment to fostering a quality mindset at Olympus. Areas identified for further opportunity include employee reward and recognition, as well as innovation.

Key strengths

Patient Safety Priority

Patient Safety is recognized as a priority across departments.

Quality Ownership

Employees understand that quality is a shared responsibility across all functions.

Clarity on Expectations

Expectations regarding Patient Safety, Quality, and Compliance are clearly understood.

Manager Focus on Quality

Managers prioritize quality improvement processes as a major focus area.

Recognition

Recognition was determined as an area in need of support, and we have implemented multiple immediate actions across Olympus to address this. Please refer to the details on the right.

Immediate Actions

Performance Management

The continued evolution of MyPerformance (global approach to performance management) is critical to our cultural journey. In fiscal year 2025, we expanded calibration to include all those that took part in year-end performance evaluations. In fiscal year 2026, we aim to introduce the ability to request and receive real-time feedback supporting opportunities for learning, growth, recognition and engagement.

Events to Celebrate Impressive Achievements

Alongside the global CEO Award nomination process and ceremony, Olympus created awards events in all five regions to compliment our global awards ceremony.

Recognition Toolkit & Information Sessions for Leaders

We developed a set of best practices for leaders to effectively incorporate recognition in their leadership practices. These are supported by Leader Information sessions, which are interactive and actionable live sessions designed to enable and guide leaders in using recognition effectively.

Longer Term

In the longer term, Olympus will further explore solutions that will enable and improve the ability to reward and recognize consistently across all Olympus regions and entities.