Initiatives for Patient Safety and Growth

QARA Investments for Patient Safety and Our Future Growth

Commitment to Product Quality and Safety

Nothing is more important to Olympus than patient safety. The situation that we are in today is an opportunity for us all to recognize that we must fundamentally improve our quality and regulatory systems. We take this challenge extremely seriously and are working tirelessly on structural and cultural changes to meet the regulators' expectations, and this remains the Company's highest priority.

We have already started with significant investments and commitments to transform Olympus' quality management processes into a consistent global system for both patient safety and quality management. A right-sized quality

assurance and regulatory affairs (QARA) organization is being built to support this effort and to make sure processes are adopted consistently and globally across manufacturing, repair and distribution centers.

In addition, we have established the Quality Assurance and Reguratory Affairs (QA&RA) Committee, which ensures we live up to our patient safety aspirations and diligently respond to regulators and fulfill our commitments. We will continue to invest in patient safety and our business' growth, which are fundamental to our organization's long-term sustainability.

Enhance Global Quality and Compliance Functions to Ensure Consistent Execution

- Develop a robust organization and supporting processes to ensure consistent execution of Quality System requirements, quality improvements, identification and resolution of compliance risks
- Integrate Quality Engineering and Quality Leadership organizations globally across all three regions, manufacturing plants, repair and distribution centers.



Execute Transformation with the Aim of a Single Global Quality System and Fully Harmonized Processes

 Build and implement a Single Global Quality System
 Develop streamlined digitally-enabled processes to support the global execution of the Quality System, including Complaint Management & MDR, Process Validation, Design Controls, Management Review, Internal Audit, Regulatory Commitment Tracking, etc.

Resolve Compliance Issues and Complete Remediation

 Ensure all commitments to regulators are implemented on time meeting regulator's expectations

CQO's Message



Pierre Boisier

Executive Officer and
Chief Quality Officer

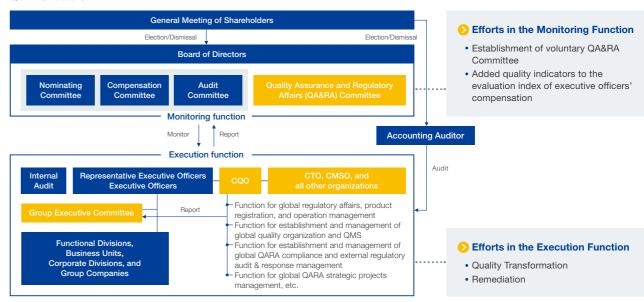
To strengthen QARA, we have established an independent worldwide quality and regulatory organizational structure where the Chief Quality Officer (CQO) oversees the activities and reports directly to the CEO. After I joined Olympus, we analyzed the skill sets and talent of the people in the QARA department. From the results, we created a QARA organization plan that could implement the functions within a unified global quality management system.

Based on this new QARA organization plan, we addressed skill set and knowledge needs in quality and regulatory compliance by continuing to hire MedTech leaders with expertise in areas such as complaint handling, regulatory affairs, product quality, and compliance. Keeping up with the latest regulatory interpretations is also very important for us and it is essential to have the right skilled people and foster talent. I think we have built a very good foundation with the senior team and we are now ready to move forward to build a globally coherent quality mindset that ensures patient safety as our top priority.

Our design assurance (quality side of R&D) team is set up to make sure that we design products consistent with applicable regulations and meet the demands of regulators. Our R&D is mostly in Japan and our design assurance team works very closely with these Japanese R&D teams. Their collaboration is getting better and they are designing products within applicable global regulatory guidelines. We are focusing on bringing the quality management system to a global standard. We are unifying our quality management system to consolidate requirements for critical processes ensuring that relevant global regulatory requirements are consistently met.

The entire company is working diligently to remediate the issues identified in the warning letters and trying to prevent similar incidents from happening again. During this process, we are closely communicating with the regulatory authorities. Patient safety is our highest priority. I am confident that these efforts will help our QARA become globally unified and enable Olympus to transform into a 100% global MedTech company.

QARA Structure



Establishment of QA&RA Committee

We established a QA&RA Committee at the Board of Directors in April 2023. This is a voluntary committee composed of outside directors and related functions such as QARA, R&D, Legal, and Supply Chain will report monthly at this Committee. The Committee oversees and provides advice for the development of global quality management systems to meet the expectations of regulators and to ensure compliance with relevant laws and regulations.

This Committee shall resolve or deliberate on the following matters and report such matters to the Board of Directors as appropriate:

1) Oversight and advice on Company plans for the quality management system as required of a global MedTech company, including the Management Review process.

2) Oversight and advice on regulatory communication strategy and engagement.

3) Provide recommendations to management for resourcing and areas of planning and execution.

4) In addition to the above, monitor any significant resourcing requirements outside of management plans and/or address any matters that have been requested by the Board of Directors with regard to QARA.

Outside Director, Gary John Pruden (Chairperson)
Outside Director, Jimmy C. Beasley
Outside Director, Luann Marie Pendy

Message from Chairperson of the QA&RA Committee



Gary John Pruden
Outside Director

Our Committee oversees the development and execution of Olympus' QARA strategy to make sure we meet all regulatory standards required for a global MedTech company. Our aim is to enhance our global capabilities to make sure we avoid future regulatory challenges. Thus it is essential to remediate our processes, standards, and capabilities. The Committee will also review and oversee root cause analysis, support the transformation of the corporate culture, and monitor the establishment of a robust global quality management system.

I bring over 35 years of experience in global healthcare organizations with extensive knowledge of the medical device industry, including quality management systems and regulatory affairs. My fellow committee members, Mr. Beasley and Dr. Pendy, are also very experienced in quality and regulatory and bring a wealth of global medical device knowledge to their roles as outside directors. We hope to make full use of our expertise to help oversee the transformation at Olympus and provide advice where necessary. We will support Olympus' transformation into a global MedTech company where patient safety is our first priority and the focus of our entire organization.

16 Olympus Integrated Report 2023