

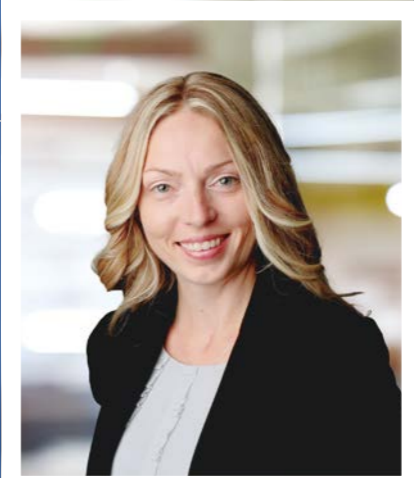
Strengthening Our Commitment to Patient Safety, Driven by Holistic Remediation and Transformation Program *Elevate*



Aimee Gogarty
Patient Safety & Quality Culture Workstream Lead
Based in the U.S.



Hitoshi Ogura
Production & Process Controls Workstream Lead
Based in Tokyo



Melissa Lake
Management Responsibility, Document Controls Workstream Lead
Based in Canada



Shigeru Imai
Design Controls Workstream Lead
Based in Tokyo

What are the differences between Olympus before the remediation and quality transformation program *Elevate* and now after it has begun?

Imai: *Elevate* is a program that started in 2023, and within that program, we are working together with our fellow global employees on quality management system (QMS) activities. I believe this has been a very positive experience, especially for those of us who work in Japan. I was previously involved in R&D with new product development, including production and process management. In the past, Olympus manufacturing in Japan was a closed loop in terms of product development. That meant the culture, design innovation, and any product launches were all based on a Japanese mindset. Of course, what might seem typical in Japan is not the same worldwide, and at the time there was a gap between what was being done globally and what was being done in Japan. However, through *Elevate* and communication with our global members, I feel like we have made

great strides to close that gap. By collaborating with different types of people, we are able to gain new insights.

Ogura: I joined Olympus as an engineer, and based on my years in the company, I can see four specific differences in the *Elevate* program. First, the governance has been enhanced significantly, and priorities as well as goals are now clear and well defined. Second, the priority of *Elevate* is being announced broadly and internally. This is something I personally appreciate and would like to see continue, as I feel confident consulting with different departments within Olympus because we are all aware of *Elevate*, and cooperation is quite efficient. Three, global initiatives: because of *Elevate*, we have begun seeing a higher participation rate of global employees in company initiatives, and I believe that it is important to involve employees with the knowledge and experience of quality assurance and regulatory affairs (QARA) from around the world. Four, thinking about patient safety on a daily basis: this is a priority for Olympus, and *Elevate* has been able to help with this

cultural transformation.

Gogarty: When I first joined Olympus, I was excited to be part of QARA Transformation, one of strategic priorities of *Transform Olympus*, and I agree with Hitoshi (Ogura) that the enhancement of the governance model has been an important difference. It is now easier to stay informed and escalate decisions or risks. Communication, now aligned with our new core values, has also improved as information penetrates both up and down the ladder of management and also across, since collaboration between different workstreams has also improved.

Lake: I joined Olympus in April 2023, leading a project under QARA

Transformation and quickly advancing under *Elevate*. The governance has been enhanced through *Elevate* with a cross-functional view. A strong feature of *Elevate* is its ability to foster collaboration across the organization. *Elevate* does this by allowing communities to be built and enables communication across workstreams and communication channels. It is also very refreshing to see that prioritization of initiatives is clear. Prioritization is essential for delivering success, and it is encouraging to see these successes being shared organization-wide.

What are some challenges to us as a MedTech company and any current initiatives to address the same?

Ogura: As a MedTech company, I believe Olympus needs to enhance four

different components. Those components are always changing, and improvements are being made, but we still have more we can do.

The first component is expertise and technology integration. As a MedTech company, in addition to our core technologies such as optical technology, we need deep knowledge of medicine and biology as well as more and more specialists collaborating for the development of medical devices. The second is regulatory affairs. Medical devices are strictly regulated and in different ways in different countries, so we work with regulators from around the world. We need to be able to comply with these regulations in our processes. The third component is an understanding of the market and customer needs. In the healthcare market, there are many different facilities, including hospitals and clinics, and we have to have an understanding

of their needs at a very deep level. As Shigeru (Imai) mentioned, in the past, R&D functions in Japan had many roles, including exploring customer needs, but customer needs have to be addressed globally. The fourth is quality and risk management. As a MedTech company, quality and risk management are extremely important.

Imai: Hitoshi has made many observations I agree with, but I would just like to add a couple more. For a very long time, Olympus had been using an old model of development process. We needed to improve the process, but those historical processes were limited by a sense of culture that isolated the function, and that was a challenge. We would assume that as long as the standard operating procedures were followed in development, there would be no issues. In reality, the development



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Shigeru Imai

process and our QMS need to be tightly linked with one another. With *Elevate*, the development process and QMS are more interconnected, and with the introduction of more global perspectives, we are better able to identify opportunities for improvement and to deal with challenges from different angles.

What is the current progress of the workstreams you are working on?

Gogarty: For us, much of 2023 revolved around awareness activities regarding patient safety and quality. It was a first time for all employees to have the same quality goal, and we had every employee working together to achieve progress toward that goal. We were doing multiple engagements both regionally and globally to increase awareness and ensure clear

communication from the executive team. Our Core Values were refreshed, and that was a huge change for our company culture. We are now holding ourselves to enhanced standards as a company and shifting both our focus and our product portfolio.

Lake: Under *Elevate*, my team leads two workstreams: Document Controls and Management Responsibility. For Document Controls, we are ensuring efficient, simplified, and scalable processes across sites. This is really important as we standardize in a global environment.

Our goal is to guarantee that our processes are globally understandable without adding unnecessary burdens, thereby driving both operational efficiency and regulatory compliance.

This workstream is structured around three core areas. One, streamlined processes: we recently released our Global Quality Manual, Global Quality Objectives, and the Global Quality Policy, all which have been deployed across all Olympus sites. We are also developing global harmonized standards to ensure that we meet or exceed MedTech industry expectations. Two, we have established improved governance to ensure changes fit our systems, and then we monitor and assess their impact at various sites. We have implemented performance metrics to evaluate our new processes, driving continuous improvement and accountability. And three, we are establishing communication channels to convey expectations to the teams while also providing a space for individuals to start facilitating knowledge sharing, capability building, and best practice dissemination.

Management Responsibility is focused on providing a robust framework for management responsibility so that it can serve as the backbone of our QMS at all layers. This

framework aims to improve insights to our QMS's performance to help identify trends and proactively address risks. It will also provide transparent performance and insights to executive leadership. This new process will provide leaders with clear, context-rich data so they can make informed decisions, but this also enables a comprehensive view of the QMS to identify improvement areas, issues, escalations, and how to optimize resources. We aim to facilitate data aggregation, supported by enhanced IT systems, and timely escalations from the worksites to the division and then global levels.

We have also developed leadership training on management responsibilities within the QMS. This will empower all leaders at all layers to be able to identify the impact of their decisions and the consequences of inaction.



Patient safety is a priority for Olympus, and *Elevate* has been able to help with this cultural transformation.

Hitoshi Ogura

Have you noticed any secondary impacts from the work that has already been done?

Imai: The workstream I have been working with concerns design validation. For a long time, we have been conducting design validation mainly in Japan. Now we are able to realize design validation on a global field, because we are able to collaborate with our global colleagues to accumulate information. We produced a Design Validation Playbook for new product development that includes know-how from *Elevate* activities. We think we have been able to utilize *Elevate* as an opportunity.

Gogarty: Culture is an enabler to all other workstreams. The activities we have planned and those currently in place will have a ripple effect across Olympus. By keeping a steady drumbeat of activity not only for leaders but for employees as well, we can refine and evolve our culture as people are open about concerns and know their voices are being heard.

In Group Executive Committee (GEC) meetings, the patient perspective is present in each meeting. An individual takes up the patient perspective and is able to advocate on their behalf, always keeping Our Purpose as the foundation of decision-making. Another initiative in place is to have the executive team spend physical time in a clinical setting and bring that experience back to their teams. In manufacturing, for example, there is less opportunity to interact with patients than in other parts of the company, and the lack of patient connection can be felt. By having the executive team spend time in a clinical setting and then relaying the experience back, they are bridging

that disconnect, and employees realize how meaningful their work is and the connection to the patient. The executive team also considers Our Purpose and Our Core Values when making decisions. This demonstrates that leadership embodies these core values in their day-to-day routines.

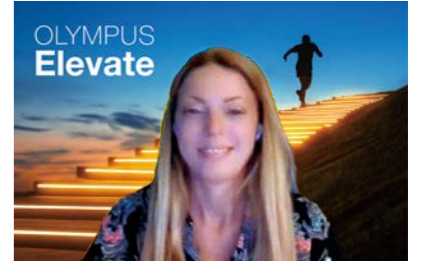
Through this cultural change, we are empowering employees to take pride and responsibility in their work and ensuring that the voice of the patient is represented.

Ogura: Through the *Elevate* program, we are working to ensure that process validation is done properly on our products in the market. I believe that improving the product lifecycle as well as ensuring the launch and spread of new products that comply with the latest laws and regulations will improve patient safety.

Changing culture is difficult. How can we make sure we can evaluate and demonstrate that the culture has evolved?

Gogarty: Our team has spent an extensive amount of time determining good methods to measure both process implementation and behavior change. We have decided to approach the metrics uniquely because the complexity of culture change requires a dynamic approach. We expect the metrics and targets to evolve as the organization harmonizes and we adopt the new cultural norms over time. This approach requires we be open to new ideas and adaptable to cultural shifts.

We launched our first Patient Focus Survey in July 2024. This is an anonymous all-employee survey intended to give our organization a snapshot of the perception of our culture by our employees. There will be another employee survey, after a set



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Melissa Lake

amount of time has passed, in order to see what progress has been made. From this, we will get both the managerial and employee perspectives on how the changes to our culture are permeating within the organization.

Culture change is a journey, and there will be expected and unexpected cultural shifts. As a company, we need to be dynamic and ready to adapt. We are confident that implementing this methodology based on the evolving culture signals will arm our leaders and employees with the information they need to make sure the organization stays on the right path and ultimately reaches our intended destination.

How has the mindset of you or those around you changed through *Elevate*?

Lake: One of the most significant changes I've observed is the change to a more proactive communication style,

Elevate Employees Roundtable Discussion

with employees taking greater ownership of their projects. Employees, particularly our colleagues in Japan, are now proactively reaching out and fostering conversation. By having these communications, employees are feeling more confident in the processes and in their approaches.

Collaboration has also been notably improved. For example, if there was a team member who was not very confident in their understanding of a specific process, another team member, possibly at another site entirely, would step in to explain their understanding. After discussion, they would verify their mutual understanding. I would like this type of collaboration to continue to extend globally, beyond individual areas.

As I progress through my career at Olympus, I aim to continually promote a culture of quality. I aspire to lead efforts to embed quality and culture together, as well as really drive the management review process to monitor

the health of the QMS. I know this is a journey that will take time, but enhancing and harmonizing the global quality systems remains a key aspiration of mine.

Gogarty: For me it is important to have not just reactive tasks but proactive ones motivated by patient focus. I would like to see incremental improvement based on a quality mindset and to not just uphold the status quo.

As we move into a different mindset, I would like to see improved collaboration across Olympus and an improved relationship with regulatory authorities. I would like to see us ensure a good reputation within our industry and raise the bar so that other companies are looking to Olympus for best practices.

Ogura: Before *Elevate*, each site in Japan operated under its own individual standard operating procedures. Now we have global procedures, and not just implemented nationally but worldwide with global process validation. This is a great transformation for Olympus.

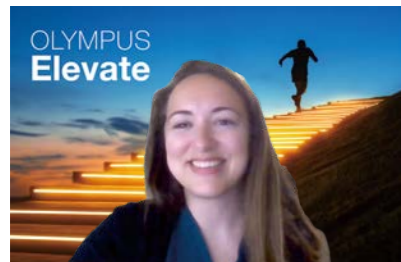
When it comes to the employee mindset, I think there are many factors involved with how it is changing. We had COVID-19, very rapid digital transformation penetration, and at the same time, Olympus is in the middle of globalizing. Now we have transformed into a global MedTech company, and we have more specialists focused on healthcare. Our Core Values have also been refreshed, with an additional emphasis on patient safety, and I think that more and more employees are beginning to partake in this mindset. I believe this is a very positive thing for Olympus.

Imai: The mindset of Olympus is changing, and that includes the

mindset of our leaders. Our Core Values emphasize our focus on patient safety, and our executive team has been a strong voice for those values. Because of this strong messaging and endorsement by leadership, I think everyone feels like they have ownership of and are responsible for living those core values.

Despite our successes, there is always more we can do. By those in leadership continuing to reinforce Our Core Values at our sites, we can be confident that all employees at all levels will live Our Core Values every day. Looking at myself within Tokyo, we have a team of people who have been important for our transformation. In the past, local leaders were message towers for those on the ground. If we can maintain both good, cultural communication at the top management level and within that local leader level, I think the culture will continue to improve.

Going forward, I would like to continue supporting and nurturing local leaders. I believe that QMS activities and productivity are very important. We need to achieve a balance of both at a standardized, globalized level. I believe QMS has improved greatly thanks to *Elevate*, but we cannot just focus on that improvement and get complacent. We need to continually refocus in order to achieve both improved QMS and productivity at the highest level. There needs to be a process to support these achievements, and I would like to be a part of that in the future.



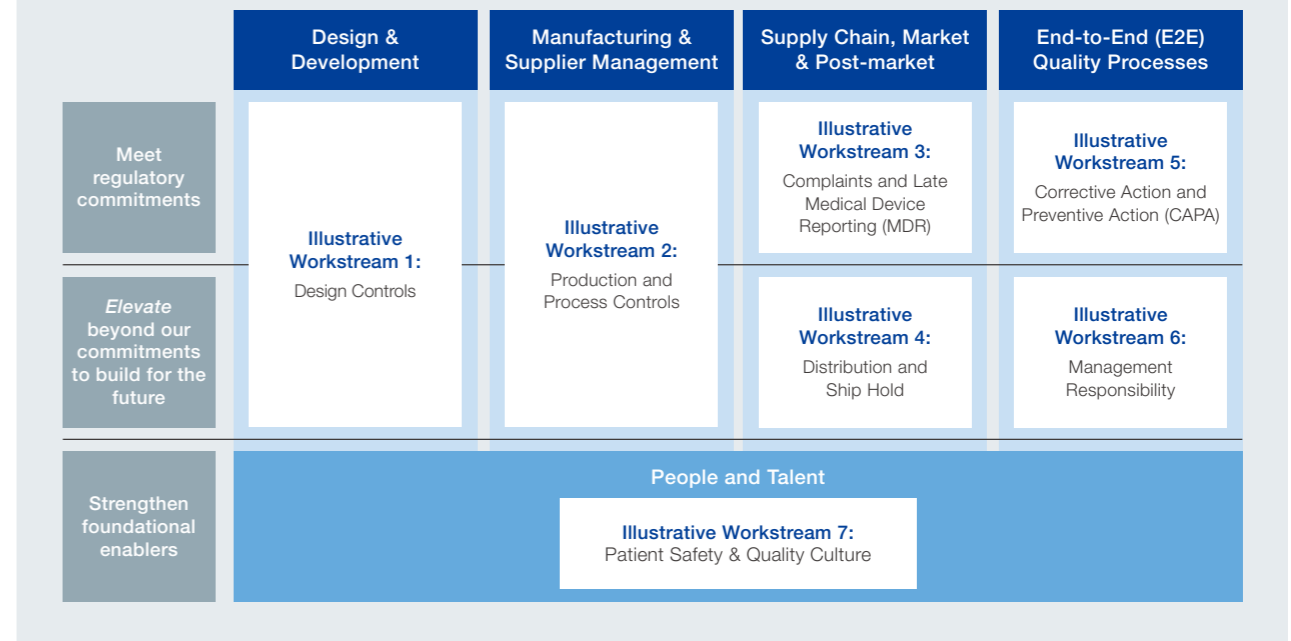
I would like to see us ensure a good reputation within our industry and raise the bar so that other companies are looking to Olympus for best practices.

Aimee Gogarty

Workstreams of Elevate

Elevate consists of 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, build a solid future, and strengthen the foundation of our quality culture.

Here are some of the workstreams for illustrative purposes:



Illustrative Workstream 1 Aims to complete design validation remediation activities for Japanese Olympus sites and create an internal playbook to guide future design validation activities. This workstream will also ensure that all Japanese sites adopt the design-control related standard operating procedures of the Olympus Medical Business Standard, after an extensive review and update to include leading industry best practices.

Illustrative Workstream 2 Aims to complete commitments related to production and process controls (P&PC), as well as develop an internal playbook and training program to enhance P&PC self-governance across Japanese/global sites.

Illustrative Workstream 3 Aims to enhance the ways in which we manage complaints to better support our top priorities of patient safety and product quality. This workstream represents one of our most important authority commitments. The new process is supported by a new Global Complaint Handling System (GCHS) which we started in December 2023 and are implementing in a phased product-based approach by which we will gradually ramp up additional product categories until the transition of all product groups to the GCHS is complete. This workstream’s goals are to:

- globally harmonize internal complaint handling processes
- improve Olympus’ ability to report to the regulatory bodies in a timely matter
- deliver on regulatory expectations with increased agility and efficiency
- drive data insights that can be used to improve products, processes, and services across the globe

Illustrative Workstream 4 Will establish a Quality Assurance organization/operating model at all warehouses and distribution centers (DCs) and implement a Global Distribution Quality Management System. Wherever appropriate, processes will be digitized, automated, and integrated into the Supply Chain Management process landscape to ensure visibility across global DCs.

Illustrative Workstream 5 Will establish a Global CAPA (Corrective and Preventive Actions) organization that will implement efficient and robust CAPA processes compliant with regulatory expectations. It will enable Olympus to raise and execute effective, appropriate, and timely CAPAs to address root causes of regulatory observations.

Illustrative Workstream 6 Will develop and implement a robust standardized framework for Management Responsibility that serves as the backbone of our Quality System.

Illustrative Workstream 7 Aims to position patient safety and quality at the forefront of all employees’ minds, not just for those who work in QARA, research & development, and manufacturing. It anchors patient safety in existing Olympus cultural frameworks, processes, and systems and endeavors to help all employees recognize the importance of patient safety and quality in their work and how their commitment to patient safety and quality supports our company strategy.