Keiko Oishi – President and Representative Executive Officer, CMIC

We have evolved well beyond the traditional CRO model

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Global biopharma companies are looking at Japan through a different lens, seeking partners that can navigate an increasingly complex regulatory landscape while supporting integrated development across Asia. At the heart of that evolution is CMIC, whose President and Representative Executive Officer, Keiko Oishi, discusses the company's transformation into a Pharmaceutical Value Creator, its international ambitions, the role of artificial intelligence, and the leadership principles shaping its next chapter.

How has your career journey shaped your approach to leading CMIC?

My career began in 1982 at Nikkei/McGraw-Hill, now Nikkei Business Publications, where I worked as a staff writer for *Nikkei Biotech*, Japan's first specialist biotechnology newsletter. That role gave me an early perspective on the emerging biotechnology sector before I moved into the industry itself, first with Genzyme Japan and later with Genentech Japan.

I joined CMIC in 1996 as Manager of the Strategy Development Department, where I focused on corporate strategy and regulatory planning for pharmaceutical development. As the business evolved, so did my responsibilities, expanding into international business development, where I worked closely with overseas pharmaceutical and biotechnology companies seeking to establish a

presence in Japan while supporting CMIC’s expansion across Asia, including South Korea, China, Singapore, and Taiwan.

When I joined, CMIC was still a small organisation of around 20 to 30 people. Over the following three decades, I had the opportunity to grow alongside the company, taking on broader responsibilities as the business expanded. I became President in 2018 and today oversee business strategy and execution across the entire CMIC Group, encompassing our CRO, CDMO, Site Support Solutions, Market Solutions, and broader healthcare businesses. That journey has shaped my leadership style: I make decisions with an end-to-end view of the value chain, stay grounded in execution, and focus on building trust and mutual respect—both with clients and within our employees.

What distinguishes CMIC today, and how has the business evolved to support the changing needs of the pharmaceutical industry?

Since establishing Japan’s first Contract Research Organization in 1992, we have evolved well beyond the traditional CRO model. Today, we define ourselves as a Pharmaceutical Value Creator because our role is to create value across the entire pharmaceutical lifecycle, from drug development and manufacturing through to commercialisation, market access, and healthcare solutions. Rather than operating as a collection of individual business units, we bring together our CRO, CDMO, Site Support Solutions, commonly called Site Management Organization (SMO) capabilities, Market Solutions, and Healthcare businesses into a single, integrated platform that supports clients throughout the pharmaceutical value chain. Our ambition is not simply to provide services, but to help innovative medicines reach patients faster and more efficiently.

Our clinical CRO and CDMO businesses continue to be our primary revenue drivers, but our client portfolio has evolved significantly over time. While our non-clinical CRO business remains focused largely on Japanese pharmaceutical and biotechnology companies, our clinical CRO business has become global. Historically, we worked predominantly with domestic pharmaceutical companies. Today, more than half of our clinical CRO clients are emerging biopharma companies from the US and Europe entering the Japanese market or conducting global multi-regional clinical trials (MRCTs) across Asia Pacific (APAC), particularly Australia, South Korea and China. That evolution reflects both the changing dynamics of global drug development and CMIC’s role as a trusted partner for companies looking to establish and expand their presence in APAC region.

How is CMIC’s partnership with Blackstone supporting the company’s international ambitions, and how does that fit within your broader vision for Asia?

Our partnership with Blackstone represents an important step in CMIC’s international growth strategy. Blackstone is far more than a financial investor; it is a strategic partner that brings extensive healthcare expertise, strong relationships across the global pharmaceutical and biotechnology industries, and significant operational experience. Together, we are building on our position as Japan’s leading CRO while strengthening our standing as an internationally recognised partner for innovative drug development, particularly for global biopharma companies seeking to enter Japan. Through Blackstone’s global network and strategic support, we are also expanding our relationships with innovative biotechnology companies, global partners, and artificial intelligence solution providers.

Japan remains our top priority, but APAC region continues to be central to our long-term strategy. We believe the region should increasingly be viewed as an integrated platform for clinical development, and CMIC is well positioned to help build that ecosystem. South Korea has played an important role since we established our first overseas CRO operation there in 1996, and over the years we have built a mature and highly scalable business supporting both local and multi-regional clinical development programmes. That experience has strengthened our belief that clients benefit most from a coordinated regional approach that combines local expertise with a broader strategic perspective.

This same philosophy is reflected in our Pharmaceutical Value Creator approach. From the client’s perspective, drug development should be one continuous journey rather than a series of separate business units, so we organise our support around each programme rather than our internal structure. Our account leaders and programme managers bring together expertise across regulatory consulting, clinical development, site support, manufacturing, and commercialisation, ensuring that clients experience CMIC as one connected partner through a seamless, end-to-end platform.

Why do global biopharma companies continue to see Japan as an attractive market, and how does CMIC help them navigate that landscape?

Japan remains one of the world’s most important pharmaceutical markets, but successfully navigating its clinical development and regulatory landscape requires deep local expertise. One of the challenges facing the market today is drug loss, which is ultimately a patient access issue

rather than simply a regulatory one. Our role is to remove the practical barriers that can prevent innovative therapies from reaching patients in Japan. Alongside our CRO capabilities, CMIC has built an extensive SMO network spanning approximately 4,050 hospitals and clinics nationwide. By connecting sponsors with the right clinical sites, supporting investigators through experienced clinical research coordinators, and facilitating patient identification and enrollment, we help make clinical development in Japan faster, more predictable, and operationally less complex. While this cannot address every cause of drug lag or drug loss, it can significantly reduce the uncertainty that may otherwise discourage global biopharma companies from including Japan in their development strategies.

That operational expertise is underpinned by more than three decades of experience in Japan. Over that time, we have developed trusted working relationships with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), enabling us to guide international sponsors through Japan's regulatory pathway with greater confidence and help them understand evolving regulatory expectations at an early stage. At the same time, the PMDA has made considerable efforts to align more closely with global clinical development, encouraging Japan's earlier participation in MRCTs and making the country an attractive destination for innovative research.

Japan also continues to offer significant strengths as a pharmaceutical market. It remains one of the world's largest and most strategically important markets for innovative medicines, supported by a sophisticated healthcare system and an efficient framework for bringing new therapies to patients. While drug pricing is often part of the international discussion, it deserves a balanced assessment, particularly as innovative and orphan medicines continue to receive competitive pricing. We therefore continue to encourage global biopharma companies to bring their innovations to Japan, and our role is to help them navigate the market efficiently so that new therapies can reach Japanese patients as quickly as possible.

Where do you see the future of multi-regional clinical development across Asia Pacific?

I see APAC continuing to grow into a more coordinated development region for global programmes, with MRCTs becoming more common. That will require more practical alignment across markets, while still respecting local requirements.

With that in mind, our objective is to support global sponsors' drug development across APAC by combining deep local expertise with common governance, shared training, and consistent

communication. This helps sponsors run MRCTs more efficiently, while staying fully compliant in each market and maintaining strong local execution.

I believe greater regulatory harmonisation across APAC is both realistic and achievable. From my experience, if countries can work together with clearly defined rules, strong technical expertise, and mutual respect, closer alignment is entirely feasible. As more global sponsors look at APAC as a single development region rather than a collection of individual markets, that level of collaboration will become increasingly important in strengthening the region's competitiveness for clinical research.

How is artificial intelligence reshaping the way CMIC operates, and what role do you see it playing in the company's future?

Artificial intelligence is becoming an increasingly important part of how we work, but I do not see it replacing scientific expertise; I see it as amplifying human expertise. By automating repetitive tasks such as drafting and quality review, AI allows our experts to devote more time to scientific judgement, strategic thinking, and client engagement, while improving both speed and consistency. To put that into practice, we are working with Bluenote to embed agentic AI into our documentation workflows. Our collaboration with Bluenote has progressed very smoothly, and we have achieved most of the key performance indicators established for the partnership while continuing to refine our processes through ongoing operational improvements. Overall, it has helped us reduce manual effort and improve consistency, without compromising quality or compliance.

That evolution is also shaping how we think about talent. While developing our own people remains fundamental, we see value in complementing our internal capabilities through collaboration with external organisations that bring specialised expertise and new technologies. Our partnership with Bluenote reflects that philosophy, and I believe this more collaborative approach will play an even greater role as our industry continues to evolve. Over time, I expect AI to become a standard part of how we deliver—supporting speed, quality, and scalability—while our experts remain accountable for scientific judgement and client outcomes.

Looking ahead, what are your priorities as President and Representative Executive Officer, and how has your leadership philosophy evolved over the course of your career?

Our mission to be a Pharmaceutical Value Creator will continue to guide our direction, and my priority is to strengthen cross-group integration that allow us to deliver on that mission across the CMIC Group. As our business continues to evolve, I want to ensure that we keep creating value across the entire pharmaceutical lifecycle while preparing the organisation for the opportunities ahead.

Having grown with CMIC for nearly three decades, I have learned that our business is fundamentally built on trust. Working across different functions has allowed me to view decisions from the perspective of the entire pharmaceutical value chain rather than any single business, and that experience has shaped my approach to leadership. For me, leadership is not about being in the spotlight, but about creating an environment where talented people can succeed and where the organisation continues to create value long after today’s leaders have passed the baton.

That is also why sustainability is one of my most important priorities. Beyond delivering results today, I believe we have a responsibility to prepare CMIC for the long term by developing the next generation of leaders and giving them the opportunities, capabilities, and support they need to succeed. Ultimately, sustainable leadership is measured not only by what we achieve ourselves, but by the organisation and people we leave behind, and ensuring a successful transition to the next generation remains one of the most important pillars of our strategy.

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