2026 CEO Message

A Decade of experience in Japan, now ready to accelerate patient access in Japan

Dr. Suzan Davis
President & CEO
Global Regulatory Partners Japan

Dear Valued Partners and Customers,

As we welcome the New Year 2026, I would like to begin by wishing you and your families a healthy and successful New Year, and to extend my sincere appreciation for your continued trust, support, and collaboration during the past year. The year 2025 was marked by a challenging global and local environment. Economic uncertainty, evolving regulatory expectations, and growing demands for local accountability continued to shape the life sciences landscape, particularly in Japan. Despite these challenges, Global Regulatory Partners (GRP) was able to achieve strong performance in Japan, that was driven by the efficient execution of GRP's MAH platform and the consistent efforts and dedication of our employees.

More importantly, 2025 represented a strategic turning point for GRP Japan. We transformed our MAH platform to meet Japanese market needs. We restructured our Regulatory Affairs and Compliance solutions under our MAH business model and successfully introduced and launched new manufacturing, distribution, 3PL, and commercial operations. This expansion transformed GRP into a fully integrated MAH partner, capable of supporting products' registration, market entry, sustained supply, and long-term commercialization in Japan. As we enter 2026, the integrated foundation built over the past decade —and strengthened in 2025 now positions us to move forward with confidence and purpose. Embracing the Year of the Horse—a symbol of energy, progress, and momentum, we are ready to accelerate our growth and deliver even greater value in Japan.

Ten (10) Years of Trusted Presence in Japan

In 2026, Global Regulatory Partners (GRP) proudly marks its 10th anniversary. Since our establishment in 2016, we have built a strong foundation rooted in regulatory excellence, local accountability, and long-term partnership, earning the trust of regulators, healthcare professionals, distributors, manufacturers, customers and patients across Japan. This decade of experience in Japan has shaped GRP's integrated MAH business model, providing a single, locally accountable platform that simplifies market entry, reduces risk, and enables sustainable commercialization in Japan.

From Foundation to Execution: Scaling and Extending the GRP MAH Business Model

As we enter 2026, the strong integrated foundation we've built, especially strengthened in 2025, positions us to move forward with confidence and purpose. With the GRP MAH platform firmly in place, GRP Japan is not only executing at scale but also achieving operational excellence, improving efficiencies and reducing products registration timelines while being in compliance with local regulations. Embracing the **Year of the Horse**, symbolizing energy, progress, and momentum—we're ready to accelerate our growth and deliver even greater value for our partners and patients in Japan.

Our focus is now on operational execution—ensuring that regulatory strategy, quality oversight, supply, distribution, and commercialization all function seamlessly as one locally accountable system. This execution-driven approach allows us to accelerate market access for innovative products, particularly in biotech, cell therapy, and advanced MedTech. By acting as a single MAH partner throughout the entire product lifecycle, GRP reduces fragmentation, simplifies coordination, and lets our partners focus on innovation while we handle the execution in Japan.

Our 2026 Focus in Japan

Building on a decade of experience and a strengthened MAH platform, 2026 marks a shift from consolidation to acceleration. In the year ahead, our focus in Japan will be on the following priorities:

01. Actively contribute to reducing the drug lag in Japan by facilitating timely access to innovative therapies through the GRP MAH business model.

02. Scaling the GRP MAH business model to support multiple products and partners, across diverse therapeutic areas and emerging technologies, including biologics, cell and gene therapies, and advanced medical technologies to enter Japan.

03. Extending MAH capabilities across supply, distribution, and commercialization to ensure that regulatory approval translates into reliable product availability and sustainable market presence in Japan under a single, locally accountable framework.

04. Target expedited pathways when a product qualifies For high-innovation, high-need programs, assess SAKIGAKE (pioneering designation) and other accelerated options early. SAKIGAKE is designed to speed practical application via priority consultations, prior assessment, and priority review.

05. Ensure Supply Chain and Commercial Readiness. Prepare Japan's distribution, logistics, and supply-chain operations for upcoming GRP product approvals — ensuring reliable supply, compliant execution, and smooth commercialization

Finally, fully aligned with our mission in Japan, we remain committed to accelerating patient access to innovative, high-quality healthcare products that improve lives and well-being. Through disciplined execution of our MAH business model, we will continue to support our partners and customers, strengthen Japan's healthcare ecosystem, and contribute meaningfully to global innovation.

Dr. Suzan Davis
President & CEO
Global Regulatory Partners GK