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Foundations of Competitiveness in the Medical Device Industry (Executive Summary)

Huimin Wang, M.D.

Senior Advisor, Healthcare System Planning Institute (HSPI)

Makoto Tamura, Ph.D.

Senior Research Fellow, Medical Device Strategy Institute (MDSI)

Director, Medical Technology Policy Research Institute

American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

This paper aims to clarify the sources of corporate competitiveness in the medical device industry, focusing on four key elements: **technological innovation**, **regulatory responsiveness**, **market insight**, and **global expansion capability**. These elements are essential for medical device companies to achieve sustainable growth and compete effectively in the global market.

First, in terms of **technological innovation**, both in-house development and the acquisition of new technologies through M&A serve as sources of competitiveness. Successful examples of in-house innovation include the "da Vinci" robotic surgical system by Intuitive Surgical, the "FreeStyle Libre" glucose monitoring device by Abbott, and Olympus' endoscopic technologies, which lead the global market. All of these products were refined over the long term through proprietary technology and gained widespread trust and adoption in clinical settings. Key factors in their success include the large potential market, continuous improvement, and adaptability to evolving needs.

At the same time, many medical devices are initially developed by startups, and later acquired and commercialized by major corporations. Especially in the United States, ecosystems for medical device innovation have formed in regions like Silicon Valley and Minneapolis, making the ability to identify promising technologies and acquire them at the right timing a critical pillar of competitiveness. Case studies include Edwards Lifesciences' acquisition of PVT, which enabled leadership in the TAVI field; Canon's acquisition of Toshiba Medical Systems; and Boston Scientific's acquisition of Guidant. These cases highlight how the success of M&A depends heavily on evaluating the clinical significance, market potential, and organizational integration capacity.

Regulatory responsiveness is another vital factor, given that medical devices are developed and distributed under stringent regulatory frameworks. Companies must possess expertise in regulatory approval processes, such as regulatory affairs applications, GCP, GLP, and quality management. They must also respond swiftly and flexibly to regulatory changes and challenges during clinical trials. In reality, the quality of regulatory strategy, including relationships with authorities and clinical trial design, can determine whether a product is approved and reliably supplied—making it a critical issue throughout the product lifecycle.

Market insight refers to the ability to identify the true challenges faced by physicians and patients, and to translate those into effective product design and development. The paper emphasizes the importance of close collaboration with clinicians, extracting needs through observation and dialogue, and validating product concepts. Moreover, integrating clinicians into the entire development process is considered a key factor for success.

Global expansion capability is indispensable for maximizing economies of scale and increasing R&D investment efficiency. While the U.S. accounts for approximately 40% of the global medical device market, Japan only represents around 7%. Many Japanese companies remain highly dependent on the domestic market, and expanding into Europe and the U.S. remains a significant challenge. Companies must also understand the differences in medical practices, regulations, and healthcare systems across regions, and develop localized products and strategies accordingly—

factors that are crucial in global competition.

Among the four capabilities, the authors argue that **market insight** stands out as a true core competency—one that cannot be easily outsourced or imitated. Organizations with deep knowledge of a particular domain (e.g., peripheral vascular interventions), including past experiences, case studies, and failures, possess the insight needed to identify what problems must be solved, how they might be addressed, and what risks are involved. This accumulated knowledge and experience form a vital source of enduring competitive advantage.

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[Contact information]

Medical Device Strategy Institute,
Japan Association for the Advancement of Medical Equipment
E-mail: mdsi@jaame.or.jp TEL: +81-3-3813-8553