## INTOINWORLD

# NEWSLETTER

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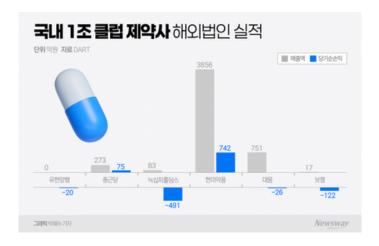
IntolnWorld Co., Ltd., established in 2015, is a Contract Research Organization (CRO) specializing in clinical trials across pharmaceuticals, medical devices, investigator-initiated trials (IIT), and observational studies (OS).

We possess comprehensive expertise in managing the full spectrum of clinical trials, from Phase 1 to Phase 3, as well as post-marketing surveillance (PMS).

Our clients' success is our core value. Guided by accuracy, ethics, and responsibility, we prioritize client achievements and patient safety, always striving to think and act one step ahead as a trusted CRO partner.

### Overseas Struggles for Pharmaceutical Companies: Streamlining Operations Through Subsidiary Liquidation

Among the six South Korean pharmaceutical companies with annual domestic sales exceeding 1 trillion KRW, four reported losses in their overseas operations last year. In particular, performance in China deteriorated due to management disputes and sluggish sales, prompting some companies to sell or liquidate their Chinese subsidiaries to improve financial stability. While operations in Indonesia have successfully turned profitable, the overseas businesses of major pharmaceutical companies continue to face challenges with lackluster performance and ongoing restructuring efforts.





## Business Sector: "Biotech Industry, a Key Driver for Future National Growth"

Five major business organizations, ahead of the 2025 presidential election, urged a comprehensive policy shift to foster the biotech industry as a future growth engine, calling for tax incentives, infrastructure development, and financial support. They emphasized that regulatory uncertainty and inconsistent policies have weakened South Korea's competitiveness, advocating for enhanced global competitiveness through eco-friendly material development and expanded support for mid-sized enterprises.



## "World's No. 2 in New Drug Development": China's Rapid Rise and Implications for K-Bio

According to the Korea Pharmaceutical and Bio-Pharma Manufacturers Association, China has nurtured its pharmaceutical and biotech sector as a core industry, achieving a 9.5% annual growth rate, developing 47 new drugs, and securing technology transfers worth 48.5 trillion KRW. This success stems from comprehensive policies, including the establishment of a National Bio-Committee, capital market reforms, and increased R&D investment. To stay competitive, South Korea must enhance its new drug development capabilities through sustained R&D and open innovation.

#### Cancer Treatment Trends Shift Toward 'Bispecific Antibodies': Where Does South Korea Stand?

As research on PD-L1 and VEGF combination therapies gains momentum, bispecific antibodies targeting both antigens simultaneously are emerging as a new trend in cancer treatment. While Chinese companies lead the charge. South Korean firms are also pursuing bispecific antibodies and novel targets to bolster global competitiveness in treating liver cancer and solid tumors.





## FDA Restructuring and Al Regulatory Changes: Response Strategies for Korean Pharmaceutical Companies

Amid concerns over review delays due to FDA staff reductions and budget cuts, the agency is advancing the adoption of generative AI and shifting toward data security-focused regulations. Meanwhile, relaxed M&A regulations are opening up opportunities for corporate collaborations. Korean pharmaceutical companies are expected to leverage AI, enhance documentation, and adopt real-world data-driven strategies to stay competitive.