

March 21, 2025
Sysmex Corporation
Japan Tissue Engineering Co., Ltd.

Sysmex and J-TEC Sign a Research Collaboration Agreement Regarding Sterility Testing in Regenerative Medicine and Cell Therapy

Sysmex Corporation (HQ: Kobe, Japan; President: Kaoru Asano) and Japan Tissue Engineering Co., Ltd. (HQ: Gamagori, Aichi Prefecture; President & CEO: Ken-ichiro Hata; hereinafter "J-TEC") announced that they signed a research collaboration agreement regarding sterility testing in regenerative medicine and cell therapy ("the Agreement") as part of strategic approaches based on the basic agreement* concluded in December 2024.

Sysmex aims to develop fast and safe sterility testing for regenerative medicine and cell therapy by applying its flow cytometry technology, where microscopic particles are passed through a flow channel for optical analysis of each particle as it flows, in collaboration with J-TEC's expertise and knowledge.

*December 5, 2024 news release: "Sysmex and J-TEC Sign a Basic Agreement to Advance Manufacturing Capabilities for Regenerative Medicine and Cell Therapy" <https://www.sysmex.co.jp/en/news/2024/241205.html>

In regenerative medicine and cell therapy, because living cells are used as raw materials and because of individual differences in cells, quality control testing to ensure the safety and effectiveness of the products is extremely important. Particularly, sterility testing is important because viable cells can be a source of infection. Furthermore, expanding the scale of production and increasing efficiency are key issues in the regenerative medicine and cell therapy industry, and speeding up quality control testing is expected to help resolve these issues.

Against this background, the two companies concluded a research collaboration agreement in March 2025 to jointly develop quality control testing by combining Sysmex's quality control inspection systems with J-TEC's experience in developing and manufacturing regenerative medicine and other products.

Research conducted in collaboration with academia has suggested that Sysmex's flow cytometry technology could be used for sterility testing in regenerative medicine and cell therapy, and the company plans to introduce its flow cytometry technology to the market (for research use) during fiscal 2025.

J-TEC will work to optimize Sysmex's technology in light of J-TEC's experience in manufacturing, developing and selling regenerative medicine and other products so that the technology can be introduced into such products.

If the joint research can demonstrate that flow cytometry technology provides equivalent sensitivity and rapid results compared to conventional methods, it is expected that sterility testing, which traditionally takes several weeks, could be shortened to just a few tens of minutes while

maintaining product safety. The global market size for sterility testing in the manufacturing of regenerative, cell, and gene therapy products is estimated to reach approximately \$280 million in 2022 and \$1.36 billion by 2033.

Through this activity and new strategic themes being considered by both companies, Sysmex and J-TEC seek to resolve issues in quality control and other related areas of regenerative medicine and cell therapy, contributing to the development of a sustainable regenerative medicine and cell therapy industry in Japan.

About Sysmex Corporation

Sysmex Corporation, headquartered in Kobe, Japan, is a global leader in *in vitro* diagnostics. Since its foundation in 1968, Sysmex has focused on diagnostics as the core of its business, and today, it supports the health of people in over 190 countries and regions worldwide. Sysmex continues to innovate in diagnostics, and to collaboratively create unique values in the areas of personalized medicine and novel treatments, under its long-term vision of "Together for a better healthcare journey." Through its unique technology, solutions, and co-creation with various partners, Sysmex delivers new value and addresses the universal desire of people to live longer and healthier lives. For more information about Sysmex, please visit www.sysmex.co.jp/en/.

About Japan Tissue Engineering Co., Ltd.

J-TEC is a maker of regenerative medical products. Our vision is "Creating a Future for Regenerative Medicine", and we have been a member of the Teijin Group since March 2021.

As the top runner in Japan's regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ✓ Approved Oct. 2007: Autologous Cultured Epidermis JACE® – Japan's first regenerative medical product
- ✓ Approved July 2012: Autologous Cultured Cartilage JACC® – Japan's first regenerative medical product in the plastic surgery field
- ✓ Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC® – Japan's first regenerative medical product in the ophthalmology field
- ✓ Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
- ✓ Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN

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