



**INTERNATIONAL  
SOCIETY FOR  
STEM CELL  
RESEARCH**

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## **The ISSCR Releases Report of First Regulatory Meeting with Japan's PMDA and Korea's MFDS**

**Evanston, USA** – The International Society for Stem Cell Research (ISSCR) convened its first-ever meeting with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and Korea's Ministry of Food and Drug Safety (MFDS), marking a major milestone in the Society's global regulatory advocacy efforts. The meeting took place on 7 November 2024.

The dialogue brought together leaders from the ISSCR and regulatory authorities in Asia to discuss key considerations shaping the safe and effective development of pluripotent stem cell (PSC)-based therapies. Discussions focused on the manufacture of PSC banks as starting materials for allogeneic therapies, the genetic assessment of PSCs, and jurisdictional differences in guidelines for biological ancillary materials.

Current ISSCR President Hideyuki Okano opened the session with an overview of the Society's international membership and forthcoming resource, Best Practices for the Development of PSC-Derived Cellular Therapies. Dr. Okano invited regulators to participate in the review process, underscoring the ISSCR's role as a convener of global expertise.

Presentations from experts in Japan, Korea, and the ISSCR highlighted both consensus and regional differences in regulatory approaches. PMDA and MFDS representatives provided perspectives on the use of non-GMP reagents in early PSC seed bank development, genetic safety assessments, and testing strategies for ancillary materials. Both agencies emphasized the importance of traceability, comprehensive documentation, and rigorous quality standards to ensure the safety and reliability of PSC-based products.

The PMDA also outlined Japan's conditional and time-limited approval pathway for regenerative medicine products, while the MFDS shared updates on South Korea's regulatory framework under the Advanced Regenerative Medicine and Advanced Biological Products Act.

Since 2019, the ISSCR Manufacturing, Clinical Translation, and Regulatory (MCTR) Committee has hosted annual meetings with the U.S. Food and Drug Administration, and these dialogues have since extended to the United Kingdom's Medicines and Healthcare products Regulatory Agency, and the European Medicines Agency. The meeting with regulators in Asia builds on these prior engagements. The ISSCR will continue expanding its outreach to regulatory bodies worldwide, reinforcing its mission to promote excellence in stem cell science, foster global collaboration, and responsibly advance clinical translation.

The official [meeting summary](#) is now available.

### **About the International Society for Stem Cell Research ([ISSCR.org](https://www.isscr.org))**

With nearly 5,000 members from more than 80 countries, the International Society for Stem Cell Research (ISSCR) is the preeminent global, cross-disciplinary, science-based organization

**Excellence in stem cell science and applications to human health.**

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dedicated to stem cell research and its translation to the clinic. The ISSCR mission is to promote excellence in stem cell science and applications to human health.

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