MITSUI-SOKO GROUP

Press Release

December 24, 2024

MITSUI-SOKO HOLDINGS Co., Ltd.

MITSUI-SOKO HOLDINGS obtains a license to manufacture regenerative medicine products and establishes a two-base structure in Eastern and Western Japan

Secures a business license for its facility in Kobe, Hyogo, following the one in Tokyo, thereby enhancing its storage and transportation services

MITSUI-SOKO Holdings Co., Ltd. (Headquarters: Minato-ku, Tokyo; President and CEO: Hirobumi Koga; hereinafter, "we" or "our") has secured a license for the manufacture of regenerative medicine products (packaging, labeling, and storage criteria)[1] at its facilities in Kobe, Hyogo, following the license obtained in Tokyo. We will commence an end-to-end service providing high-quality storage and transportation in compliance with GCTP[2] in the field of regenerative medicine starting January 2025.

In January 2021, we obtained a license to manufacture regenerative medicine products at our high-functionality facility[3] in the Kanto region. Since August of the same year, we have been offering services to major pharmaceutical companies and other entities involved in regenerative medicine[4]. Building on the expertise developed in the Kanto region, we have established a dedicated space within our Kansai P&M Center in Kobe, Hyogo. This facility is equipped with an organization and equipment compliant with GCTP standards, and we have successfully obtained a business license.

With GCTP-compliant facilities established in both East and West Japan, we are now well-positioned to respond flexibly to customer needs, including BCP measures. This will facilitate the optimization of the supply chain, ensuring an efficient and stable supply of regenerative medicine products and investigational drugs for future regulatory approval.

The MITSUI-SOKO Group is committed to actively establishing facilities crucial for achieving optimal supply chain management tailored to the diverse needs of customers in the medical industry. We will contribute to the growth of our customers' businesses by continuously developing advanced management systems that adhere to stringent quality management standards.

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1 The license described in (ii) type of manufacturing where only wrapping, labeling, and storing are conducted in the manufacturing process for regenerative medicine products, as outlined in Article 137-9 (License Criteria for Manufacturing) of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. This license represents a significant hurdle to obtain.

2 GCTP stands for Good gene, Cellular, and Tissue-based products Manufacturing Practice. It pertains to the ordinance issued by the Ministry of Health, Labor and Welfare (MHLW) that outlines the standards for manufacturing control and quality control of regenerative medicine products.

3 The facility meets high-security standards, including seismic isolators, private power generators, and dock shelters, as well as surveillance cameras, infrared sensors, and IC card management.

4 Press release dated July 29, 2021: MITSUI-SOKO HOLDINGS obtains a license to manufacture regenerative medicine products and launches integrated cryogenic storage and transportation services

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