sojitz News Release

September 29, 2010

Sojitz Corporation

Sojitz launches generic drug development business overseas

- Provision of consistent pharmaceutical services from ingredients to finished products -

Sojitz Corporation has launched generic drug development business overseas during the latter half of 2010. Through the development of pharmaceuticals overseas, it has developed a structure enabling it to provide consistent pharmaceutical services from ingredients to finished pharmaceutical products (pharmaceutical intermediates, active pharmaceutical ingredients (APIs), drugs (pharmaceuticals)) to generic drug producers in the domestic market.

Sojitz is reinforcing the pharmaceutical field, especially its generic drug business, in healthcare and life science operations, where efforts are being focused in the chemical and functional materials sectors. Although the development of APIs had been limited to the domestic market, the company ventured into the generic drug development business overseas upon the revision of the Pharmaceutical Affairs Law in 2005 permitting the development of finished pharmaceutical products overseas.

Sojitz currently imports APIs and intermediates from API producers in China and India that are in conformity with Good Manufacturing Practices (GMP). Companies that import APIs from overseas are also deemed to be “manufacturers” under the revision of the Pharmaceutical Affairs Law and Sojitz promptly submitted an application for the certification of API producers overseas as foreign manufacturers and set up a system enabling it to carry out GMP compatibility inspections internally. It furthermore developed a system known as Master File (MF) enabling the registration of APIs and ingredients and has promoted the enhancement and reinforcement of management with the aim of ensuring the quality of pharmaceuticals.

Sojitz not only produces APIs in response to requests from domestic generic drug producers but also produces intermediates on consignment. With the start of its drug development business overseas, it will take active steps hereafter to provide support for the consignment of manufacturing overseas by generic drug manufacturers.

Moreover, it will cooperate with producers of intermediates and APIs both in Japan and

overseas in response to the projects of generic drug producers and, besides products (intermediates, APIs, pharmaceutical formulations), it will develop a system that will enable it to respond to wide-ranging needs relating to generic drugs by also promoting the reinforcement of GMP compatibility inspections and other areas.

Needs relating to healthcare and life sciences will steadily expand along with the declining birthrate and aging population. In the future, in the generic drug market, which is expected to continue growing due to the need to restrain medical costs and other factors, Sojitz will promote the development of a consistent value chain from the supply of APIs and intermediates to drug manufacturing overseas based on the keywords of safety and security while promoting the enhancement of quality in pharmaceutical production.

□ GMP（Good Manufacturing Practices）
These are production and quality management standards for the purpose of maintaining quality in pharmaceutical production. They represent a systems enabling verification of quality assurance with a scientific base.

□ Master File (MF) system
This is a system which, in the event that a producer of APIs or other products does not desire to disclose manufacturing methods or other expertise to approval applicants, consists of the registration of data including that expertise as a Master File (MF) and, by having applicants for the production of drug formulations cite the MF registration number of an API or other product used in that production as a part of the approval application documentation, enables the reviewing authorities to screen detailed data regarding APIs or other products noted in the MF.

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