Fujian South Pharma passed USFDA on-site inspection in Oct 2024.

January 15,2025

Mingxi,China

In January 2025, Fujian South Pharmaceutical Co.,Ltd.(FSP) received the cGMP Establishement Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA), and we officially passed the FDA cGMP inspection.

In October 2024, the US FDA conducted a 5-day cGMP on-site Pre-approval inspection of FSP.The inspection involved the production and manufacturing of Docetaxel API (profile CSN (non sterile API by chemical synthesis) and profile CEX (starting/intermediate derived from plant/animal extraction).

The inspection scope covered six major systems: Quality, Production, Facilities and Equipment, Laboratory Control, Materials, Packaging and Labeling.

The official EIR resulted no issuance of an FDA 483. The inspection was classified as NAI (No action indicated).

Pass of this inspection resulted our partner complete the approval of the formulation in US market as well as other markets.

We will continue to improve our cGMP implmentation，to fulfil our quality commitment to regulatory agency and business partners in the world.

FSP adheres to the road of internationalization, continuously improves the quality management level and company operation level to the international high level, and becomes a trusted partner in the pharmaceutical industry, empowering the internationalization efforts of our business partners.