Sino Biopharmaceutical Limited

Quality and Safety Management Policy

1. Purpose

Sino Biopharmaceutical Limited together with its subsidiaries (hereinafter referred to as "Sino Biopharmaceutical", "the Group") strictly complies with the Drug Administration Law of the People's Republic of China, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Product Quality Law of the People's Republic of China and relevant laws, and other pertinent regulations and regulatory requirements in the places of operations to firmly safeguard product quality and safety up to the highest standards. This policy is formulated to safeguard product quality of the Group.

2. Product Quality Management

(1) Management mechanism

Strictly adheres to Good Manufacturing Practice (GMP) standards and aligns with the requirements of the ISO 9001 quality management system and internationally recognized quality management frameworks to establish a robust and compliant quality management system.

(2) Business continuity risk control

Analyze and assess risks affecting business continuity, eliminate or reduce risks from different levels through various measures, and regularly check or drill relevant measures to ensure the effectiveness of the emergency system.

(3) Deviation investigation and correction

For any deviation from approved product standards, regulations, conditions, safety, environment, etc., the Group shall initiate deviation investigation procedure to find out the cause of the problem and take further corrective and preventive measures according to the cause. After completion, the effectiveness of the corrective and preventive measures shall be evaluated.

(4) Medication safety management mechanism

A Pharmacovigilance Department is set up to monitor and report adverse drug reactions to prevent medication safety risks.

(5) Quality culture construction

Continue to build the quality and safety culture of the Group, and carry out quality and safety training covering all staff at least once a year.

3. Supplier Quality Management

(1) Supplier development

Select suppliers based on the principle of paying equal attention to quality, cost, delivery and service, and do sufficient preliminary research before the development of suppliers.

(2) Daily management of suppliers

The Group has established a supplier database with unified management and continuous optimization, formulated a complaint handling process, and the Procurement Department and relevant quality department should update the qualification of suppliers regularly.

(3) Supplier quality training

Carry out regular training covering all suppliers at least once a year, the training shall cover the topics of quality management, environmental management, safety management and other topics, and conduct regular or irregular visits to suppliers.

(4) Supplier performance management

The Procurement Department and the user department shall evaluate the supplier's services, and formulate hierarchical incentive schemes according to the performance assessment results of suppliers.

(5) Supplier quality audit

Suppliers are divided into four categories according to the impact degree of the materials they provide on the quality of products.

On-site audit shall be conducted every 3 years for Category 1 suppliers (except packaging material suppliers), on-site audit shall be conducted every 5 years for Category 1 suppliers and domestic and foreign packaging material suppliers, and letter audit shall be conducted every 5 years for Category 2, 3 and 4 suppliers.

In case of major quality problems or changes of suppliers, unqualified incoming inspection for two consecutive times, or potential quality problems found in the process of use, conduct additional audit to ensure that the material quality meets the Group's product requirements.

(6) Supplier quality management system certification.

The Group encourages suppliers to obtain quality management system certification. For major sub-suppliers of the Group, the Procurement Department or a third party shall carry out supplier certification.

4. Supplementary Provisions

Anything not covered in this policy, or contrary to the relevant laws, regulations, or normative documents of the People's Republic of China, should be implemented in accordance with the relevant laws, regulations, or normative documents of the People's Republic of China.