Quality Management

Pharmaceuticals are associated to people's life and health, as a professional pharmaceutical manufacturer, quality guarantee is an essential part, and also the key to success of the Group as always. In order to reach the highest degree of quality guarantee, the Group has been strictly complying with The Pharmaceutical Administration Law of the PRC, the Good Manufacturing Practice, Measures for the Supervision over and Administration of Pharmaceutical Production, Measures for the Administration of Drug Registration and other related laws and regulations. We have established a comprehensive quality management system, which helps realize effective quality control procedures through composition test, sample test, label and packaging inspection, transportation and storage management as well as strict control and testing over every processes from raw and auxiliary materials, unfinished products to finished products. Through our vertically integrated production and operation model, every production process and quality control procedure, starting from the entry of raw materials to the export of finished products, is traceable so as to ensure all the products meet the relevant standards.

QUALITY CONTROL

The quality management system established by the Group contains a series of comprehensive procedures, such as the warehousing, storage and shipping procedures of raw materials, auxiliary materials and finished products, so as to implement strict quality control on the various raw materials, auxiliary materials and finished products. When raw and auxiliary materials are accepted, the acceptance personnel must confirm the supplier is a qualified supplier, and shall check the packaging completeness, batch number, specification, storage condition and production date of the batch of raw and auxiliary materials. In order to ensure the health and safety of raw materials, we would sign quality guarantee agreements with suppliers, and require the suppliers to provide the related safety evaluation reports. The material storage is also an important step of production process, so the Group has formulated related regulations on warehouse storage, temperature and humidity control, set proper storage environments for different materials to ensure the materials to be properly stored. In the aspect of transportation, we have signed quality guarantee agreement with the commissioned logistic company to guarantee the quality of products while delivering.

Besides, we have also formed the related procedures for passing products through procedures, which stipulated that only the raw materials, unfinished products and finished products that have passed quality test could be passed to the next procedure, so as to prevent any raw materials, unfinished products and finished products that are nonconforming to standards and specifications being used for production or sales. For nonconforming raw materials and finished products, we will implement identification, investigation, return or collective destruction based on the related management procedures of the nonconforming products. In order to further improve quality management, the Group would implement annual review of product quality in every year, implement evaluation and propose improvement methods for all the quality indicators, deviations in production process and changes of production equipments continuously optimize the quality management system of the Group.

QUALITY CERTIFICATION

The Group's efforts in the aspect of ensuring product quality in the years could be proved by the certifications that we have obtained. In the aspect of production and management, the Group has always been strictly complying with GMP requirements, and is the first comprehensive pharmaceutical enterprise in China that obtained the comprehensive GMP certification. In the aspect of quality management, the quality management system implemented by us was formed in accordance with the national "Quality Management System Requirements", which is equivalent to the adoption of ISO9001: 2008 Standard. Besides, multiple bulk medicine of the Group have obtained certifications from official authoritative institutions, such as China Quality Certification Center, Europe CEP, US FDA, German BGV, Mexico Cofepris, etc. In the Year, the Memantine Hydrochloride Tablets and Memantine Hydrochloride Oral Solution were both included in the 2017-Edition National Health Insurance Catalogue, which further recognized the quality of the Group's products and its status in the pharmaceutical circle.

In the Year, the Quality Inspection Center of the Group's manufacturing base in Zhuhai has obtained the recognition of the China National Accreditation Service for Conformity Assessment (CNAS) for the third times, as well as received the honorable title of the "National 1st May Female Model Position". Besides, the products of the Group, including the insulin bulk medicine, penem-type preparations, Memantine Hydrochloride and penem-type antibiotic bulk medicine received the "Promotion Catalogue Certificate of Key Products of Strategic Emerging Industries in Zhuhai City", which was a major proof of the high-quality manufacturing of the Group. Under the high-level, high-requirement quality control, the Group has obtained multiple awards and honors, for example, the Zhuhai Manufacturing Base received many honorable titles, including the "2017 China Pharmaceutical Industry Top 100 (Overall Power) Industrial Enterprise", the "2017 China Pharmaceutical Industry Bulk Drugs Export Enterprise Outstanding Brand", the "2017 China Pharmaceutical Industry Biochemical Products Outstanding Brand" and the "2017 China Pharmaceutical Industry Anti-Infective Products Outstanding Brand", which has greatly enhanced the good will and brand awareness of the Group.

Zhuhai Company - 2017 China Pharmaceutical Industry Anti-Infective Products Outstanding Brand

Zhuhai Company - 2017 China Pharmaceutical Industry Top 100 (Overall Power) Industrial Enterprise

Zhuhai Company – 2017 China Pharmaceutical Industry Biochemical Products Outstanding Brand

USERS' FEEDBACK

Users' opinions are the source of continuous improvement and advancement of an enterprise. Therefore, no matter if they are positive or negative evaluation, the Group will consider them as valuable opinions. For the complaints of users, the Group treats them even more carefully. We have established a set of comprehensive user complaint handling system based on the related procedures of handling users' complaint to enable various departments to coordinate the acceptance, communication, evaluation and response of complaints with each other. After accepting complaints from users, the related departments will classify complaint types based on the classification method, so as to decide the subsequent investigation directions, such as inspecting the production record, quality situation of raw and auxiliary materials, and environmental factors of manufacturing process, and then adopt corresponding handling methods and reply to users.

In order to further regulate the process of complaint handling, the Group has also established relevant procedures of product return and callback. While maintaining the reputation and interests of the enterprise, such establishment of procedures could also meet the demands of users. As for the adverse reactions that different drugs may cause to individual user, we have also set the related procedures to handle adverse reactions, make efforts to handle such special circumstances as soon as possible, and prevent the effect from spreading. In the Year, the Group has only received 10 complaints, and all the individual cases have been properly handled according to related procedures.

QUALITY MANAGEMENT TRAINING

The establishment of a comprehensive operation procedure is the foundation of quality management, while the actual operation relies on the professional knowledge and judgment of quality management personnel. In order to enable quality management personnel to familiarize the operation and keys of various procedures, and enhance their professionalism on quality control, the Group regularly holds various types of quality management trainings, the contents of which range from recognition of systems and procedures, mastering of operating procedures, to the studying of theoretical knowledge, Through intensive teaching, on-site instruction and case analysis, along with examination and practice, all the quality management personnel could only start working after mastering the related knowledge, and ensure the level of quality management of the Group.