Good Manufacturing Practices for Cosmetics

Chapter I General Provisions

Article 1 In order to regulate the quality management of cosmetics production, these Practices are hereby formulated in accordance with the *Cosmetics Supervision and Administration Regulations* (CSAR), *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other regulations and rules.

Article 2 These Practices are the basic requirements for quality management of cosmetics production. All cosmetics registrants, notifiers and entrusted production enterprises shall abide by these Practices.

Article 3 Cosmetics registrants, notifiers and entrusted production enterprises shall be honest and self-disciplined and be in accordance with the requirements of the Practices to establish a production quality management system to realize the control and traceability of the entire process of cosmetics material purchase, production, testing, storage, sales and recall, so as to ensure continuous and stable production of cosmetics that meet the quality and safety requirements.

Chapter II Institutions and Personnel

Article 4 Cosmetics registrants, notifiers and entrusted production enterprises (hereinafter uniformly referred to as the "enterprises") engaged in cosmetics production activities shall establish an organizational structure that is compatible with the type, quantity, and production license items, *etc.,* of the cosmetics they respectively produce, define the responsibilities and authorities of quality management, production and other departments, be equipped with the technical personnel and testing personnel that are compatible with the type, quantity, and production license items, etc., of the cosmetics they respectively produce.

The quality management department of enterprises shall be set up independently, perform quality assurance and quality control responsibilities, and participate in all activities related to quality management.

Article 5 Enterprises shall establish a cosmetics quality and safety responsibility system, specifying the responsibilities of the enterprises' legal representative (or the person chiefly in charge, the same below), person in charge of quality and safety, person in charge of the quality management department, person in charge of the production department, and other posts related to cosmetics quality and safety. The personnel in each post shall perform the corresponding responsibility for cosmetics quality and safety level by level according to the post responsibility requirements.

Article 6 Legal representatives shall be fully responsible for the quality and safety of cosmetics, and shall be in charge of providing necessary resources, rationally formulating and organizing the implementation of quality policies, and ensuring the realization of quality objectives.

Article 7 Enterprises shall assign a person in charge of quality and safety who shall master professional knowledge related to cosmetics quality and safety such as

cosmetics, chemistry, chemical engineering, biology, medicine, pharmacy, food, public health or legal science, *etc.*, and be familiar with relevant laws and regulations, mandatory national standards, technical specifications, and have more than 5 years of experience in cosmetics production or quality management.

The person in charge of quality and safety shall assist the legal representative to undertake the following corresponding product quality and safety management and product release responsibilities:

(1) Establishing and organizing the implementation of the enterprises' quality management system, implementing quality and safety management responsibilities, and regularly reporting the operation of the quality management system to the legal representative;

(2) Making decisions on product quality and safety issues and issuing relevant documents;

(3) Managing the review of product safety assessment reports, formulas, production techniques, material suppliers, product labels, *etc.*, and review of cosmetics registration and notification dossiers (except for entrusted production enterprises);

(4) Material release management and product release;

(5) Managing cosmetic adverse reactions monitoring.

The person in charge of quality and safety shall perform his/her responsibilities independently and shall not be interfered by other personnel of the enterprise. Based on the operation needs of the enterprise's quality management system, with the written consent of the legal representative, the person in charge of quality and safety may designate other personnel of the enterprise to assist him/her in performing the responsibilities other than (1) and (2) as specified in the above. The designated personnel shall have the corresponding qualifications and ability to perform his/her responsibilities, and the time and specific matters, *etc.*, of the personnel assisting in performing the above responsibilities shall be truthfully recorded to ensure that the act of his/her assistance in the performance can be traced. The person in charge of quality and safety shall supervise the assistance in performing responsibilities, and the legal responsibilities he/she shall bear shall not be transferred to the designated personnel.

Article 8 The person in charge of the quality management department shall master professional knowledge related to cosmetics quality and safety such as cosmetics, chemistry, chemical engineering, biology, medicine, pharmacy, food, public health or legal science, *etc.*, be familiar with relevant laws and regulations, mandatory national standards, technical specifications, and have experience in cosmetics production or quality management. The person in charge of the quality management department shall perform the following responsibilities:

(1) Review of all product quality related documents;

(2) Organizing activities related to product quality changes, self-inspection, non-conforming product management, adverse reaction monitoring, recall, *etc.*;

(3) Ensuring the effective implementation of quality standards, testing methods and