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Good Manufacturing Practices for Cosmetics

化妆品生产质量管理规范

National Medical Products Administration

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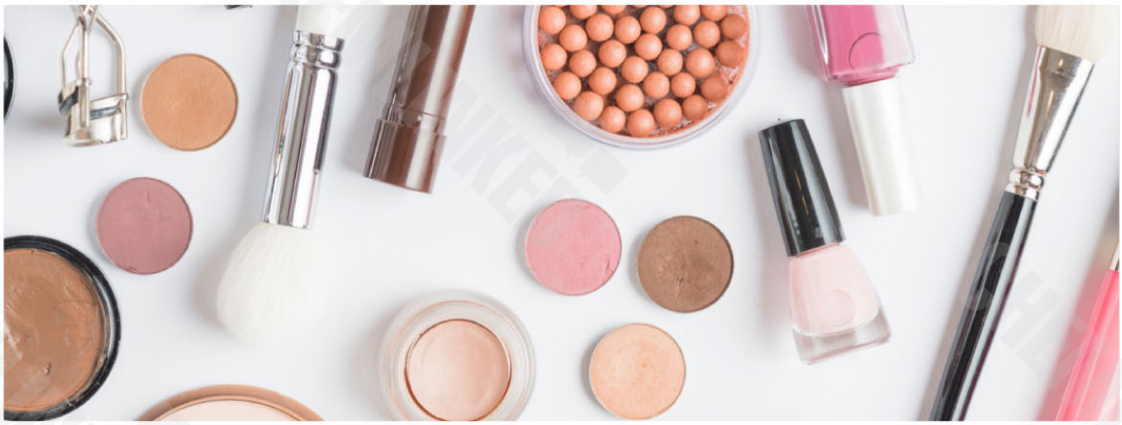

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Attachment

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

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附件

化妆品生产质量管理规范

第一章　总　则

第一条　为规范化妆品生产质量管理，根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》等法规、规章，制定本规范。

第二条　本规范是化妆品生产质量管理的基本要求，化妆品注册人、备案人、受托生产企业应当遵守本规范。

第三条　化妆品注册人、备案人、受托生产企业应当诚信自律，按照本规范的要求建立生产质量管理体系，实现对化妆品物料采购、生产、检验、贮存、销售和召回等全过程的控制和追溯，确保持续稳定地生产出符合质量安全要求的化妆品。

第二章　机构与人员

第四条　从事化妆品生产活动的化妆品注册人、备案人、受托生产企业（以下统称“企业”）应当建立与生产的化妆品品种、数量和生产许可项目等相适应的组织机构，明确质量管理、生产等部门的职责和权限，配备与生产的化妆品品种、数量和生产许可项目等相适应的技术人员和检验人员。

企业的质量管理部门应当独立设置，履行质量保证和控制职责，参与所有与质量管理有关的活动。

第五条　企业应当建立化妆品质量安全责任制，明确企业法定代表人（或者主要负责人，下同）、质量安全负责人、质量管理部门负责人、生产部门负责人以及其他化妆品质量安全相关岗位的职责，各岗位人员应当按照岗位职责要求，逐级履行相应的化妆品质量安全责任。

第六条　法定代表人对化妆品质量安全工作全面负责，应当负责提供必要的资源，合理制定并组织实施质量方针，确保实现质量目标。

第七条　企业应当设质量安全负责人，质量安全负责人应当具备化妆品、化学、化工、生物、医学、药学、食品、公共卫生或者法学等化妆品质量安全相关专业知识，熟悉相关法律法规、强制性国家标准、技术规范，并具有 5 年以上化妆品生产或者质量管理经验。

质量安全负责人应当协助法定代表人承担下列相应的产品质量安全管理和产品放行职责：

（一）建立并组织实施本企业质量管理体系，落实质量安全管理责任，定期向法定代表人报告质量管理体系运行情况；

（二）产品质量安全问题的决策及有关文件的签发；

（三）产品安全评估报告、配方、生产工艺、物料供应商、产品标签等的审核管理，以及化妆品注册、备案资料的审核（受托生产企业除外）；

（四）物料放行管理和产品放行；

（五）化妆品不良反应监测管理。

质量安全负责人应当独立履行职责，不受企业其他人员的干扰。根据企业质量管理体系运行需要，经法定代表人书面同意，质量安全负责人可以指定本企业的其他人员协助履行上述职责中除（一）（二）外的其他职责。被指定人员应当具备相应资质和履职能力，且其协助履行上述职责的时间、具体事项等应当如实记录，确保协助履行职责行为可追溯。质量安全负责人应当对协助履行职责情况进行监督，且其应当承担的法律责任并不转移给被指定人员。

第八条　质量管理部门负责人应当具备化妆品、化学、化工、生物、医学、药学、食品、公共卫生或者法学等化妆品质量安全相关专业知识，熟悉相关法律法规、强制性国家标准、技术规范，并具有化妆品生产或者质量管理经验。质量管理部门负责人应当承担下列职责：

（一）所有产品质量有关文件的审核；

（二）组织与产品质量相关的变更、自查、不合格品管理、不良反应监测、召回等活动；

（三）保证质量标准、检验方法和其他质量管理规程有效实施；

（四）保证完成必要的验证工作，审核和批准验证方案和报告；

（五）承担物料和产品的放行审核工作；

（六）评价物料供应商；

（七）制定并实施生产质量管理相关的培训计划，保证员工经过与其岗位要求相适应的培训，并达到岗位职责的要求；

（八）负责其他与产品质量有关的活动。

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