NMPA Conducts Management Review of the Quality Management Systems for Vaccine Regulatory Oversight and Drug GMP Compliance Supervision[1]

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On June 30, the National Medical Products Administration (NMPA) conducted the management review of the 2025 Quality Management Systems (QMS) for vaccine regulatory oversight and drug GMP compliance supervision. The meeting was chaired by Huang Guo, Secretary of the Leading Party Members Group and Commissioner of the NMPA. He fully affirmed the suitability, adequacy and effectiveness of the Vaccine QMS and the Drug GMP Compliance Supervision QMS implemented by the NMPA headquarters.

Establishing and operating the Vaccine QMS and the Drug GMP Compliance Supervision QMS is an important measure to promote the improvement of national regulatory capacity for vaccine oversight and drug GMP compliance supervision. It also meets the requirements of the World Health Organization (WHO) for the assessment of national regulatory authorities responsible for vaccine regulation and those of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The NMPA attaches great importance to QMS development. Adhering to both a goal-oriented and a problem-oriented approach, it has continuously strengthened the routine and standardized operation of the systems and steadily improved regulatory performance.

During the management review, the Department of Policies and Regulations and the Department of Drug Regulation respectively reported on the overall implementation and operation of the Vaccine QMS and the Drug GMP Compliance Supervision QMS at the NMPA headquarters in 2025. They also presented the issues identified, the specific corrective actions taken, and recommendations for further improvement of the systems. The meeting reviewed the annual operation of the systems across the General Affairs Department, the Department of Policies and Regulations, the Department of Drug Registration, the Department of Drug Regulation, the Department of Human Resources, and other constituent departments.

Huang Guo pointed out that, through the establishment of the regulatory QMS, the NMPA has continuously improved and refined its regulatory work, strengthened resource support and workforce development, and provided effective support for enhancing the quality and effectiveness of vaccine regulatory oversight and drug GMP compliance supervision. All departments have strictly implemented risk management requirements, carried out in-depth risk identification and prevention, and continuously optimized whole-process management.

[1]Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

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Following three consecutive years of sustained efforts, all provincial medical products administrations have completed observation and learning of the internal audits conducted by the NMPA headquarters. Building on this foundation, efforts should be made to further advance coordination and alignment throughout the regulatory system and continuously improve the quality management systems.

Huang Guo emphasized the need to further study the integrated development of the quality management systems and regulatory work, further deepen and solidly advance QMS development, enhance the effectiveness of vaccine and drug regulation, and provide strong support for the modernization of the regulatory governance system and regulatory capacity.

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