Notice of Comprehensive Department of National Medical Products Administration on Issuing the Good Manufacturing Practice Guidelines for Onsite Inspection of Stand-alone Software

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To medical products administration of all provinces, autonomous regions, and municipalities directly under the Central Government, and the Xinjiang Production and Construction Corps:

In order to enhance the supervision and inspection of medical device manufacturers in implementing *Good Manufacturing Practice for Medical Devices* and GMP annex on stand-alone software, guide supervision department to conduct onsite inspection and inspection result evaluation, National Medical Products Administration has developed *Good Manufacturing Practice Guidelines for Onsite Inspection of Stand-alone Software*. It is hereby printed and distributed to you. Please carry out the details accordingly.

Comprehensive Department of National Medical Products Administration

May 29, 2020

Good Manufacturing Practice Guidelines for Onsite Inspection of Stand-alone Software

Chapter	Article	Contents
Organization and personnel	1.1.1	Management organization corresponding to the production of medical devices should be established along with organization chart. **Check the quality manual submitted to verify whether it includes the organization chart of enterprise and clarifies the interrelation of all departments.**
	*1.1.2	The responsibilities and authorities of all departments and quality management function should be specified. **Check the quality manual, procedure documents or relevant documents to verify whether the responsibilities and authorities of all departments are specified; quality management department should exercise the function independently. Check the documents of quality management department to verify whether the decision making right on relevant product quality matters is specified.**
	1.1.3	Person in charge of production management department shall not be the same one for quality management department. **Check the appointment document or authorization document of the company and compare them with the records on production, inspection and other duty execution to check whether they are consistent with authorization.**
	1.2.1	Person in charge of the entire enterprise shall not be the same one for the quality of medical device products.
	1.2.2	Person in charge of the entire enterprise should formulate quality policy and quality target. **Check the formulation process and authorizing officer of quality policy and quality target.**
	1.2.3	Person in charge of the entire enterprise should guarantee the human resources, infrastructure and working environment required for the effective operation of quality management system.
	1.2.4	Person in charge of the entire enterprise should organize and implement management review, evaluate the operation of quality management system, and conduct improvement continuously. **Check management review documents and verify whether person in charge of the entire enterprise organizes and implements management review.**
	*1.2.5	Person in charge of the entire enterprise should ensure that enterprise organizes production in accordance with the requirements of laws and regulations.
	1.3.1	Person in charge of the entire enterprise should identify an executive representative. **Check the appointment document of the executive representative.**
	*1.3.2	Executive representative should be responsible to establish, implement and keep quality management system, report the operation situations and improvement requirements of quality management system, and improve personnel's awareness to meet the requirements of laws, regulations and customers.