**Work Procedure for Collaborative Drug Registration Inspection of Manufacturing Site and Pre-market Good Manufacturing Practice (GMP) Inspection**

 **(Trial)**

**Article 1** In order to standardize the work procedure for collaborative drug registration inspection of manufacturing site (hereinafter referred to as registration inspection) and Pre-market Good Manufacturing Practice (GMP) compliance inspection (hereinafter referred to as Pre-market GMP inspection), and to ensure the quality and efficiency of collaborative registration inspection and Pre-market GMP inspection, this Procedures is formulated in accordance with the *Drug Administration Law of the People's Republic of China, Vaccine Administration Law of the People's Republic of China, Measures for Administration of Drug Registration* and *Measures for Supervision and Administration of Drug Production.*

**Article 2** This Procedure shall be followed in the collaborative drug registration inspection of manufacturing site carried out by the Center for Food and Drug Inspection (CFDI) of the National Medical Products Administration (NMPA) (hereinafter referred to as the CFDI) and the Pre-market GMP inspection carried out by the drug regulatory authorities of relevant provinces, autonomous regions and municipalities directly under the Central Government (hereinafter referred to as the provincial authorities).

**Article 3** When the CFDI coordinates the collaborative inspections with provincial authorities, both parties shall, in accordance with the regulatory requirements and their respective functions, follow the concept of risk management and work together to ensure the smooth collaboration between registration inspection and Pre-market GMP inspection.

**Article 4** If the Center for Drug Evaluation of NMPA (hereinafter referred to as the CDE) decides to initiate a registration inspection during the review of a drug registration application, it shall notify the CFDI to conduct an inspection, provide relevant information required for the inspection, and at the same time inform the applicant and the relevant provincial authority where the applicant or the manufacturing site is located.

If the Pre-market GMP inspection is required according to the regulations, the provincial authority shall communicate with the CFDI within 5 days upon receipt of the notification from the CDE, when they consider it is necessary to carry out the drug registration inspection of manufacturing site at the same time.

**Article 5** After confirming the inspection arrangements with the applicant taking consideration of the characteristics, processes, risks, etc. of the product, the CFDI shall work together with the provincial authorities to agree on the work arrangements to clarify the composition of the inspection team and the inspection time.

**Article 6** In accordance with the requirements and functions of laws and regulations, the CFDI and provincial authorities shall form inspection team in accordance with procedures to complete the drug registration inspection and Pre-market GMP inspection.

The CFDI and the provincial authority may form separate inspection teams or jointly form an inspection team. In principle, the registration inspection, and the Pre-market GMP inspection should be carried out in the same production period.

**Article 7** The professional background and numbers of inspectors shall be determined taking consideration of the characteristics, process, and risks of the inspected product, as well as the actual production conditions of the medicinal product.

If an inspection team is formed together, the inspection team leader and team members should be qualified national GMP inspectors. The inspection team leader shall be determined by the CFDI and the provincial authority through joint discussion.

**Article 8** During the collaborative inspection, the inspection team shall conduct inspection in accordance with the established inspection program. If they’re two independent inspection teams, they shall maintain good communication and cooperation while performing their respective duties, such as holding the open and close meetings and discussing major issues together.

**Article 9** The inspection team shall write registration inspection and Pre-market GMP inspection reports and draw conclusions on registration inspection and Pre-market GMP inspection respectively based on the on-site inspection.

After the inspection, the inspection team shall formally submit the registration inspection report (one copy) and the drug on-site inspection question sheet to the observer and send them to the relevant provincial authority.

**Article 10** The CFDI and the provincial authorities shall establish a routine communication and information sharing mechanism to ensure that the interface between registration inspection and the Pre-market GMP inspection is carried out in an orderly manner.

**Article 11** The Procedures shall come into force on January 1, 2022.