SFDA

Progress of Chinese Drug GMPs

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Background

- The Ministry of Health of the People's Republic of China enacted the first *Standards for the Administration of Drug-production Quality of China* in accordance with the Law on *the Administration of Drugs* in 1988 and revised the Standards in 1992.
- In 1995, the Ministry of Health established the China Certification Committee for Drugs together with the departments concerned, announcing the formal start of government drug GMP certification.
- In 1998, the State Drug Administration (SDA) was founded, which amended the drug GMPs and promulgated *the Standards for the Administration of Drug-production Quality* (Administration Order No.9) and *the Procedures the Administration of Drug GMP Certification* in June, 1999, which were effective from August 1, 1999.
- In 1998, in order to unify standards, standardize certification inspections and assure the quality of work, *the Standards for the Certification, Inspection and Evaluation of Drug GMPs (Interim)* were formulated and promulgated.

Latest Progress

- The Standards for the Certification, Inspection and Evaluation of Drug GMPs were amended

  (Promulgated on October 24, 2007, and effective from January 1, 2008)
- *The Standards for the Administration of Drug-production Quality* are being amended urgently.

Amendment of *Standards for the Certification, Inspection and Evaluation of Drug GMPs*

Background of amendment

1. *The Standards for the Certification, Inspection and Evaluation of Drug GMPs (Interim)* were promulgated and put into practice on November 9, 1999, nearly 8 years ago from today. With the deeper implementation of the GMP work, deficiencies in the prevailing standards have emerged.
2. To suit the current trend of drug supervision and further improve the quality of drug GMP certification, *the Standards for the Certification, Inspection and Evaluation of Drug GMPs* have to be amended.

Amendment of *Standards for the Certification, Inspection and Evaluation of Drug GMPs*

Amendments

1. The former standards with 225 clauses have been amended to include 259 clauses, including 92 key (**) items and 167 ordinary items.
2. The items have been adjusted and some items added. The former 56 key items have been adjusted to 92 key items, and the former 169 ordinary items to 167 ordinary items. Key items have been added in relation to personnel, software and manufacturing process management.

Amendment of *Standards for the Certification, Inspection and Evaluation of Drug GMPs*

3. The expression of the clauses has been changed. The former expression of “yes/no” has been changed to “shall” or “shall not” to further define the requirements.
4. It is stressed that raw drugs and preparations must be manufactured in accordance with the process approved for registration.

Amendment of *Standards for the Certification, Inspection and Evaluation of Drug GMPs*

5. Evaluation method of amendments

- The option of nonconformity inspection after rectification has been cancelled; the provision that only when no defect is found or any ordinary defect found has been corrected can the drug pass the GMP certification is kept. If any serious defect is found or any ordinary defect found has not been corrected, the enterprise shall not pass the certification.
- If any defect can be corrected immediately, the enterprise must correct it immediately; if not, only if the enterprise provides a defect correction report and a correction plan can it pass the certification.

Amendment of *Standards for the Certification, Inspection and Evaluation of Drug GMPs*

6. Inspection and evaluation shall be made based on the dosage form or variety submitted for certification respectively. If an enterprise submits several dosage forms or varieties for certification simultaneously and the defect found in the certification inspection is present in all dosage forms or varieties, these shall be calculated respectively. If a serious defect is present in all scopes of certification of the enterprise, none of these scopes shall pass the certification.

Amendment of Drug GMPs

- The GMPs are being amended; it is expected that the draft for comment will be completed by the end of 2008 and available on the Internet. The preliminary plan will be amended and improved in 2009.
- The GMPs shall be suited to China's national conditions, acceptable to all parties and of high quality.
- The Standards for the Certification, Inspection and Evaluation of Drug GMPs are also amended to drive the implementation of the GMPs actively and steadily, improve China's implementation level of GMPs gradually and suit them to China's practical situation.

Comparison between Chinese and Foreign GCPs

- Commonalities

1. Compliance with international GCP essences and principles
2. Largely compliant with international GCPs
3. Compliance with Chinese laws and regulations on drug supervision and administration
4. Suitability with China's national conditions, which can be achieved through efforts

Differences

1. The clinical testing of new drugs must be approved by the drug supervisory authorities in writing;
2. The testing institution must be selected from those defined by the SFDA;
3. A single discipline of a clinical drug testing institution shall not conduct clinical test research of varieties submitted by different applicants concurrently and shall not conduct clinical research of too many varieties concurrently;
4. The ethics committee shall be affiliated to a medical institution and there shall be no commercially independent ethics committee.

Implementation

As at September 1, 2007, SFDA had released thirteen *Qualification Bulletins of Clinical Drug Testing Institutions* in total, approving:

- 178 clinical drug testing institutions (including 136 Western medicine hospitals and 31 traditional Chinese medicine hospitals), involving 1,233 specialized departments, distributed in 27 provinces (municipalities, cities) of China
- Three hospitals in the Hong Kong Special Administration Region (Prince of Wales Hospital, Queen Mary Hospital, Hong Kong Eye Hospital)
- For the detailed list see the SFDA website: www.sfda.gov.cn.

The approved clinical drug testing institutions can largely meet the present demand for clinical testing; however, the clinical testing institutions of the following special diseases cannot meet the demand yet:

- Department of AIDS
- Department of pediatrics
- Vaccines
- “Orphan drugs”, etc

Over the past 10 years, the present implementation of China's drug GCPs is characterized in that:

- First, there are established legal and regulatory requirements for the supervision of the implementation of GCPs;
- Second, there are established procedures and standards for the qualification of medical institutions;
- Third, the sense of GCP of medical institutions, drug manufacturers and all levels of drug supervisory personnel has improved greatly;
- Fourth, the number of international multi-center clinical tests has increased year by year;
- Fifth, the GCP supervisory requirements are gradually up to the international standards.

Thank you!