CHINA

Update on medical device regulations

Department of medical device registration
China Food and Drug Administration

2013.11

Reorganization

- According to the decision of NPC and State Council, CFDA (China Food and Drug Administration) was established incorporating SFDA (State Food and Drug Administration) and some responsibilities of other government departments in the April 2013, after the IMDRF-3 meeting.
- CFDA is a ministerial-level agency directly under the State Council of the People's Republic of China, which is in charge of administration and supervision of food (including health food), drugs, cosmetics, and medical devices.

Reorganization

- The authority and strength of medical device supervision was reinforced in CFDA.

Original **Department of Medical Device supervision in SFDA divided into** two new departments in CFDA:

1. **Department of Medical Device Registration**, which is responsible for pre-market approval;

2. **Department of Medical Device supervision**, which is responsible for post-market supervision.

Regulations

- The revision of "Regulations for the Supervision and Administration of Medical Devices" (State council decree No.276) is near the end, it is expected to be issued in 2014.

- Currently, Some matching regulations of future new State council Decree have been formulating or revising.

For example:

Provision on medical device registration

(current version: SFDA decree No.16)

during the revision process, we have learned from the international medical device supervision experiences.

we will try to adopt the GHTF-STED principles and EP checklist as the registration application material by the manufacturer.

Regulations

Provisions on the approval for medical device clinical trial

For some high risk class III medical devices, for example: pacemaker, Artificial heart valve, 3D printed orthopedic implants and so on.

These medical device must acquire the CFDA approval before clinical trial start.

The rules have collected the advices on CFDA website.

Regulations

GCP for Medical Device

(current version: SFDA decree No.5)

Refer to ISO14155.

Add the clinical trial protocol technical requirements.

Strengthen the responsibility requirements of the sponsor, investigator and hospital.

The rules have collected the advices on CFDA website.

Regulations

- The second list of the class II medical device for exemption from clinical trial data submission

Published in Oct 2013. Including 140 kinds of class II medical devices.

Up to now, 294 kinds of class II medical devices needn't to submit the clinical trial data when they applying the product approval.

For example: condom, sterilizer, porcelain powder and so on.

Details on CFDA website.

Efficiency

- Special procedure for Innovative medical device registration

  For innovation medical device, which, for example, had acquired the china invention patent, and has initiative mechanism of action/principle of operation in china, CFDA will give the priority to handle the registration application, but still according to the same evaluation requirements.

  The rules have completed the consultation and the WTO/TBT notification.

Efficiency

- Rules for simplification of medical device re-registration requirements

  when applying the re-registration, sponsor just submit the technical evidences related to the changes of the medical device , if it doesn't substantially influence the safety and effectiveness, unnecessary to submit all the technical documents.

  Aim to improve the re-registration efficiency.

  The rules have completed the consultation and the WTO/TBT notification

Abolish

3C (China Compulsory Certification) of eight kinds of medical device have been abolished in china.

Afterwards, these medical device just need to obtain the medical device registration certificate issued by CFDA and local FDA in china.

3C product list:

Medical X-ray equipment, haemo-dialysis equipment,

Blood purification device of extracorporeal circulation pipes,

hollow fiber dialyzer, artificial heart-lung machine,

Electrocardiograph, Pacemaker, condom

Abolish

- The abolishment of 3C for some medical device will reduce the manufacturer's burden, and reduce the cost for the Chinese market access, the products needn't to take reduplicate testing and reduplicate factory audit.
- In addition, the abolishment means CFDA will take the full responsibility for the medical device market access.

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- Questions ?