IMDRF International Medical Device Regulators Forum

Update on China medical device regulatory

CFDA

GCP

- Good Clinical Trial Practice(CFDA Decree No.25)
- Carried out from 2016.6.1
- Learn from ISO 14155 and adopted some requirements of the standard
- The clinical trials means the clinical trials carried out in China, under normal use conditions, during the process of confirmation or verification of safety and effectiveness of Medical Devices which apply for registration.
- The decree is not applicable to in vitro diagnostic reagents.

GCP

GCP has 11 chapters and 96 articles

And cover the whole process of clinical trial, including the design, implementation, monitor, check and inspection of clinical trial protocol, collect, record and analysis of clinical data and report and so on.

For example:

The GCP demand the medical device for clinical trial must be development under the GMS, and imported the conception of defection of medical device, and the GCP also give a clear explanation of multi-center clinical trials requirements.

GCP

Accompany with the implementation of GCP, CFDA will strengthen the check of clinical trials, in order to against the behavior of providing the untruthful clinical data.

Recently, we have rejected four medical device registration application，for providing the untruthful clinical data

Recommendation on medical device review and approval reformation

- No. 44 document, State Council, 2015.8.18

1.Draft the new version of the catalogue of medical device classification, will for public comment in near future.

2.Draft the second batch list of exemption of clinical trials of medical device, including 259 kinds of the class II medical device and 66 kinds of class III medical device, and also including the IVD products for the first time. We hope the files can be published recently.

Recommendation on medical device review and approval reformation

3.increase the transparency of review and approval information, for example：publish the medical device approval and filing information each month and publish the annual report of medical device registration on 2015, this is the first time, CFDA publish the relevant report for public.

Post-market

- The last year, CFDA started the pilot of overseas manufacturer inspection, this year, we will expand the scope and quantities of inspection for quality management system of overseas manufacturer.
- In future, it will become a routine work.

IMDRF

◆RPS

- We build a team to attend the pilot of RPS
- give the favorable requirements for the medical device, which apply the pilot in China, For example, review and approval with priority.
- About more than 10 items are reviewing in CMDE and we have approve 3 items, including 2 types of registration: the first registration, the change of registration, and we will continue the RPS pilot on schedule, and feedback the problem and suggestion to the RPS WG.

◆GRP

The CMDE, belong to the CFDA, plan to build the internal management system, and we also hope to adopt the GRP WG achievements and strengthen our management level.

Thank you

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