



IMDRF International Medical
Device Regulators Forum

Update on China medical device regulatory

**CFDA
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New regulation system

- Last year, **New Regulation for the Supervision and Administration of Medical Devices** had been released and implement after 1st June. After that, about more than 20 rules and Normative documents on registration and manufacture had been issued by CFDA.
- The new regulation system had been established, but CFDA still has a lot of work to do to improve the whole system, including revision of more regulations and deal with the problem accompany with the implementation of new regulations.



Basic regulations

Revision of some regulations had been pushing forward

- ◆ medical device code system (UDI)
- ◆ Provisions on medical device nomenclature
- ◆ Provisions on medical device classification
- ◆ catalogue of medical device

We are used to calling these work above “basically work”, because these decide the control scope of medical device in china, how to track the medical device, how to named a medical device, and so on



GMP for different kinds of medical device

Three annex of GMP had finished the comments And will released in near future

- Sterile medical devices
- Implant medical devices
- IVD

The three normative documents are based GMP requirements, and include the detailed requirements meet the sterile/implant MD and IVD special characteristics.



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IEC 60601-1-2 for class II medical electrical equipment

2012, CFDA issued electromagnetic standard applies to medical device, an industry standard in china, called YY 0505-2012, equal to the IEC 60601-1-2:2004

Last year, the class III medical electrical equipment had been asked for the electromagnetic compliance test report as the registration documents.

From 1st, JAN, 2015, the class II medical electrical equipment should submit the same documents, including the continuous registration.



Clinical evaluation on medical device

- Guidance for medical device clinical evaluation are drafting.
- The same requirements for domestic and imported medical device
- We plan to add more medical devices into the catalogue for medical device without clinical trials, in order to hold the quantity of medical trials on reasonable level.



Thank you

- ◆ The new regulation system need to be improved in advance, CFDA are doing this work.
- ◆ We will resolve the problem accompany with the implementation of new regulation.
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