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International Medical  
Device Regulators Forum

# **Update on Medical Device regulatory in China**

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## Key words

- Encourage
- Strengthen
- Scientific



## Prior approval procedure for medical device

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For medical device below:

1. Diagnostic and therapeutic for rare disease, with Obvious clinical advantages
2. Diagnostic and therapeutic for malignant tumor, with Obvious clinical advantages
3. Diagnostic and therapeutic for elderly residents specific and frequently-occurring disease, without available diagnostic and therapeutic method now



4. For children, with Obvious clinical advantages
5. Clinical imperative, without the same kinds of medical device had been approved in china

CMDE and CFDA will review and approve such medical device registration application priority, accelerate the work progress, in order to shorten the review and approval time, It is a method to encourage the development of medical device industry and satisfied for the demands of the patient.



# The provision on medical device recall

- ✓ The old version of the provision had been published on 2011.5.2
- ✓ CFDA degree No.29
- ✓ Published on 2017.1.25
- ✓ Will Carry out on 2017.5.1

## Main change:

1. Determine the subject of liabilities for recall, especially for imported medical device, the agent which was designated by the foreign manufacturer is the subject of liabilities ,it should charge for the medical device recall.



## 2. Determine the range of the medical device with defect.

Including:

- may be of unreasonable safety or health hazards to people when operated under normal conditions;
- don't comply with the mandatory standard/product technical requirements that had been registered or filed;
- may be of unreason risk because the product don't comply with the requirements by medical device manufacture or sale regulatory.
- others.

## 3. Strengthen to open the information of recall for public



## The second batch of medical device catalogue exempt the clinical trials

- CFDA Notice 2016 No.133
- Published on 2016.9.27
- Including 359 kinds of medical device, 267 kinds of medical device are class II medical device, 92 kinds of medical device are class III medical device. Especially, 15 kinds of IVD was listed in the catalogue at the first time.
- In order to decrease the quantities of clinical trials in china , set the scientific requirements on clinical evaluation for medical device.



## International cooperation

- Prepare for the IMDRF rotating presidency in the next year
- Continue to carry out the RPS Pilot
- Study the achievements of IMDRF WG and guidance





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## Thank you

1. Encourage the innovation development of medical device industry
2. Set scientific requirement on medical device registration
3. Strengthen post-market surveillance
4. Prepare for IMDRF work in the next year