IMDRF International Medical Device Regulators Forum

# Update on regulatory development

China Food and Drug Administration

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## ➢The rule for medical device classification

2015.7.14 CFDA Decree No.15

1. Revised

2. Guide the drafting of the classification catalog of medical device .

3. Add the rule for compound (device and drug)medical device, medical dressing , Orthopedic instruments.

4. Modified some definition and improve some requirements, for example, modified the definition of “invasive device”, excluded the Reusable surgical instruments, and so on.

5. CFDA are preparing to establish the Expert committee for medical device classification

6. The classification catalog of medical device will be adjusted according to the administration requirements.

# ➢Guidance for Medical Device Clinical evaluation

2015.5.19 CFDA 2015 No.14 Announcement

1. 79 Class III, 488 Class II medical device needn't clinical trial, According to the CFDA 2014 No.12 and No.13 Announcement

2. If you can find a medical device which had approved in china and the medical device is substantial to your product which will register in china a, you should submit the legal data to prove the substantial ,meanwhile , you also should to give the enough clinical Literature data and experience data you can find to prove the safe and efficiency of the medical device.

3. Clinical trial: in the list of the high risk class III medical device which should be approved before clinical trial, about 8 kinds of medical device, must launch the clinical trial in china.

# ➢Guidance for Medical Device Software Registration

2015.8.7 CFDA 2015 No.50 Announcement

1. Including the standalone software and embedded software(software components)

2. Some definitions, standalone software , the classification of risk level and so on, absorbed the IMDRF relevant guidance

3. Update of software is be divided for two classes, one is major update, the other is minor update, the major update must submit the alteration registration and must acquire the pre-market approval.

## ➢Post market

1. Train the GMP inspector.

2. next step, CFDA will arrange the inspector to carry out the abroad GMP inspection.

3. Published the annex of GMP for sterile medical device, the implant medical device and IVD, detailed rules and requirements for these three kind medical device.

- Thank you
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