CFDA 国家食品药品监督管理总局
China Food and Drug Administration

Medical Device Regulation Developments in China

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Medical Device Industry

Some numbers in 2014

- Manufacturing
  - Company: ~16,000
  - Revenue: $60 billion(company revenue>3M)
- Distribution company: ~180,000
- Total Trade Volume: $ 35.8 billion
  - Import: $ 15.8billion
  - Export: $ 20billion

Elements of CFDA Regulatory System

- Classification, Nomenclature, Standard
- Premarket controls and review
- Laboratory testing/investigations
- Quality systems requirements
- Post-market Surveillance

New legislation and regulations

New Regulatory System

- Order 650 - New Regulation for the Supervision and Administration of Medical Devices was implemented since 1st June, 2014.
- After that, more than 70 department regulatory documents, rules and Normative documents on registration and manufacturing 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 problems accompany with the implementation of new regulations.

Nomenclature Classification and Catalog

- July 2015
  - Medical Device Classification Rules was promulgated
- Medical Device Naming Rules was published for comments

On-going

- Prepare to establish Technical Committee and Specialty Groups
- Comprehensive overhaul of existing classification guidance
- Develop new Medical Device Classification Catalog

Standard System

- Total Device Standard: 1317
  - National Standard is 210
  - industry standard is 1107
- 90% International standards was converted
- Revise or develop 100 standards each year
- Revising Regulation on Medical Device Standard Management

Innovation Device Registration

- Feb. 2014, Special Evaluation and Approval Procedure for Innovation Device
- Encourage development and innovation
- Promote new technology and industry development
- 30 devices entered into express channel
- 8 approvals, i.e. Proton Heavy Ion Treatment System, 2nd Generation PMGTM

Technical Guidance

- 120 technical guidance
- In 2015
  - Guidance for Medical Device Software Registration
  - Guidance for New Technology Registration of Imaging Ultrasound Diagnosis Equipment
  - EMC testing for Class II device.

Guidance for Medical Device Clinical Evaluation

May 2015, CFDA 2015 No.14 Announcement

- 79 Class III, 488 Class II medical devices don't need clinical trial in China.
- If there is a medical device which is approved in china and it is substantial to the product which will be registered in china, applicant should submit the legal data to prove to be the same device, meanwhile , applicant should provide the enough clinical evidence (literature data and clinical experience data) to prove the safe and effectiveness of the medical device.

Clinical Trial

- Oct. 2014, Medical Device List which Need Preapproval for Clinical Trial, 8 kinds of high risk devices are included
- July 2015, announcement on how to file a clinical trial
- Drafted out Medical Device GCP
- Drafted out Administration of Qualification for Medical Device Clinical Sites

Post market

- Trained the GMP inspectors， CFDA will conduct oversea GMP inspection
- Sept.2015, 4 guidance of GMP site inspection
  - General guidance of GMP site inspection
  - GMP site inspection guidance for sterilization medical device, implantable medical device and IVD.

Post market

- December 2014, Medical Device GSP
- October 2015, Site Inspection Guidance of GSP
- October 2015, Regulations on Supervision and Administration of Medical Device Utilization
- Intensive dawn ride inspection

UDI

- CFDA is doing research for establishment of UDI system in China.
- Device coding rules is under discussion.
- Phase in and pilot run approach is considered, starting from implantable device.

International Exchange

- CFDA participate IMDRF meetings and actively engaged in the following projects:
  - Patient Registry
  - GRP (Good Review Practice)
  - RPS (Regulated Product Submission)
  - MDSAP Pilot
  - NCAR Pilot
- Exchange and dialogs with US, European and other counties. Participated the activities hold by international standard organization

Thank you

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