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International Medical
Device Regulators Forum

Update on China medical device regulatory

**CFDA
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Reformation

- Recommendation on drug and medical device review and approval reformation
- No. 44 document, State Council, 2015.8.18

In order to resolve the problem of the big **backlog** of Drug registration application, and improve the scientific and quality of the review and approval on drug and medical device

Including a few requirements for medical device



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- ◆ increase the transparency of review and approval information

for example: open the medical device approval relevant information, Acceptance of information, The standards and technical requirements



◆ Encourage the innovation of medical device

For

- Invention patent in China
- Huge Clinical application value
- Finalize the design of the product

- Innovation medical device special approval procedure
- CFDA normative document

- review and approval with priority



- ◆ Increase the adoption rate of international standards, when the standards transform to China medical device standards, ISO/IEC and so on

- ◆ Adjust the classification of medical device
 - Establish the classification expert committee

 - Revise the classification catalogue of medical device, may finish in this year



other

- ◆ The second batch of catalogue of medical device, exempt from the clinical trial, is drafting.
- ◆ The provision on use quality supervision of medical device had been published on 10.21, 2015,
The CFDA decree No.18
The regulation will improve the system of medical device supervision in the whole process.



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◆ 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
- We are accumulated the problem, suggestion, and feedback the RPS WG.



◆ MDSAP

CFDA is drawing up the requirements for medical device audit, the MDSAP guidance will be the important reference for CFDA.

◆ SaMD

The medical device software review guidance had been released on our website, the content of the guidance adopted the SaMD achievements, including the definition of standalone software.



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As the members of IMDRF, CFDA will increase the cooperation with other members, adopt the IMDRF achievements according to our regulation system, improve the implementation of IMDRF guidance



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Thank you

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