



IMDRF

International Medical
Device Regulators Forum

China Update

**IMDRF Open Stakeholder Forum
March 21, 2018**



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Reformation on MD Approval System

“Propositions on deepening approval system reformation and encouraging innovation ”

Issued on 2017.10

General Office of the Central Committee &
General Office of the State Council, 2017 No.42

●Comprehensively enhanced reformation of the examination and approval system for medical devices in China.



Measure 1:

“Special approval procedures for innovative medical devices” .

- Special approval was given to innovative MDs which have the core technology patent and the significant clinical application value.
- 9 products were approved by now.

“Prior approval procedure for medical device” .

- Priority was given to the MDs for diagnosis or treatment of rare diseases, malignant tumors, diseases of the elderly and children, and urgent clinical needs.
- 2 products were approved by now.



Measure 2:

“The administration measures for MD clinical trial institution criterias and MD clinical trial institution recording” .

Purpose: change the supervision approach from approval to record.

- Encourage more qualified medical institutions in china to participate in clinical trials of medical devices.
- Release clinical resources, expand the number of clinical institutions.
- Better meet the needs of industrial development.

At present, more than 30 medical institutions have been put on record in the "medical device clinical trial organization record information system".



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Measure 3:

Optimized the approval procedure for clinical trials.

Within a certain period of time after accepting the application for clinical trial, no negative opinion or challenge is deemed to be agreed. The applicant may carry out clinical trials according to the proposed scheme.

The "express" license was adjusted as "tacit approval".

To promote the clinical trial of enterprise products as soon as possible, so as to improve the product approval speed and meet the clinical needs.



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Measure 4:

“Guiding principle for accepting abroad MD clinical trial data” .

Issued on 2018.1

CFDA announcement 2018 No. 13.

To define the principles and requirements for accepting abroad MD clinical trial data.

Reduce the reduplicated clinical trials in china.

Accelerate the process of admittance.



Measure 5:

The exemption of clinical trials and Technical Examination Guidance

“The third batch of medical device catalogue exempt the clinical trials” .

Issued on 2017.10

CFDA announcement 2017 No. 170

To further extend the medical device catalogue exempt the clinical trials.

Decrease the quantities of clinical trials in china.

For now, 1090 products are included in.

Issued new Technical Examination Guidance for 80 products.



Measure 6: Strengthened examination capacity

The China medical device evaluation center improve the communication system of expert advisory committee, and formed a review team, which is responsible for the evaluation of innovative products.

Further improved the QMS for review of medical devices and implemented the QMS to Strengthen the team building.

We also strengthened the training of reviewers, and increased the salary of the reviewers, to strengthen the evaluation team.



MD standard and Classification

**“The measures of medical device standard management”
“The regulations of medical device standard revision work
management” .**

- Organized 86 item of medical device industry standard revision.
- Issued 98 standards for medical devices industry.



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New edition of “Catalogue of medical device classification” .

Issued on 2017.8

CFDA announcement 2017 No.104

- The new catalogue further optimizes the overall framework, refines the product category, expands the product coverage, adjusts the product management category reasonably.
- Significantly improves the scientificity and guiding significance of the catalog.



Supervision of clinical trials

Strengthened the supervision and inspection of clinical trials.

Implement the GCP of medical devices, to strengthen supervision and inspection.

Made the results public.

Clinical trial data that did not passed the examination were not accepted.



Implementation of GMP

Strengthened the supervision and inspection of GMP of the manufactures.

We fully implemented the GMP for medical devices. From January 1, 2018, all medical device manufacturers shall be fully comply with the GMP.

We strengthened the inspection of the GMP for domestic manufactures, and organized the on-site inspection of some overseas manufactures, both of which had achieved good results.

For the manufactures with problems, we urged the enterprise to rectify, to extent the degree of compliance, and effectively eliminated the risk.



Adverse events monitoring and recall

Continually improve “The measures for adverse events monitoring and re-evaluation of medical devices”

- Define manufacturer responsibility for adverse event monitoring and re-evaluation of MD.
- Strengthen monitoring of adverse events in medical devices and improve the ability to monitor risks.
- New edition of the policy will be issued soon.

“The measures for medical device recall management”

- Clarify the manufacture responsibility of medical device recall.
- Promote the work of medical device recall.



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IMDRF achievement transformation

1. The construction of the inspection team:

In the training, assessment, selection and daily management of national inspectors, the relevant achievements of MDSAP have been drawn.

For further enhancing of the inspector's ability and Expanding of the inspectors' international horizons,



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2. Medical device coding:

Through understanding the relevant experience of the IMDRF MC, improving the coding requirements of medical devices in China.

“The rules for the UDI system” is now asking for public consultation.



3. Established a system Software and network guidelines:

Issued:

The guidance of security technology review for medical devices.

The guidance for technology review of mobile medical devices.

The guidance for the technology review of medical device software.

A complete system of software and mobile medical devices is established.

4. RPS pilot project:

- Three product approved according to the pilot scheme.

- CMDE is studying the adjustment of medical device registration requirement.



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Thank you!