Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Progress of Medical Device Regulation in China

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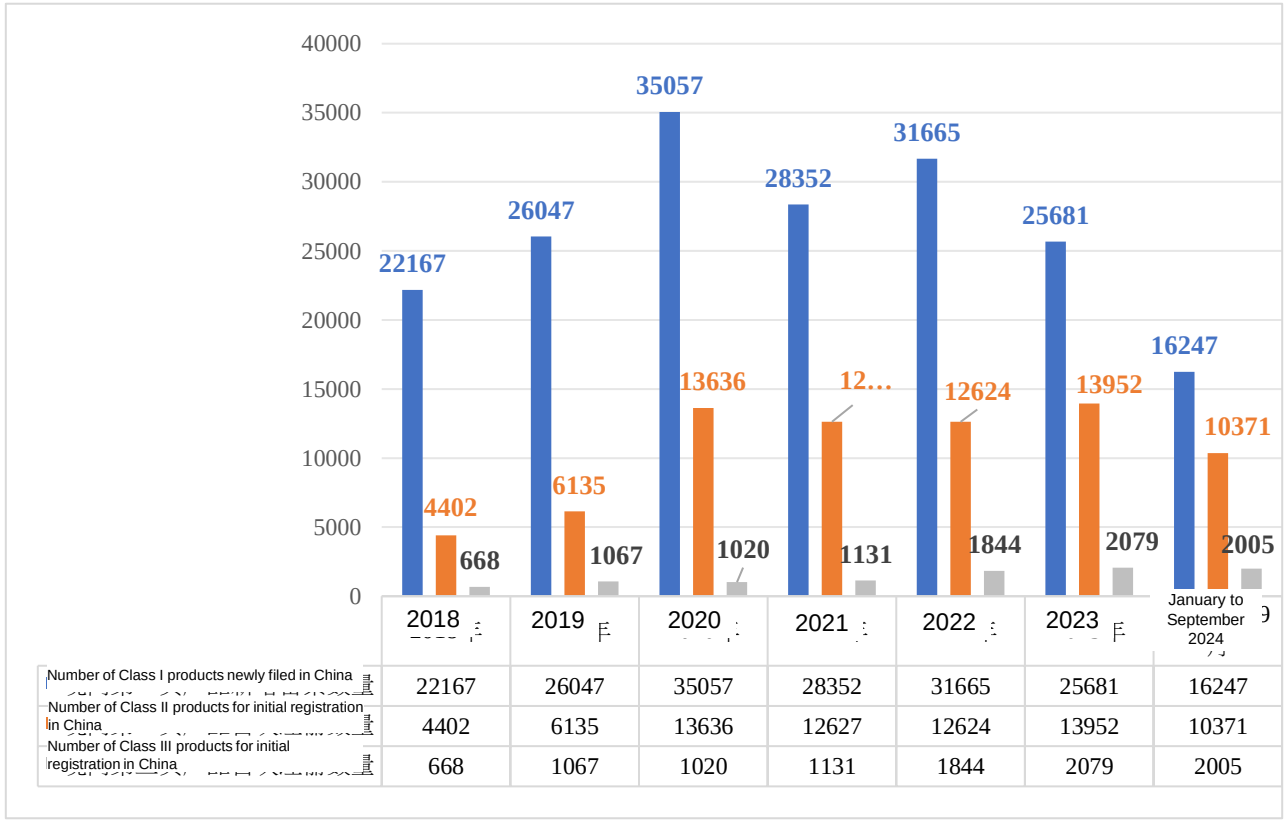
Steady expansion of the industry scale

1 The number of product registrations/filings has grown steadily

- From January to September 2024, a total of 12,944 various medical devices were approved for initial registration nationwide. Among them, 10371 domestic Class II medical devices and 2005 domestic Class III medical devices were approved for initial registration, respectively, and 568 imported medical devices (including Hong Kong, Macao, and Taiwan) were approved for initial registration.
- In the past five years, the registration/filing of medical devices in China has made great progress, especially the **annual compound growth rate of the number of Class II and III products for initial registration in China was 17.9% and 14.3%**, respectively, and mid-to-high-end products are increasingly favored by capital.

Number of Medical Device Products Newly Registered/Filed in China from January 2018 to September 2024 (Unit: piece)



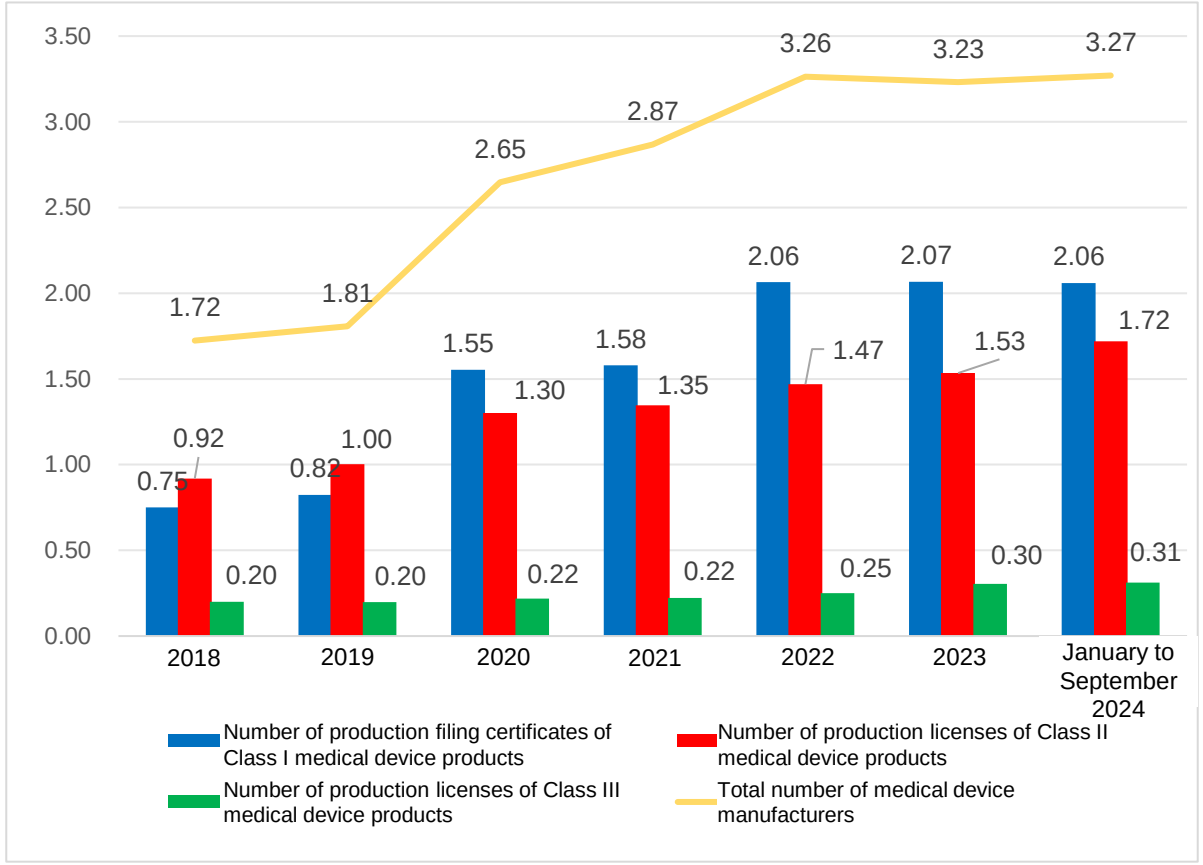
	2018	2019	2020	2021	2022	2023	January to September 2024
Number of Class I products newly filed in China	22167	26047	35057	28352	31665	25681	16247
Number of Class II products for initial registration in China	4402	6135	13636	12627	12624	13952	10371
Number of Class III products for initial registration in China	668	1067	1020	1131	1844	2079	2005

Data source: National Medical Products Administration

2 The number of manufacturers has grown steadily

- In 2023, there were 32,300 medical device manufacturers in China, of which there were 3049 Class III medical device manufacturers, with an **increase of 21.5% year-on-year**.
- As of the end of September 2024, there were **32,700** medical device manufacturers.

Trend of the total number of medical device manufacturers in China from January 2018 to September 2024 (Unit: 10,000 manufacturers)



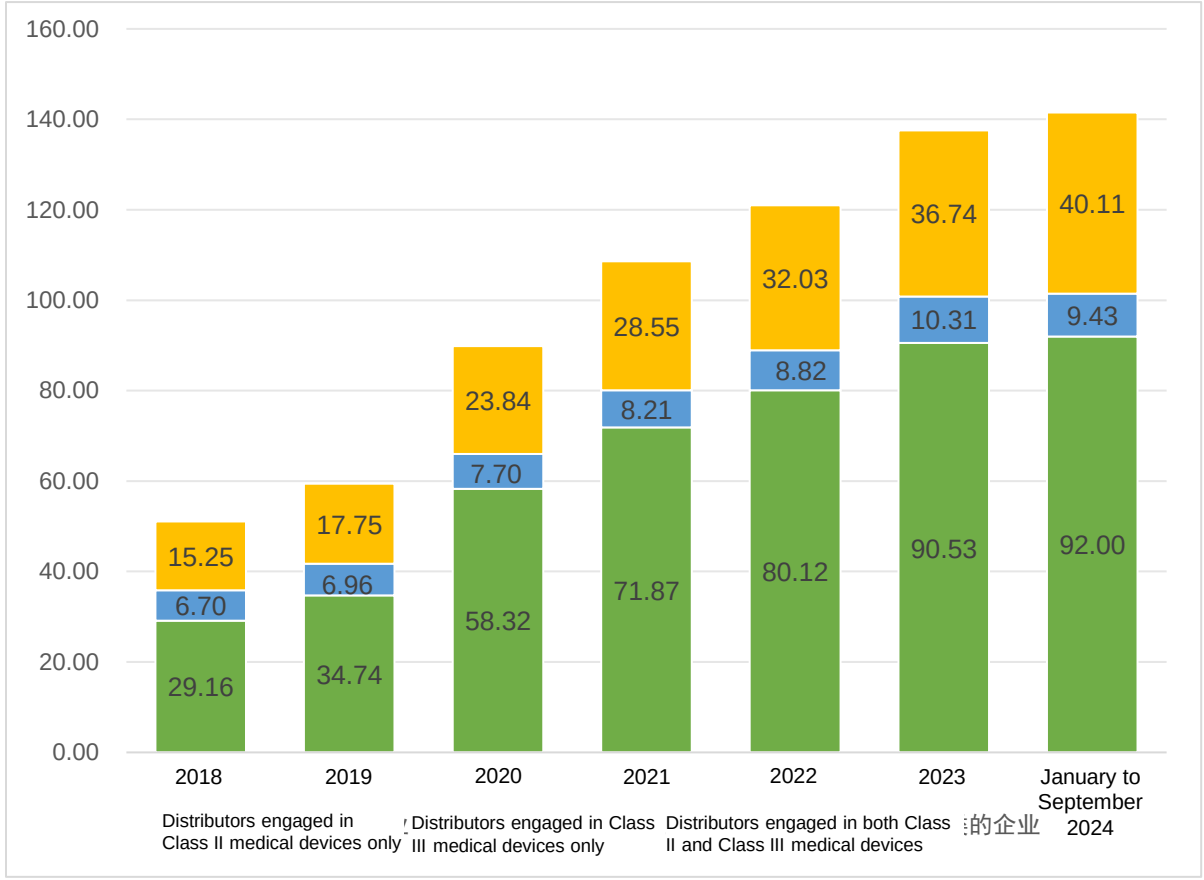
Note: An enterprises producing both Class I and Class III products is counted separately as manufacturer of Class I devices and Class III devices, and as one in the total number of enterprises.

Data source: National Medical Products Administration

3 The number of distributors has increased rapidly

- In 2023, there were 1.3757 million Class II and III medical device distributors in China, with an **annual compound growth rate of 24.62%** from 2014 to 2023. The **rapid expansion** of the medical device **market, the need for professional services in medical institutions,** and **the expansion of the retail market** are the main drivers for the growth of distributors.
- As of the end of September 2024, there were **1.4154 million** Class II and III medical device distributors in China, and it is expected to reach 1.47 million for the whole year. The continuous expansion of the scale of medical device distributors has also promoted the vigorous development of the whole industry.

Total number of medical device distributors in China from January 2018 to September 2024 (Unit: 10,000 distributors)

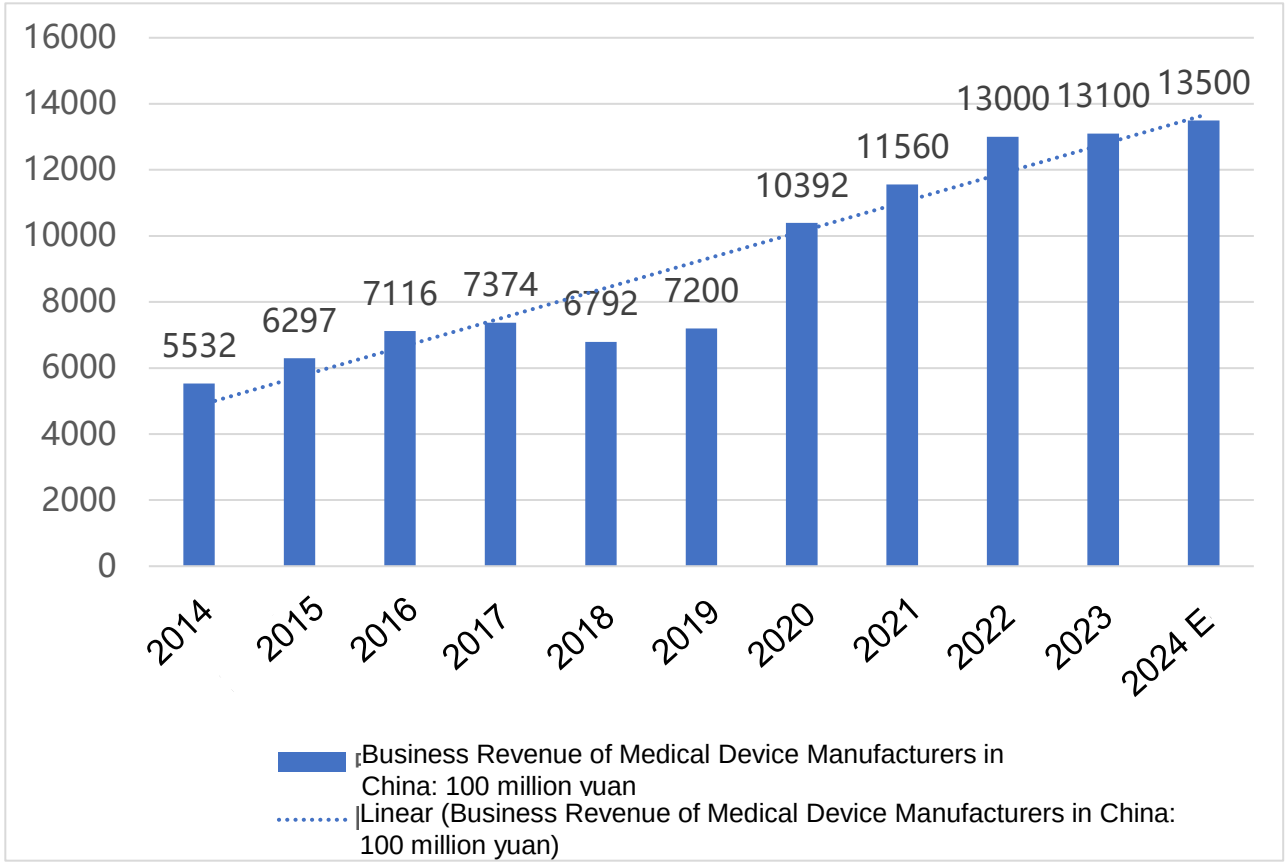


Data source: National Medical Products Administration

4 The scale of revenue has grown steadily

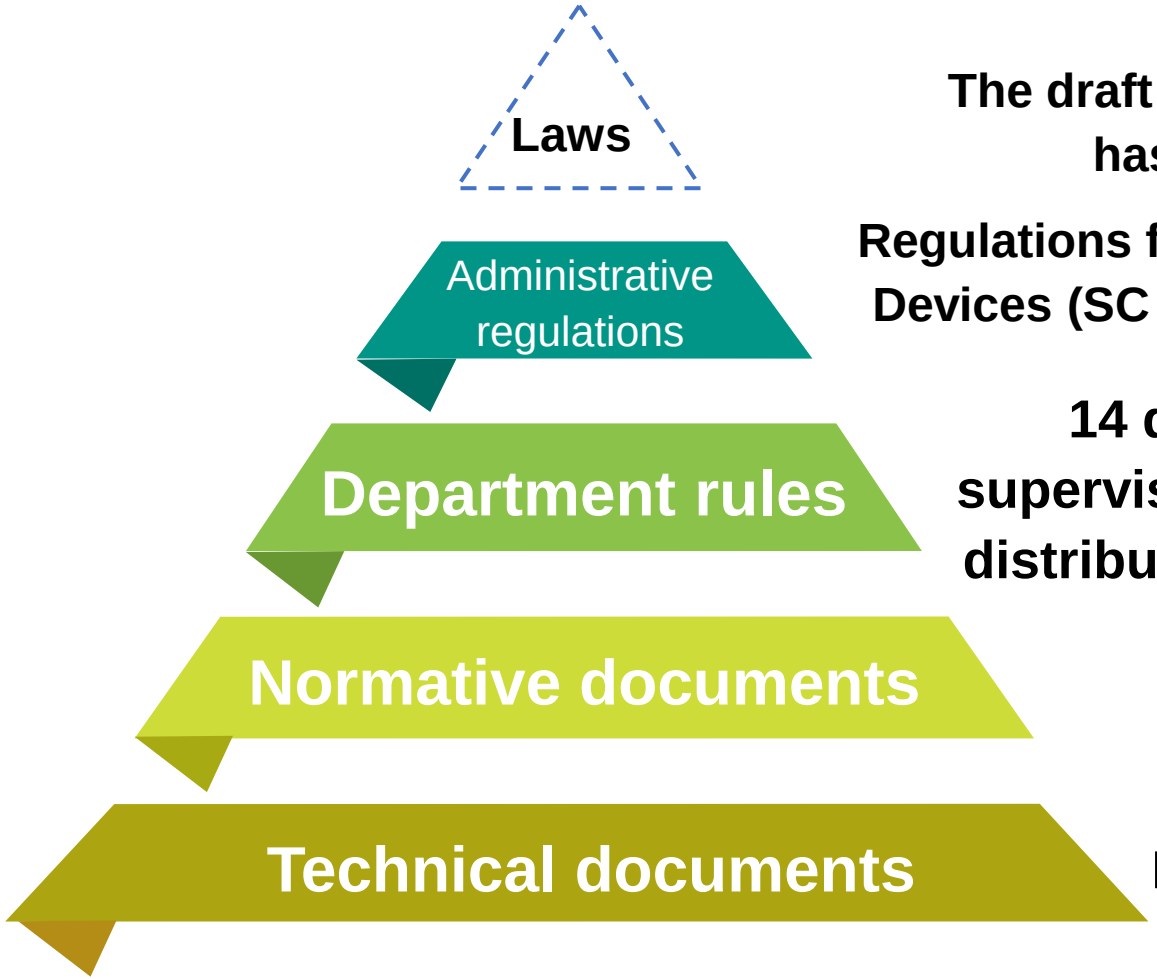
- According to the estimate by the NMPA Southern Medicine Economic Research Institute, the business revenue of the whole medical device industry in China in 2023 was **1.31 trillion yuan**, with an annual compound growth rate of **10%** from 2014 to 2023, and the business revenue of manufacturers in China in 2024 was 1.35 trillion yuan, showing a slight increase compared with the previous year.

Business revenue and forecast of medical device manufacturers in China from 2014 to 2024



Data source: NMPA Southern Medicine Economic Research Institute

Continuous improvement of the regulatory system



The draft of the Medical Device Administration Law has been released for public comment

Regulations for the Supervision and Administration of Medical Devices (SC Decree No. 739), which came into force on June 1, 2021

14 department rules covering the full life cycle supervision including product registration, production, distribution, use, adverse event monitoring, recall, etc.

More than 140 normative documents

2017 medical device standards
More than 600 technical guidelines related to registration, production and distribution

Continuous improvement of the regulatory system

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Adhering to open-door legislation


国家药品监督管理局
National Medical Products Administration

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索引号	FGWJ-2024-10001	主题分类	法规文件 / 征求意见
标题	国家药监局综合司公开征求《中华人民共和国医疗器械管理法（草案征求意见稿）》意见		
发布日期	2024-08-28		

国家药监局综合司公开征求《中华人民共和国医疗器械管理法（草案征求意见稿）》意见

The NMPA has drafted the Medical Device Administration Law of the People's Republic of China (Draft for Comment), which was released for public comment on August 28. During the solicitation of comments, the NMPA organized representatives of enterprises, industry associations, experts and scholars, and regulatory representatives to hold special meetings on registration, production, distribution, use, online trading, import and export and other fields to listen to the opinions of all sectors of society.

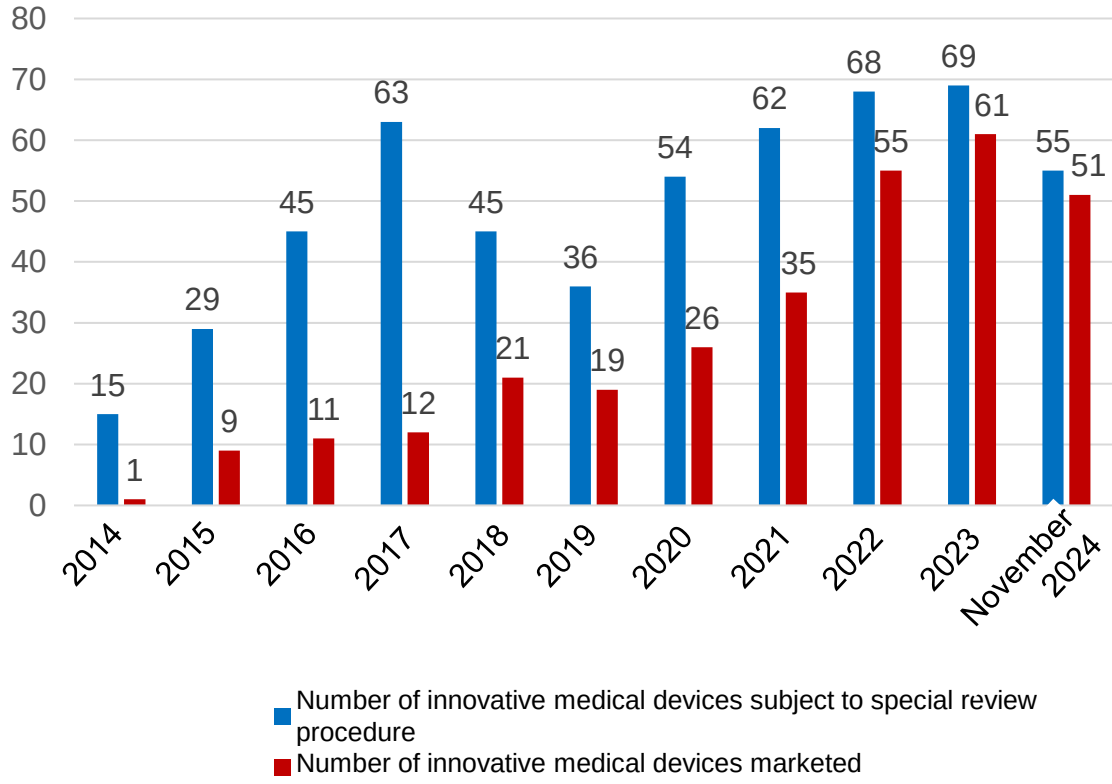
Continuous manifestation of regulatory effect

Encouraging and supporting the development of innovative medical devices

- Guided by clinical needs, we have established a robust special review procedure for innovative medical devices, a priority approval procedure for medical devices, an emergency approval procedure for medical devices, and a conditional approval system for medical devices to speed up the marketing of innovative medical devices and medical devices in urgent clinical need.

- As of November 10, 2024, the NMPA has **approved 51 innovative medical devices**, an increase of 8.5% over the same period last year. **A total of 301 innovative medical devices have been approved.**

Review and registration of innovative medical devices from 2014 to November 2024



Note: Data as of November 10, 2024
Data source: National Medical Products Administration,Center for Drug Evaluation

Continuously promoting the improvement of standards

A Coordinately promote the implementation of the new GB9706 series standards

B Revise the classification catalogue for in vitro diagnostic reagents

C Scientifically and dynamically adjust management categories

D Organize the implementation of the third batch of UDIs

Continuously strengthening the supervision of quality and safety throughout the life cycle

- Enhance the regulation of registrant entrusted production
- Strengthen routine regulation over key products
- Intensify unannounced inspection
- Continuously conduct overseas inspections

- Formulate sampling inspection plan as a whole
- Release the sampling inspection results in real time
- Timely handle the defective products

- Establish an information network monitoring platform
- Dynamic monitor the online trading market
- Clean up violation information in time
- Crack down on violations of laws

Continuous enforcement of regulatory inspection

Accurate and efficient regulatory sampling inspection

Effective online monitoring

Improvement of distributing specification

Steady improvement of monitoring and evaluation

Deepened risk consultation

- Publicizing and implementation of new Good Supply Practice
- Guide enterprises to conduct self-inspection and self-correction
- Rectify and regulate enterprises that violate regulations

- Explore the establishment of a vigilance system
- Carry out pilot vigilance
- Conduct special inspection for adverse events

- Quarterly risk consultation mechanism
- Risk negotiation mechanism for innovative product
- Risk list cancellation mechanism
- Closed-loop management for risk signals

Strengthening regulatory capacity building in an all-round way

- The construction of the review system has been comprehensively strengthened. As of the end of September 2024, there were 632 guidelines for the registration of medical devices in practice, and 1209 technical review points for medical devices formulated. The registration guidelines and technical review points have covered 96.1% of the Level 1 product categories in the Medical Device Classification Catalogue.
- The regulatory system and regulatory capacity continue to improve. There have been 265 national GCP inspectors and 546 national GMP inspectors. The inspector training and practical training have been well completed. A total of 8 medical device GMP inspector training sessions have been held in 2024, training a total of 9,317 national and provincial inspectors.

Adhering to social co-governance

Insist on the popularization of laws

Since 2020, the NMPA has continued to carry out publicity activities such as Medical Device Safety Promotion Week and National Drug Safety Promotion Week. By carrying out regulation publicity training, themed open day activities, discussions on supervision regulations, and publishing popular science works, we have comprehensively introduced medical device supervision regulation systems and common sense of safe use of devices to the society, enterprises and the public to ensure and promote public safety in the use of devices.

Adhering to social co-governance

Strengthen industry self-discipline

Issue the Provisions for Supervision and Administration of Enterprises Implementing Responsibility as Entity of Medical Device Quality and Safety

Give play to the role of relevant organizations such as the medical device industry associations

Establish safety risk co-governance alliance for online sales

Active engagement in international cooperation

Active engagement in international cooperation

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IMDRF International Medical Device Regulators Forum

Actively participating in GHWP, Xu Jinghe, Deputy Commissioner of China's NMPA, was elected as the new president.

4 IMDRF clinical evaluation guidelines have been issued under the leadership of China's NMPA.

Actively participate in ISO and IEC activities.

A total of 432 experts registering in international standards organizations have been dispatched to participate in the standard development and revision meetings of corresponding international organizations.


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Thank You