Regulatory Update from NMPA - China

Yuan Peng
Director, Medical Device Registration Department
NMPA
March 12, 2024

IMDRF International Medical Device Regulators Forum

Accelerate the launch of innovative medical device

In 2023, the NMPA approved 61 innovation medical devic, The number of approved innovative medical devices increase 6 compared to 2022. till now, we have approved 253 innovative medical device

For example:

In 2023, the NMPA approved

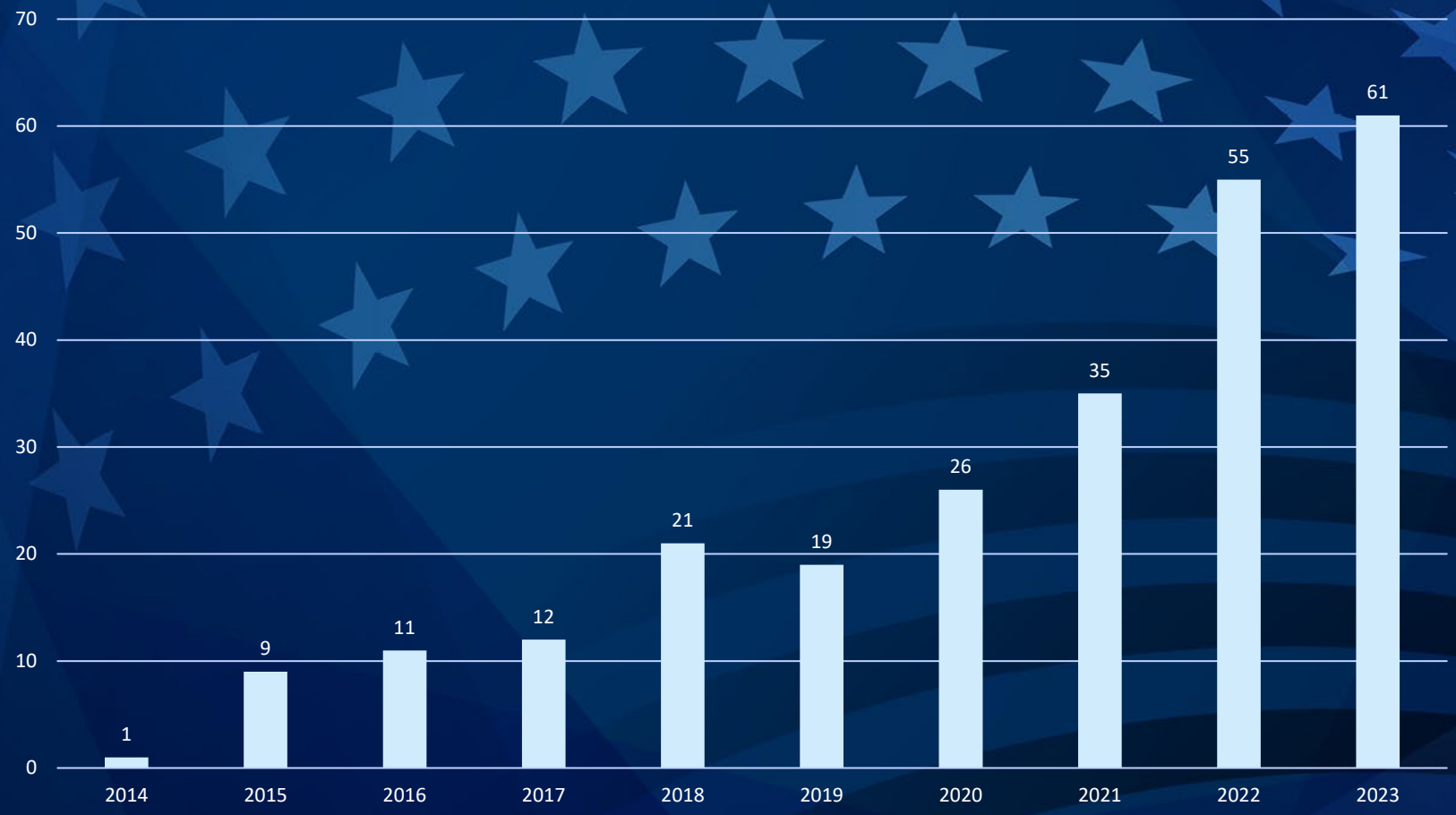
the use of disposable circular pulmonary artery radiofrequency ablation catheters for the treatment of pulmonary hypertension by disrupting the sympathetic nervous system at first in the world.

The SPECT,

The intraperitoneal endoscopic single hole surgical robot,

The intracranial thrombectomy stents

Better meet the needs of clinical diagnosis and treatment



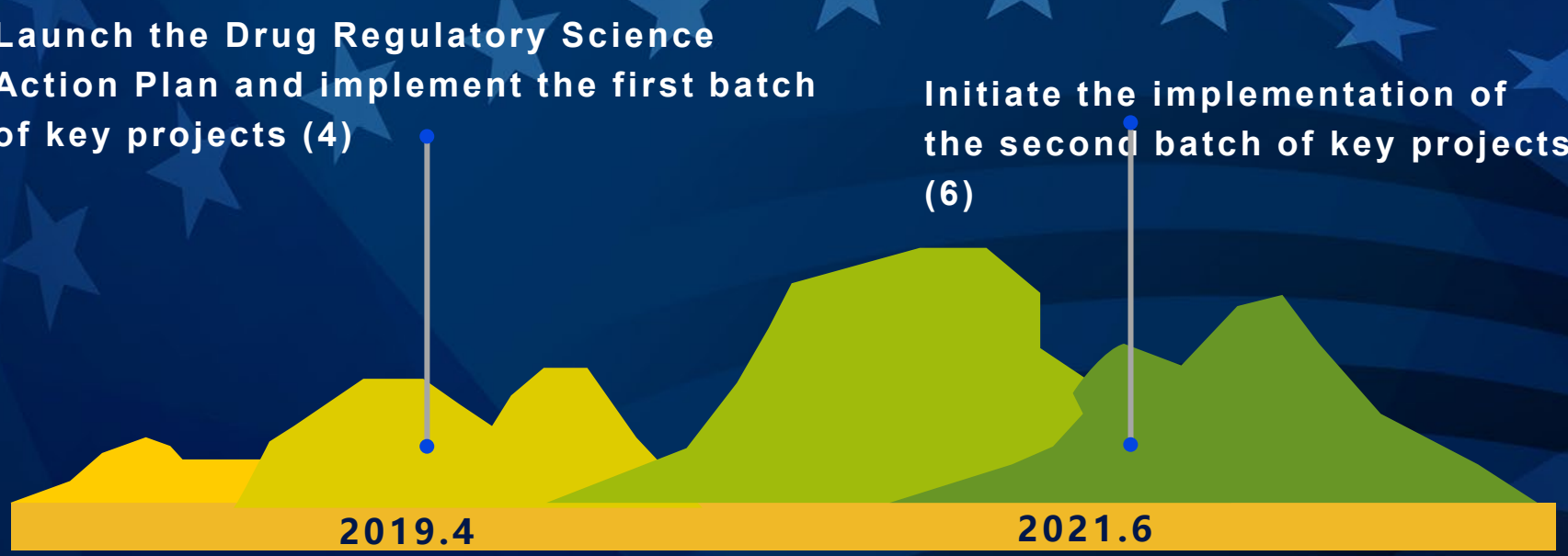
Number of approved innovative medical devices

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Promoting regulatory science research



Centered around the theme of "innovation, quality, efficiency, system, and capability",Promote innovation in regulatory concepts, mechanisms, and accelerate China's transition from a pharmaceutical big country to a pharmaceutical strong country

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

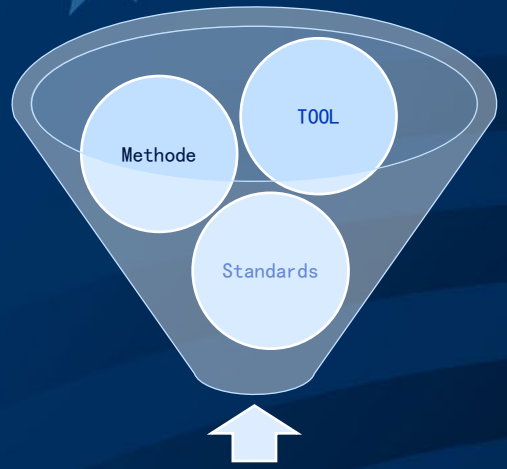
01 FOCUS

Based on the actual situation of drug supervision in China

Reform and innovation around evaluation and approval

Tracking the forefront of international regulatory development

02 INNOVATIVE



03 ACHIEVEMENTS

- policy
- guidance
- test and inspect technoloy
- techinical standard

Resolve prominent issues that affect and constrain innovation, quality, and efficiency, and accelerate the modernization of the drug governance system and governance capabilities.

Research Item:

- Research on Technical Evaluation of Pharmaceutical Device Combination Products
- Research on Safety and Effectiveness Evaluation of Artificial Intelligence Medical Devices
- Research on the supervision of new materials for medical devices
- Research on using real-world data for clinical evaluation of medical devices
- Research on evaluation methods for medical devices supported by real-world data for innovation and urgent clinical needs
- Research on the Evaluation of Diagnosis Products for Emerging Outbreak Infectious Diseases, etc

next step:

next-generation gene sequencing products

quality evaluation methods for digital therapy medical devices,etc

Improve the quality of medical device standards

- Revise and release the Work Rules for Approval and Release of Medical Device Standards, the Work Rules for Verification of Medical Device Standards, and develop the Work Rules for Implementation and Evaluation of Medical Device Standards, making the management of standard formulation and revision more refined.

- In 2023, Publish 28 national standards for medical devices, 131 industry standards, and 14 industry standard revision forms. As of the end of 2023, there are a total of 1974 medical device standards, including 271 national standards and 1703 industry standards. The consistency with international standards exceeds 90%.

- The international standard ISO 24072 "Test Method for Aerosol Bacterial Interception of Intake Devices for Infusion Devices" led by China has been officially released.

- Two Chinese experts have been elected as Vice Chairmen of the Technical Committee and Chairmen of the Sub Technical Committee of the International Electrotechnical Organization (IEC).

- The standard "Performance Test Method for Pulmonary Imaging Assisted Analysis Software of Artificial Intelligence Medical Devices" has been approved as an international standard project.

Continue to promote the formulation of the Medical Device Management Law

- On September 8th, the 14th Standing Committee of the National People's Congress iss ued a legislative plan, which included the Medical Device Management Law for the first time in the second level of "A draft law that needs to be urgently worked out and submi tted for review when conditions are mature" projects.

- Regulations on the Supervision and Administration of Medical Devices(state council de cree No.739), which is currently valid, was rivesed and issued in 2021, but as we know, t here are still some issues that need to be revised in the regulations, such as the manage ment of medical device standards.

- NMPA has established a working group to draft the text of the Device Management Law, and related work is currently underway.

Strengthen the full life cycle regulation.

- Focusing on certain products with high risks, NMPA carried out in-depth investigations and special programs to address potential risks.
- NMPA issued documents on tiered regulation of medical device, enhanced active surveillance on adverse events.
- NMPA also promotes the vigilance project, and conducts international exchanges of safety information within NCAR.

Carry out international cooperation in regulation

NMPA actively participated in IMDRF

issued related guidelines, and made timely application to China 's regulatory practice

most of the IMDRF guidelines had been implemented in China.

Conclusion

Accelerate the launch of innovative medical device

Promoting regulatory scientific research

Improve the quality of medical device standards

Continue to promote the formulation of the Medical Device Management Law

Strengthen the full life cycle regulation

Carry out international cooperation in regulation


IMDRF
International Medical Device
Regulators Forum
United States
of America
2024