IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory Update for China

Wen Gao

Consultant, Medical Device Registration Department

NMPA

Overview

- Revision: Classification Catalogue of IVD
- Supervision: Domestic medical Device Clinical Trial Institutions
- Guidance: Inspection of Medical Device distribution
- Innovative medical devices
- Preparation and Formulation: Medical Device Management Law

Revision of the Classification Catalogue of IVD

- The Classification Catalogue is based on the IVD Classification Rules.
- The structure of the Classification Catalogue consists of six parts: "primary serial number, primary product category, secondary serial number, secondary product category, expected use, and management category". Among them, the "primary product category" is mainly established according to the Classification Rules, with a total of 25 parts; The 'second level product category' is a further refinement under the first level product category, mainly based on the detection target setting, and generally does not include methods or principles, with a total of 1852 categories

NOTE: The Classification Catalogue excluding IVD legally used for blood source screening and those labeled with radioactive isotopes.

Revision of the Classification Catalogue of IVD

- For IVD certificates approved and effective before January 1, 2025, they shall remain valid during the approved validity period.
- Starting from January 1, 2025, for IVD that have applied for registration for the first time, product registration applications shall be accepted in accordance with the Classification Catalogue.
- For extension registration applications that have been accepted before January 1, 2025, but have not yet been approved, continue to review and approve them in accordance with the original "Classification Catalogue"

Revision of the Classification Catalogue of IVD (catalogue sample)

- Classification Catalogue of IVD

First level serial number	first level product category	second level serial number	second level product category	expected use	class level
01	Reagents related to the detection of pathogenic pathogen antigens, antibodies, and nucleic acids	01001	Group A, B, and C meningococcal polysaccharide IgG antibody detection reagents	used to detect Group A, B, and C meningococcal polysaccharide IgG antibodies in human samples. Used clinically as an auxiliary diagnosis for meningococcal infection.	Ⅲ
01	Reagents related to the detection of pathogenic pathogen antigens, antibodies, and nucleic acids	01002	Group A Streptococcus antigen/nucleic acid detection reagents	used to detect Group A Streptococcus antigen/nucleic acid in human samples. Used clinically as an auxiliary diagnosis for streptococcal infections.	Ⅲ
01	Reagents related to the detection of pathogenic pathogen antigens, antibodies, and nucleic acids	01003	Group B Streptococcus antigen/nucleic acid detection reagents	used to detect Group B Streptococcus antigen/nucleic acid in human samples. Used clinically as an auxiliary diagnosis for streptococcal infections.	Ⅲ
	.....				

Strengthen the supervision of domestic medical device clinical trial institutions

- In order to further strengthen the management of medical device clinical trial institutions and standardize the supervision and inspection of medical device clinical trial institutions, the NMPA has organized the formulation of the "Supervision and Inspection Measures for Medical Device Clinical Trial Institutions".
- The document specifies requirements for inspection agencies, personnel, procedures, and result determination

NOTE: Will be implemented from October 1, 2024.

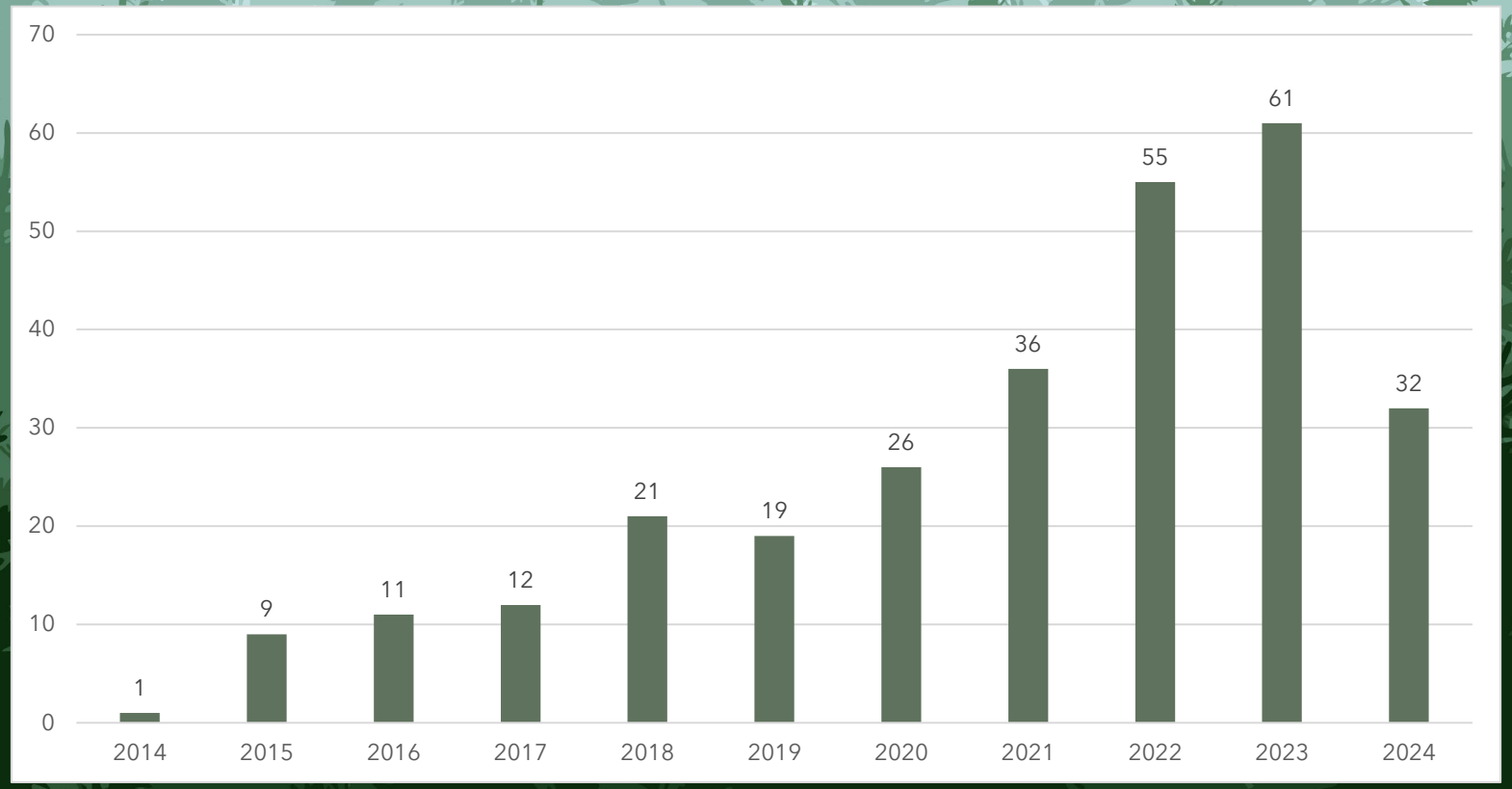
Guidance for On site Inspection of Quality Management Standards for Medical Device distribution

This Guidance apply to the on-site verification of business licenses (including changes and extensions) of medical device distribution enterprises by drug regulatory authorities in accordance with the Standards, or on-site inspections after business registration, as well as other types of supervisory inspections. During the inspection process, medical device operating enterprises can determine reasonable missing items based on their business model, scope, and variety, and provide written reasons for confirmation by the inspection team of the drug supervision and management department.

SEATTLE WASHINGTON
U.S. FOOD & DRUG ADMINISTRATION
IMDRF 2024 Chair
IMDRF
International Medical Device Regulators Forum

Accelerate the launch of innovative medical device

- In 2024,till now the NMPA approved 32 innovation medical devic, we have approved 287 innovative medical device
- NMPA will focus on medical imaging equipment, new biomaterials, artificial intelligence medical devices, and medical robot products to support the development of these industries
- Better meet the needs of clinical diagnosis and treatment



Number of approved innovative medical devices

SEATTLE WASHINGTON

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF

International Medical Device Regulators Forum

Continue to promote the formulation of the Medical Device Management Law

- On 2023, September 8th, the 14th Standing Committee of the National People's Congr ess issued a legislative plan, which included the Medical Device Management Law for t he first time in the second level of "A draft law that needs to be urgently worked out an d submitted 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 revised 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 Medical Device Manage ment Law, and related work is currently underway.
- The relevant work is currently in progress.

Conclusion

- Revision of the Classification Catalogue of IVD
- Strengthen the supervision of domestic medical device clinical trial institutions
- Guidance for On site Inspection of Quality Management Standards for Medical Device distribution
- Accelerate the launch of innovative medical device
- Continue to promote the formulation of the Medical Device Management Law

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

THANK YOU