国家食品药品监督管理总局 CFDA
China Food and Drug Administration

Overview of China Medical Device Supervision & Administration

China Food and Drug Administration

&

AHWP China Country Representative

Guobiao GAO

November 25, 2016 Cebu, Philippines

Agenda

- Overview of China Medical Device Industry Development
- Overview of Medical Device Supervision & Administration
  - Medical Device Registration Supervision
- Enhance International Communication and Collaboration

Overview of China Medical Device Industry Development

MARKET SIZE & GROWTH RATE

- From 2011 to 2015, the China Medical Device CAGR is over 20%
- In 2015, China Medical Device market size reached RMB 450 billion (approx. 65.7billion USD)

LICENSE NUMBER

- 99,000 Valid Medical Device Registration Licenses

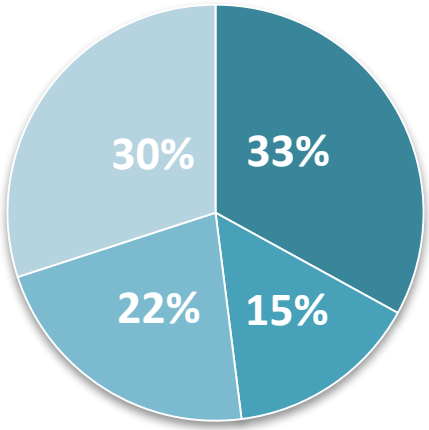
INDUSTRY PLAYERS

- MD Manufacturers: 15,000+
- MD Distributors: 260,000+

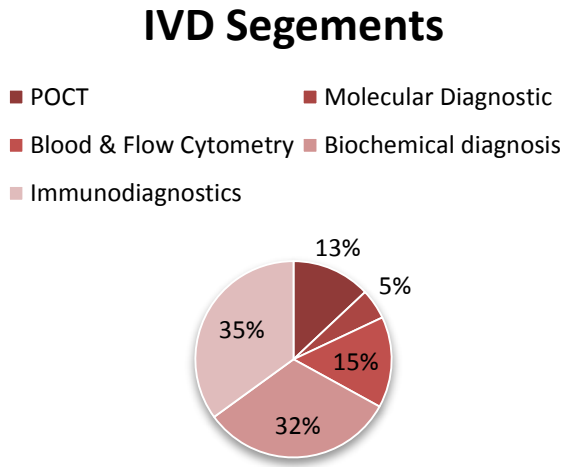
Medical Device Industry Segments

China Medical Device Market Segments

- Medicl Imagine Product
- IVD
- Low Value Consumables + ICU Opertion Room Devices
- Others



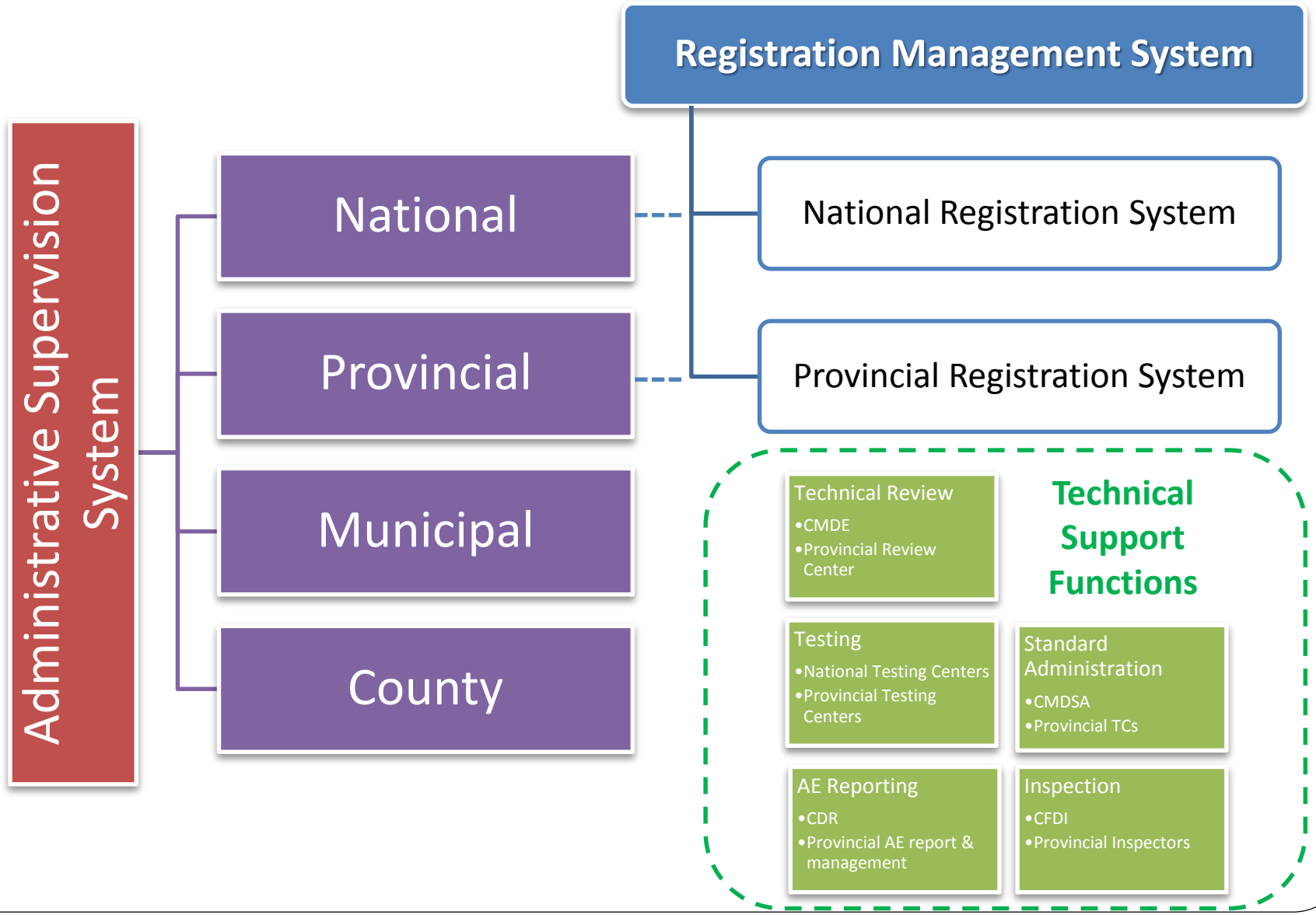
*As of 2015



*IVD industry has the highest growth rate in the medical device industry

Overview of Medical Device Supervision & Administration

Supervision & Administration System Design



CFDA's Technical Support Functions

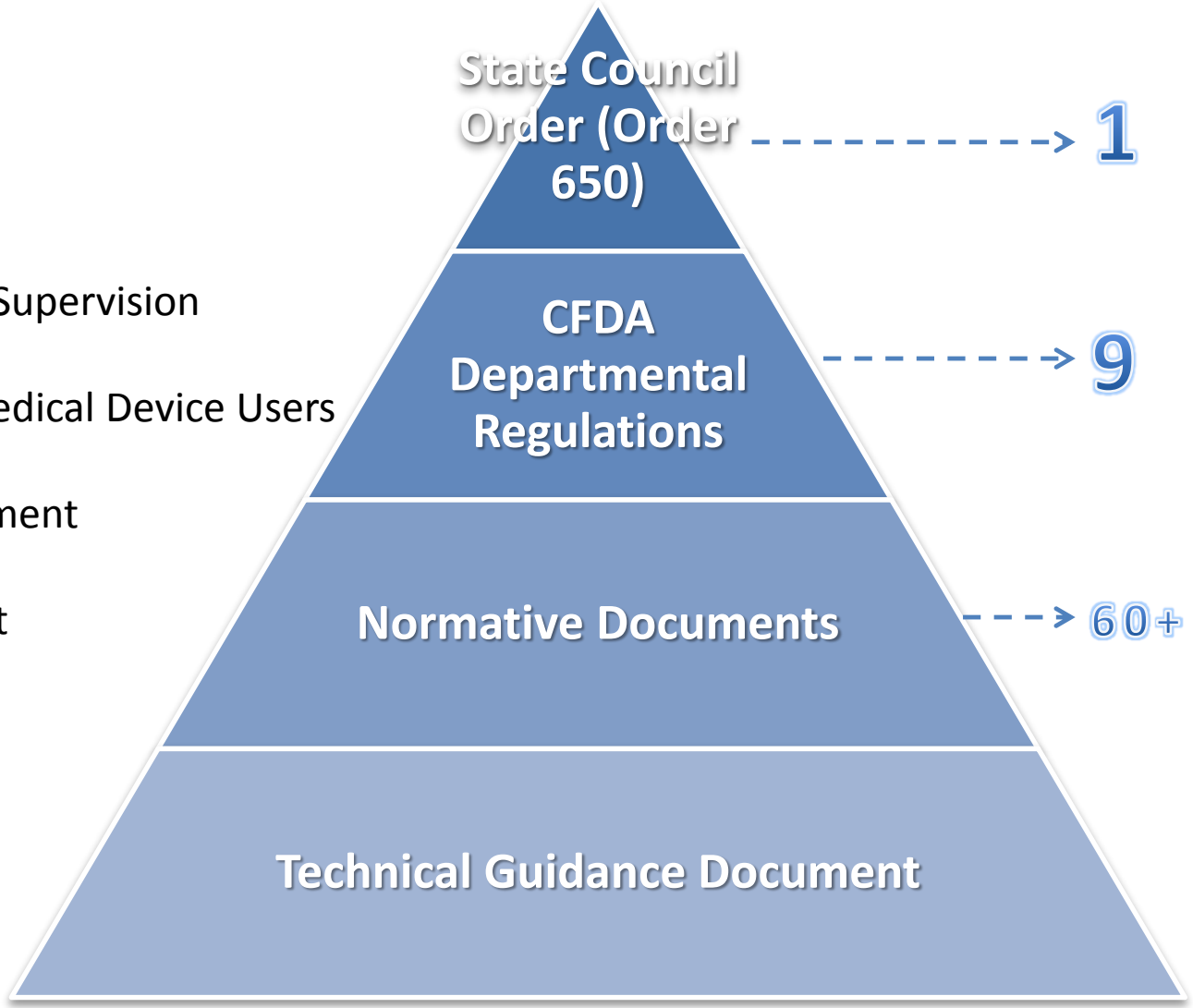
24 Medical Device Standard Technical Committees

53 Accredited Testing Institute

- 100% AE Reporting Institute coverage at Provincial level

China's Regulatory System Setting

- ✓ Complete MD Lifecycle Supervision
- ✓ Provide Safeguard to Medical Device Users
- ✓ Enhanced Risk Management
- ✓ No Group Adverse Event



CFDA Regulation On The Management Of Medical Device Registration Issued

1. Measures for the Administration of Medical Device Registration (Decree of CFDA No. 4), July 30, 2014

2. Measures for the Administration of In-vitro Diagnosis Reagents (Decree of CFDA No. 5), July 30, 2014

3. Provisions on the Management of Instructions and Labels of Medical Devices (Decree of CFDA No. 6), July 30, 2014

4. Rules for Medical Device Classification (Decree of CFDA No. 15), July 14, 2015

5. Naming Rules for the Generic Name of Medical Devices (Decree of CFDA No. 19), December 21, 2015

6. Good clinical Practice for Medical Devices (Decree of China Food and Drug Administration and National Health and Family Planning Commission of the People's Republic of China No. 25), March 1, 2016

Normative Document & Guidance On The Management Of Medical Device Registration Issued

Key Normative Document

- Requirements for Format of Registration and Application Documents and Approval Documents of Medical Devices
- Catalogue of Class II Medical Devices Exempted from Clinical Trials
- Catalogue of Class III Medical Devices Exempted from Clinical Trials
- Operation Specifications for Registration and Approval of Domestic Class III and Imported Medical Devices
- … …

Key Guidance Document

- Technical Guidelines for Clinical Evaluation of Medical Devices
- Registration and Review Guidance for Medical Software
- … …

✓ **Foundation Of Uniformed Registration Review Requirement And Scale At Both National & Provincial Level**

Standard Management for Medical Devices

Number Of MD Standard:

- Mandatory Standard: 483
- Recommended Standard: 1,032

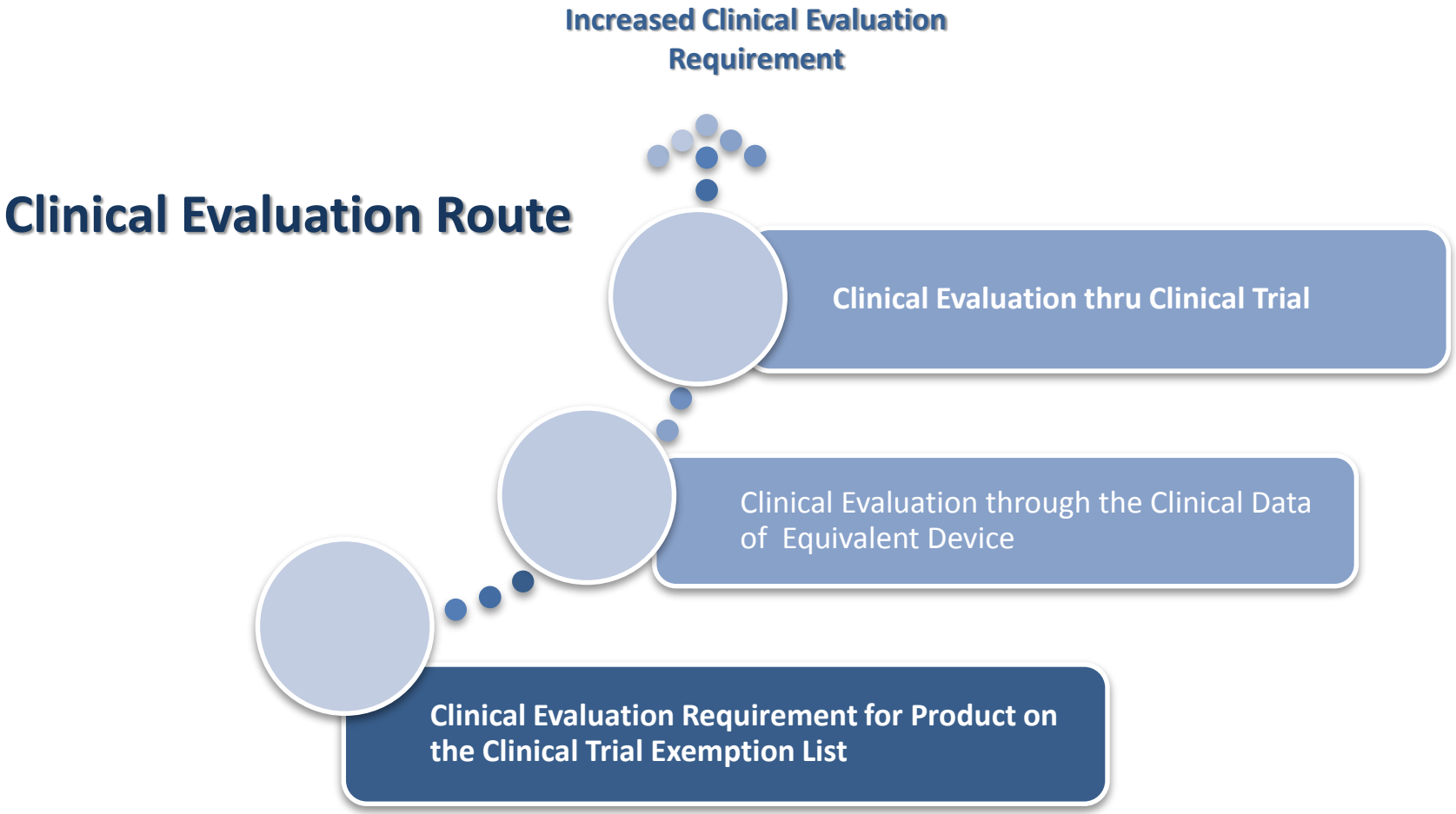
International Standard Conversion Rate

- Similar as USA

STRICT PRE-MARKET REQUIREMENT FOR MD PRODUCT IN CHINA

- Medical Device need to compliance with Mandatory Standard
- Product specification and registration testing report need to be submitted as part of the Class II and Class III Medical Device registration Dossier
- Biocompatibility Evaluation Material are needed for certain kind of device

Clinical Evaluation Requirement for Medical Device Pre-Market Application



Clinical Trial Requirement for Medical Device Pre-Market Application Issued in 2014-2016

❑ CLASS II, CLASS III MEDICAL DEVICE CLINICAL TRIAL EXEMPTION LIST (2 batches)

- Class II Medical Device Exemption List covers 755 kinds of medical devices;
- Class III Medical Device Exemption List covers 171 kinds of medical devices;

Clinical Trial Exemption List to be issued, adjust and published by CFDA

❑ CLASS III MEDICAL DEVICE PRE-APPROVAL LIST

- High risk
- In-country clinical Trial is mandatory
- Clinical Trial Protocol to be approved by CFDA before conducting the in-country trial

❑ China Medical Device GCP

- Standardized in-country Clinical trial procedure
- Focus on risk management during the clinical trial
- New clinical trial filing requirement with provincial FDA (where the sponsor is registered)

Main Work items for 2016 – Regulation & Policy Development

KEY ISSUED REGULATION - <Medical Device Prioritize Review Procedure>

Prioritized MD Criteria

- 1. The medical devices meeting one of following situations:
  - For diagnosis or treatment of rare diseases and with significant clinical advantages;
  - For diagnosis or treatment of malignant tumors and with significant clinical advantages;
  - For diagnosis or treatment of special and frequently-occurring diseases in the elderly, and there is no effective diagnostic or therapeutic means available currently;
  - For diagnosis or treatment of special and frequently-occurring diseases in children, and there is therapeutic means available currently;
  - The medical devices in urgent clinical need, but there are no similar products approved and marketed in China.
- 2. The medical devices listed in National Science and Technology Major Project or National Key Research and Development Plan.
- 3. Other medical devices that shall be reviewed and approved with priority.

KEY REGULATION UNDER DRAFTING & REVISION

- <Provision on Medical Device Standard Supervision & Administration>
- <Medical Device Classification Catalog>

Main Work items for 2016 – Review & Approval Reform

Draft And Implement Grp In Accordance With Global Best Practices	Cultivate A Professional Technical Review Team	Establish Technical Review Re-evaluation Expert Committee
Enhance Technical Standard Drafting For Medical Device Product Review	Increase And Standardize Technical Review Process And Key Review Points	Decrease The Discretionary Power Of The Reviewers.

Enhance International Collaboration

Multilateral Collaboration

- IMDRF
- AHWP

Bilateral Cooperation

- China - US: JCCT
- China – EU
- China - Japan

Summary

- ✓ **STRICT Supervision & Administration** of medical device in China
- ✓ **ENSURE PRODUCT QUALITY AND RELIABILITY** Fast Medical Device Industry Growth Rate
- ✓ **INCREASED MEDICAL DEVICE EXPORT** To Serve the Other Market
- ✓ **CONTINUOUS COMMUNICATION & COLLABORATION** With AHWP Member Economies
- ✓ **BETTER SERVE THE PATIENT** and Contribute To The Health Of The Human Being

Thank You !