

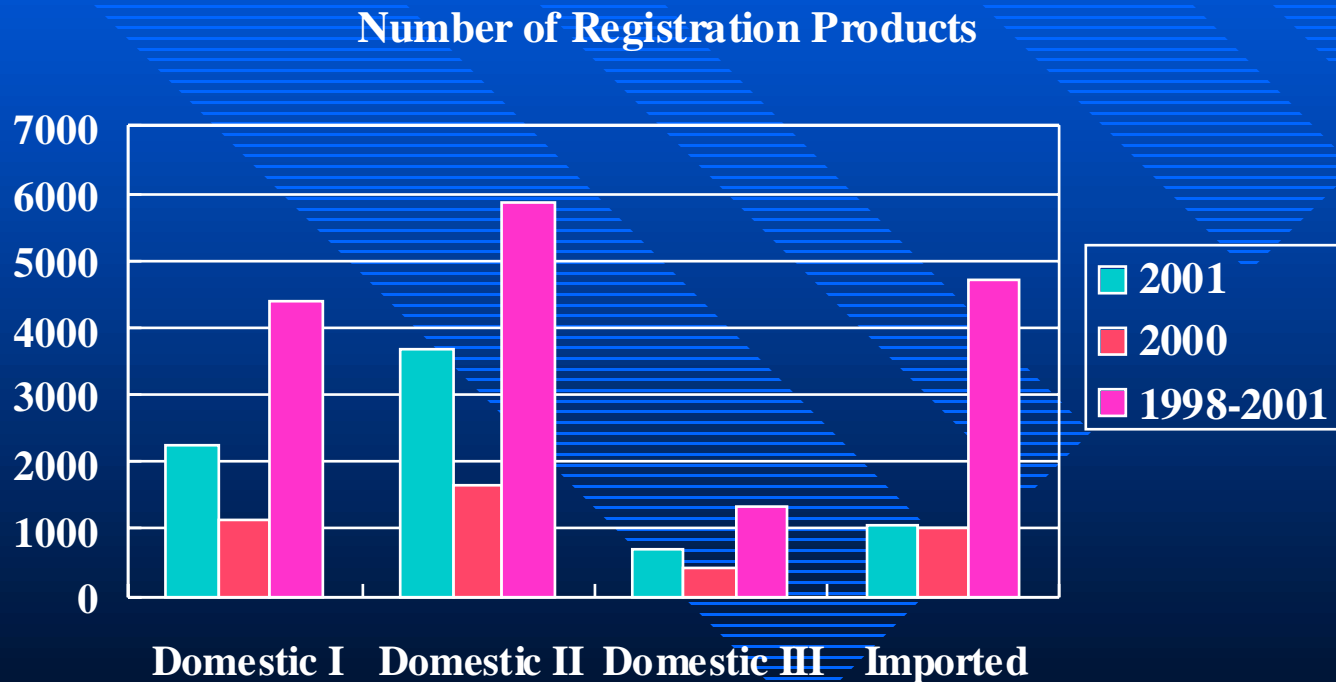
# **Introduction to Regulations for Medical Device in P.R. China**

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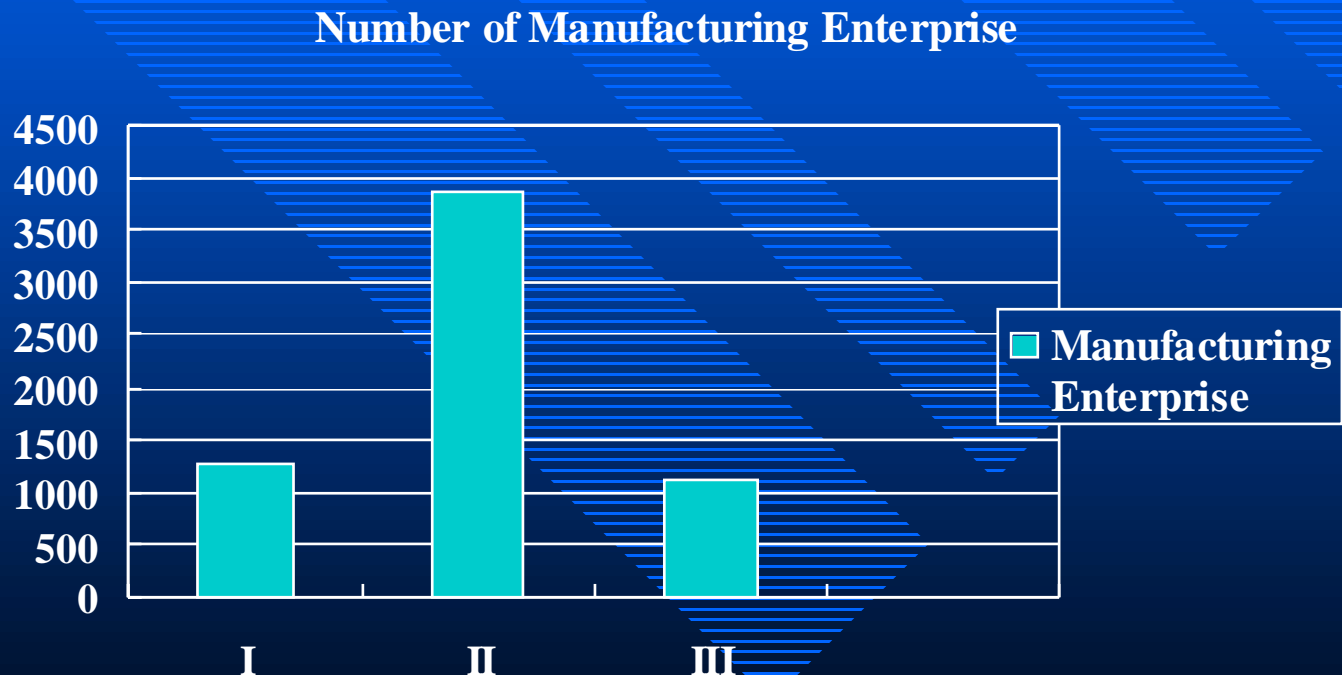
# Supervision & Administration on Medical Device in China

- Registration on class I class II class III medical device



# Supervision & Administration on Medical Device in China

## ■ Distribution of Manufacturing Enterprise License



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## ■ Distribution of Manufacturing Enterprise License

From June 20<sup>th</sup> 2001 to present, about 141 Manufacturing Enterprise Licenses were distributed to single use sterilized medical device manufacturing enterprise

# Supervision & Administration on Medical Device in China

- Training of Medical Device Monitors
  - Staff members from national medical device regulatory authorities are trained on ISO9000:2000.
  - Staff members from provincial medical device regulatory authorities are trained on biological evaluation standard.

# Supervision & Administration on Medical Device in China

- Training of Medical Device Monitors
  - Medical device monitors are trained on the implementation of manufacturing detailed rules for single use sterilized medical device enterprise
  - Staff members from overseas enterprise and their agency in China are trained on the requirements for registration application
  - The training on America medical device regulations was held in September 2001 in China.

# New Provisions on Medical Devices

- Provision on Registration and Inspection of Imported Medical Device
- Provision on Implementation on Inspection of Quality System of the Overseas Medical Device Manufacturing Enterprises .
- Provision on Single Use Medical Device
- Provision on Medical Device Instruction or Use
- Provision on Medical Device Product Specification Standardization

# Provision on Registration and Inspection of Imported Medical Devices

## ■ *Types of Inspection*

- Domestic inspection
- The approval of the overseas inspection reports
- Overseas inspection

# Provision on Registration and Inspection of Imported Medical Devices

- *Inspection principles* (to be continued...)
  - Ensure the safety and effectiveness of the approved products available on the market
  - Simplify the examination and approval procedures
  - The inspections of the imported products are exclusive and verifiable, the main objective of the inspection is to evaluate whether the product can meet the technical requirements that they have promised.

# Provision on Registration and Inspection of Imported Medical Devices

## ■ *Inspection principles*

- Safety and major performance of the products are required items of inspection
- Any destructive testing which belongs to the mandatory safety index must be performed

# Provision on Registration and Inspection of Imported Medical Devices

- *Conclusions: This Provision can*
  - Strictly assure the safety and effectiveness of the product
  - Reduce the inspecting cost,
  - Shorten the inspecting duration,
  - Lighten the burden of the applicants.

# Provision on Implementation on the Inspection of Quality System of the Overseas Medical Device Manufacturing Enterprises

- *The overseas medical device manufacturing enterprise to be inspected :*
  - Class III implantable medical devices manufacturing enterprises .
  - Other class III medical devices enterprises having more customer complaints on its post market products
  - If it is the first time for the manufacturer and its products to enter into Chinese market , we should inspect its quality system

# Provision on Implementation on the Inspection of Quality System of the Overseas Medical Device Manufacturing Enterprises

- *Requirements for the inspectors:*
  - The audit team should be comprised of 2-3 staff.
  - The inspectors should perform the necessary audit procedures strictly and answer for the audit results
  - The inspectors should be disinterested and self-discipline
  - The inspectors should safeguard the benefit of the auditee, observe all the diplomatic disciplines and perform their inspection work strictly

# Issues on Clinical Trial For Medical Device Registration

## ■ *General:*

- Any imported product available in China market must be accompanied by the clear clinical trial results to ensure its safety and effectiveness when used on the patients or users .
- It dose not mean that any clinical testing should be performed on any overseas product

# Provision on Clinical Trial For Medical Device Registration

## ■ *General:*

- These are the following situations about the clinical trial
  - ✓ Clinical trial need not be performed on Class I medical devices
  - ✓ Clinical trial should be performed on part of Class II medical devices
  - ✓ Clinical trial must be performed on Class III medical devices

# Provision on Clinical Trial For Medical Device Registration

- *The clinical trial report regulations on implantable medical device of Class*
  - If it is the first time for the manufacturer and its products to enter into Chinese market .....
  - If the enterprise already has products in the Chinese market .....
  - If the enterprise already has products in the Chinese market, the applied product and the already registered product are of the same product type but not of the same models. ....

# Standards for Product Registration

- Lawful effect of standards for product registration is equivalent with that of national mandatory standard or departmental standards
- Standards for product registration are legal basis of products traceability once adverse incident occurs on market
- Standards for product registration should be numbered and recorded in relevant registration institution

# Market Supervision on Single Use Medical Device in China

Existing problems:

- Counterfeit and poor product quality for medical devices in market

# Market Supervision on Single Use Medical Device in China

- *Accomplishment:*
  - Closed down more than twenty illegal manufacturing enterprises
  - Arrested more than 20-30 people who make and sell the counterfeit products
  - Sales volume of some companies increased sharply
  - Have investigated OK Lens Company illegal managed using foreign company name

# Conclusion Comments

- We will continue to adopt the international medical device regulation harmonized by GHTF
- GHTF conference held every year is an informative and productive event for all participants
- It help to maintain the international market order for medical device

Thank You