CFDA Medical Device
Pre and Post Market Overview

Grace Fu Palma
CEO
China Med Device, LLC
Ph: 978-390-4453 (US)
Ph: 18201749732 (China)
Email: gpalma@chinameddevice.com
Wechat: gracefumed
Agenda

• China Geopolitical Structure & Importance
• CFDA Major Changes
• CFDA Premarket Approval Overview
• CFDA Post Market
  – High Level Comparison
  – Onsite Inspection
  – Reality
• www.CFDAhotline.com
China Med Device LLC
Accelerator of U.S. medtech companies commercialization to China

• Regulatory Services
  – CFDA Strategy & Registration
  – CFDA Clinical Evaluation Report and Clinical Study
  – QMS training and consulting

• Business Services
  – Distribution Qualification and Management
  – Marketing Development in Partnership and Strategic Funding
CENTRALIZED HISTORY
Centralized Political-Geographic Structure

- >2,000 years centralized government history
- 5 Times the U.S. population with same geo size

- **Province**
  - 23 province
  - 11 other regions

- **City/County**
  - 250 major cities > 1M people

- **Town/Village**
  - In thousands
  - East coast affluent

Made in China ➔ R&D in China ➔ Innovate in China
Population Needs
Higher Quality & Affordable Care

- 260 million people with serious diseases
- >80 million handicapped people
- >200 million people are >60 years old
- 20 million births per year expected in the next few years
- 600 million in prime earning age
Top 100 Hospital Daily Outpatients Visits

<table>
<thead>
<tr>
<th>排名</th>
<th>医院名称</th>
<th>门诊量</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>中国医学科学院北京协和医院</td>
<td>12000</td>
</tr>
<tr>
<td>2</td>
<td>中山大学附属医院</td>
<td>11507</td>
</tr>
<tr>
<td>3</td>
<td>广东省人民医院</td>
<td>11260</td>
</tr>
<tr>
<td>4</td>
<td>中国人民解放军总医院(301医院)</td>
<td>11000</td>
</tr>
<tr>
<td>5</td>
<td>四川大学华西医院</td>
<td>10712</td>
</tr>
<tr>
<td>6</td>
<td>郑州大学第一附属医院</td>
<td>9863</td>
</tr>
<tr>
<td>7</td>
<td>华中科技大学同济医学院附属医院</td>
<td>9616</td>
</tr>
<tr>
<td>8</td>
<td>北京大学第三医院</td>
<td>9589</td>
</tr>
<tr>
<td>9</td>
<td>复旦大学医学院附属华山医院</td>
<td>8922</td>
</tr>
<tr>
<td>10</td>
<td>四川省人民医院</td>
<td>8900</td>
</tr>
</tbody>
</table>

12,000 to 4,000
CFDA MAJOR CHANGES
China Legal and Regulatory Structure

Laws by State Council

Regulations by CFDA

- Constitution
- Act
- Administration Law
- Bureau-level Regulations
- Documentation associated with Regulations

Regulations for the Supervision and Administration of Medical Devices (State Council Decree No. 650)
TOP 10 Country with Imported Medical Device Registration Certificates

USA about 37% > Germany + Japan.

TOP 10 countries = 90%

TOP 3: EU, USA, East Asia.
CFDA Medical Device Major Regulation Reform

• 2014-2016: years of CFDA medical device regulation reform
  – Medical device supervision and administration regulation
  – Medical device registration and administration regulation
  – IVD registration and administration regulation
  – Medical device manufacturing supervision and administration regulation

• ............

150 CFDA new documents relating to medical devices.
18 CFDA new documents relating to QMS ....
More to Continue.....
CFDA Major Regulation Changes

Provisions on Medical Device Registration
- New version effective since 2014.10.1
- Old version effective since 2004.8.9

Provisions on Instructions for Use and Labels of Medical Devices
- New version effective since 2014.10.1
- Old version effective since 2004.7.8

Regulations on the Supervision and Administration of Medical Device Manufacturing
- New version effective since 2014.10.1
- Old version effective since 2004.7.20

Regulations on the Supervision and Administration of Medical Device
- New version effective since 2014.10.1
- Old version effective since 2000.4.1

Provisions on Registration of IVD Reagents
- Effective since 2014.10.1
- Old version effective since 2007.4.19

Provisions on the Supervision and Administration of Medical Device Distributing
- New version effective since 2014.10.1
- Old version effective since 2000.4.10

Provisions on Medical Device Classification
- New version effective since 2016.1.1
- Old version effective since 2000.4.10
Major Regulation Changes

Medical Device GMP
New version effective since 2015.10.1
Old version effective since 2009.12.16

Medical Device GCP
New version effective since 2016.6.1
Old version effective since 2004.4.1
CFDA Updates and Approvals 2016

- **CFDA New Released Documents:**
  - 71 released: 19 decrees, 6 CFDA working reports, 46 feedback guidelines
  - Significant updates: device classification, CT exempt list, pre-market clinical study and evaluation, GMP, GCP, GSP, adverse events, labelling

- **CFDA Device Approvals and Rejects:**
  - 13,883 devices received CFDA approval & Updates
    - Domestic 2,400, Imports 4,558, Change Updates 6,925
  - 45 devices received innovation fast track approval
    - 5 foreign companies: BSC, BioNTech, Gore, Cardiatis SA, St. Jude
    - 40 domestics
  - 1,504 devices premarket submissions rejected by CFDA
    - # of rejects 6 times higher than 2015 (270).
    - Application areas: surgical, dental orthopedic, IVD, implants and artificial organs.
    - Manufacturers origin: imports 1,086, domestic 418
CFDA PREMAREKT OVERVIEW
# Imported vs Domestic Devices

<table>
<thead>
<tr>
<th></th>
<th>Imported Medical Device</th>
<th>Domestic Medical Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer Registration Address</strong></td>
<td>Outside China</td>
<td>In China</td>
</tr>
<tr>
<td><strong>Actual Manufacturing Address (Key processes)</strong></td>
<td>Outside China</td>
<td>Must be identical to the manufacturer registration address</td>
</tr>
<tr>
<td><strong>Regulatory CFDA Level</strong></td>
<td>Class I: Central CFDA</td>
<td>Class I: City-level CFDA</td>
</tr>
<tr>
<td></td>
<td>Class II: Central CFDA</td>
<td>Class II: Province-level CFDA</td>
</tr>
<tr>
<td></td>
<td>Class III: Central CFDA</td>
<td>Class III: Central CFDA</td>
</tr>
</tbody>
</table>
| **Qualification needed to sell the product in China (Class II/III)** | 1. Registration and QMS certification in country of origin  
2. Have a China agent  
3. Imported Product Registration | 1. QMS Audit (GMP included)  
2. Domestic Product registration Certificate  
3. Manufacturer License |
| **Pros**                     | 1. Higher margin                | 1. Future reimbursement benefit |
|                              | 2. Good brand impression        | 2. Lower Manufacturing Cost      |
| **Cons**                     | 1. Stricter CFDA regulation     | 1. Higher in-country investment  |
|                              | 2. Higher Cost for market entry | 2. Intercontinental management  |
CFDA vs. FDA

• CFDA requires predicate of country of origin approval
• Third Party Review not allowed; need approval from CFDA for all import medical device including class I.
• Classifications in FDA and CE are not necessarily the same in China CFDA.
• Physical testing must be conducted in China by CFDA certified testing centers.
• Need to submit Chinese Product Standard for CFDA review and approval.
# Tests: CFDA vs FDA

<table>
<thead>
<tr>
<th>Chinese standards</th>
<th>Title</th>
<th>Related International standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>GB 4793.1-2007</td>
<td>Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements</td>
<td>IEC 61010-1: 2001</td>
</tr>
<tr>
<td>GB/T 18268.1-2010</td>
<td>Electrical equipment for measurement, control and laboratory use --EMC requirements --Part 1: General requirements</td>
<td>IEC 61326-1:2005</td>
</tr>
</tbody>
</table>
# Fees: CFDA vs FDA

## CFDA administration after May 27 2015

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Domestic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Registration Class III</td>
<td>308,800 RMB (48.6 K USD)</td>
<td>153,600 RMB (24.2 K USD)</td>
</tr>
<tr>
<td>Initial Registration Class II</td>
<td>210,900 RMB (33.2 K USD)</td>
<td>Determined by Provincial-level CFDA</td>
</tr>
<tr>
<td>Registration renewal (every five years)</td>
<td>40,800 RMB (6.4 K USD)</td>
<td>Determined by Provincial-level CFDA</td>
</tr>
<tr>
<td>Clinical Trial Approval (High-risk MD)</td>
<td>43200 RMB (6.8 K USD)</td>
<td>43200 RMB (6.8 K USD)</td>
</tr>
</tbody>
</table>

## FDA administration fee in 2015

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(K) Premarket Notification</td>
<td>5.018 K USD</td>
</tr>
<tr>
<td>PMA (Premarket Approval)</td>
<td>250.895 K USD</td>
</tr>
<tr>
<td>PMA annual report</td>
<td>8.781 K USD</td>
</tr>
<tr>
<td>Panel-track supplement</td>
<td>188.171 K USD</td>
</tr>
<tr>
<td>180-day supplement</td>
<td>37.634 K USD</td>
</tr>
<tr>
<td>Real-time supplement</td>
<td>17.563 K USD</td>
</tr>
<tr>
<td>513(g) request for classification information</td>
<td>3.387 K USD</td>
</tr>
</tbody>
</table>
CFDA Registration Flow

Understand the Regulatory Path for CFDA Registration

Registration test in a CFDA-qualified test lab

Clinical Evaluation Report / Clinical Trial in China

CFDA 1st Review
(Class II: 3 months, Class III: 4.5 months)

Reply to remarks
(one chance only and 1 year time)

CFDA 2nd Review
(3 months)

Final Decision
DO NOT try to solve all the questions at the beginning
“Clinical evaluation” data required for all the medical devices
Clinical Evaluation Report or Clinical Trial?

• Any predictive device in China?
• Do you have the sufficient technical and clinical information of the predictive device?
• Have you done clinical trials outside China?
• Are the clinical trial data sufficient in terms of sample size, indication coverage, Asian/Chinese data subgroup?

Sufficient or not? – CFDA is the judge.

☑️ DO full evaluation with an expert

❌ DO NOT expect a 100% confirmed answer.
Clinical Trial Process in China

Ethic Committee Approval in Qualified Clinical Sites (Hospitals) - 2 - 4 months

Filling the trial in local CFDA and Health Administration

Patient Recruitment

Follow-up - 2 months

Data analysis + Clinical Report

“must do CT in China list” shall be approved by CFDA first

Follow China GCP
### Classification

<table>
<thead>
<tr>
<th>File #</th>
<th>Name</th>
<th>Chinese Version</th>
<th>English Version</th>
<th>Issued Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>Medical Device Classification List (Draft)</td>
<td>Medical Device Classification List (Draft)</td>
<td>NA</td>
<td>2016.09</td>
</tr>
<tr>
<td>133</td>
<td>Clinical Trial Exemption List for Class II Medical Device(Second Batch)</td>
<td>Annex 1 to No.133 Clinical Trial Exemption List for Class II Medical Device(Second Batch)</td>
<td>NA</td>
<td>2016.09.27</td>
</tr>
<tr>
<td>133</td>
<td>Clinical Trial Exemption List for Class III Medical Device(Second Batch)</td>
<td>Annex 2 to No.133 Clinical Trial Exemption List for Class III Medical Device(Second Batch)</td>
<td>NA</td>
<td>2016.09.27</td>
</tr>
</tbody>
</table>

Annex to No.12 Clinical Trial
## Clinical Evaluation Report & Clinical Trial

<table>
<thead>
<tr>
<th>File #</th>
<th>Name</th>
<th>Chinese Version</th>
<th>English Version</th>
<th>Issued Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Quality Management Specification for Medical Device Clinical Trials</td>
<td>No.25 Quality Management Specification for Medical Device Clinical Trials</td>
<td>NA</td>
<td>2016.03</td>
</tr>
<tr>
<td>58</td>
<td>Application Form of Ethical Review and Approval for Medical Device Clinical Trials</td>
<td>No.58 Application Form of Ethical Review and Approval for Medical Device Clinical Trials</td>
<td>NA</td>
<td>2016</td>
</tr>
<tr>
<td></td>
<td>Announcement on the Relevant Issues</td>
<td>No.87 Announcement on the Relevant Issues Concerning the</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>
CFDA QMS History

• Methods for the Quality Management System Inspection on Medical Device Manufacturing Enterprises（CFDA No.22）—2000.5.22
• Rules for the Quality Management System inspection on IVD, Detail Rules for IVD Manufacturing（CFDA[2007]No.239）
• Standards for the Medical Device Production Quality Management（CFDA[2009]No.833）
• Methods for the Inspection and Administration of the Quality Management Standards on Medical Device (Trial)（CFDA[2009]No.834）
• Implementation Details and Evaluation Standards for Production Quality Management on Sterile Medical Device (Trial)（CFDA[2009]No.835）
• Implementation Details and Evaluation Standards for Production Quality Management on Implantable Medical Device (Trial)（CFDA[2009]No.836）
CFDA Medical Device Major Regulation

GMP

• Medical Device Supervision and Administration Regulation (State Council #650)
  – Approved 2/12/2014, Implemented 6/1/2014

• Medical Device Manufacturing Supervision and Administration Regulation (CFDA #7)
  – Approved 6/27/2014, Implemented 10/1/2014

• About Medical Device Manufacturing Quality Management Regulation Announcement (CFDA #64)
  – 12/29/2014 replaced 12/26/2009 #833
QMS/GMP OVERVIEW
Product Life Circle
QMS Structure

Quality Policy
Quality Purpose

Organization & People

R&D
Adverse event monitoring and reevaluation

Procurement Control

Production Management

Factories & Equipment

Sales & Aftermarket

Quality Control

Working Environment Control

Risk management, Unqualified Product Control, Analysis and Improvement

QMS documents and records
CFDA GMP DIFFERENCES AND SIMILARITIES WITH ISO AND QSR
GMP Supervision & Administration Trends

- GMP Become Regulation
- Mandatory Implement Dates Published
- Setup of Related QMS
- Supervision & Inspection standards more
- Ways of Supervision & Inspection Added
- Violation and Fines more Severe
CFDA GMP

ISO 13485 + CHINA SPECIFICS

SIMILAR TO QSR 820
China Standards Implement Before ISO Standards

• All industries - General Quality Management System Standard

• Medical Device - Quality management systems- Requirements for regulatory purposes

<table>
<thead>
<tr>
<th>Standard</th>
<th>Publish Time</th>
<th>Implement Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13485-2016</td>
<td>Feb 2016</td>
<td>Mar 1\textsuperscript{st}, 2019</td>
</tr>
<tr>
<td>YY/T 0287-2017</td>
<td>Jan 2017</td>
<td>May 1\textsuperscript{st} 2017</td>
</tr>
</tbody>
</table>
## Comparison of GMP in Typical Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Europe</th>
<th>U.S.</th>
<th>Canada</th>
<th>Japan</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements of QMS</td>
<td>MDD/IVDD ISO13485</td>
<td>QSR 820</td>
<td>ISO 13485 CMDCAS</td>
<td>J-GMP</td>
<td>GMP</td>
</tr>
<tr>
<td>Inspection Requirements Before New Product Introduction</td>
<td>NB* proceeds on-site inspection</td>
<td>No on-site inspection</td>
<td>CB proceeds on-site inspection</td>
<td>On-site audit, Class III and Class IV-Governments, Class II-RCB</td>
<td>On-site inspection, Mfg Permit</td>
</tr>
<tr>
<td>Inspection Requirements After Release of Product</td>
<td>NB proceeds annual on-sites inspection</td>
<td>FDA proceeds on-sites spots check</td>
<td>CB proceeds annual on-sites inspection</td>
<td>Spots check</td>
<td>Routine supervision and inspection</td>
</tr>
</tbody>
</table>

*NB: notified body*
## Comparison with ISO 13485

<table>
<thead>
<tr>
<th></th>
<th>ISO 13485</th>
<th>CFDA GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Standard</td>
<td>Regulation</td>
</tr>
<tr>
<td><strong>Execution Requirements</strong></td>
<td>Voluntary</td>
<td>CFDA mandatory enforcement</td>
</tr>
<tr>
<td><strong>Inspection &amp; Execution Organization</strong></td>
<td>Certified third-party Organization</td>
<td>CFDA</td>
</tr>
<tr>
<td><strong>Inspection Timing</strong></td>
<td>After voluntary application</td>
<td>During the product registration, Daily supervision and inspection, fly inspection(unannounced)</td>
</tr>
<tr>
<td><strong>Inspection Result Documents</strong></td>
<td>Issue Certificate</td>
<td>Notification of inspection results</td>
</tr>
</tbody>
</table>
# CFDA GMP and ISO 13485 Chapter Table Comparison

<table>
<thead>
<tr>
<th>ISO 13485</th>
<th>CFDA GMP</th>
</tr>
</thead>
</table>
### Comparison with QSR 820

<table>
<thead>
<tr>
<th></th>
<th>QSR 820</th>
<th>CFDA GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Regulation</td>
<td>Regulation</td>
</tr>
<tr>
<td><strong>Execution Requirements</strong></td>
<td>FDA Mandatory</td>
<td>CFDA Mandatory</td>
</tr>
<tr>
<td><strong>Inspection &amp; Execution Organization</strong></td>
<td>FDA</td>
<td>CFDA</td>
</tr>
<tr>
<td><strong>Inspection Timing</strong></td>
<td>PMA, After product 1st being commercialized to the U.S.</td>
<td>During the product registration, routine supervision and inspection, fly inspection (unannounced)</td>
</tr>
<tr>
<td><strong>Inspection Result Documents</strong></td>
<td>None/483/Warning Letter</td>
<td>Notification of inspection results</td>
</tr>
</tbody>
</table>
### CFDA GMP and QSR 820 Chapter Table Comparison

<table>
<thead>
<tr>
<th>QSR 820</th>
<th>CFDA GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart H - Inspection Activities</td>
<td>9. Quality Control</td>
</tr>
<tr>
<td>Subpart I - Unqualified Products</td>
<td>11. Unqualified Products Control</td>
</tr>
<tr>
<td>Subpart J - Corrective and Preventive Measures</td>
<td>12. Adverse event monitoring, analysis and improvement</td>
</tr>
<tr>
<td>Subpart K – Labeling and Packaging Control</td>
<td>8. Production administration</td>
</tr>
<tr>
<td>Subpart L - Handling, storage, delivery and installation</td>
<td>8. Production administration 10. Sales &amp; Services</td>
</tr>
<tr>
<td>Subpart M - Recording</td>
<td>5. Document Administration</td>
</tr>
<tr>
<td>Subpart N - Service</td>
<td>10. Sales &amp; Service</td>
</tr>
<tr>
<td>12. Adverse event monitoring, analysis and improvement</td>
<td>12. Adverse event monitoring, analysis and improvement</td>
</tr>
</tbody>
</table>
# FDA & CFDA Label Comparison

<table>
<thead>
<tr>
<th>Item</th>
<th>US FDA</th>
<th>China CFDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the device</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Name and address of the manufacturer</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Name and address of the agent on the label</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch Number or Serial Number</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Prescription use</td>
<td>Yes with Rx only and “CAUTION Federal law restricts this device to sale by or on the order”</td>
<td>No</td>
</tr>
<tr>
<td>Certificate Number</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Language Requirement</td>
<td>English</td>
<td>Chinese</td>
</tr>
<tr>
<td>Valid period &amp; manufacture date</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
# FDA & CFDA Adverse Event Event Comparison

<table>
<thead>
<tr>
<th>Item</th>
<th>US FDA</th>
<th>China CFDA</th>
</tr>
</thead>
</table>
| 5-day report    | Triggers remedial action to prevent an unreasonable risk of substantial harm to public health  
A written request for the submission of 5-day reports | Resulting in death shall be first reported                                 |
| 15-day report   | Causing severe injuries, possibly causing severe injuries or death shall be first reported |                                                                          |
| 20-day report   | (according to Oct 2016 draft ARTICLE 16. import device manufacture has 20days to report whereas domestic manufactures follow the above 5 day/15 day report timeline)  
Within 20 working days after first report, manufacturer shall fill in the Supplementary Report Form and report the event to local provincial agency for monitoring of medical device adverse event |                                                                          |
| 30-day-report   | a reportable device-related death or serious injury, or a reportable malfunction |                                                                          |
| Supplemental report | Must be submitted within one month (30 calendar days) following receipt of the information | (according to Oct 2016 draft ARTICLE 18. device manufacture must investigate, analyze and evaluate SAE and submit evaluation result within 30 days from the date of original report or 20 days if the SAE resulting in death)  
Promptly submit to local provincial agency for monitoring of medical device adverse events |
| Who report to   | FDA MAUDE                                                              | CFDA MD Monitoring System or local CFDA monitoring office                 |
Reported AE # by Year
Reported AE # by Year

- Users: 91,322 (46.0%)
- Manufacturers: 96,870 (48.8%)
- Distribution Entities: 10,344 (5.2%)
CFDA Overseas onsite Inspection 2016

• Team: 73 Nationally accredited inspectors (From national CFDA and provincial CFDA)
  • CFDA provided a 2-month long training session to 73 CFDA GMP inspectors to ensure their expertise in July 2015.
• Purpose of overseas visits
  • self-learning, compliance of GMP to meet China specific requirements of CFDA registered products.
• 2016 Activities
  • CFDA sent 10 teams to overseas medical device manufacturers for on-site inspection. Each time visited multiple sites.
• Target manufacturers
  • High-risk products: implants (stents, orthopedics), sterile etc.
  • The major countries: USA, Germany, Japan.
  • Major companies: Johnson & Johnson, Boston Scientific, Siemens, Philips, Medtronic, Abbot, Olympus, Stryker etc.
CFDA GMP Key Implementation Dates

Published at the end of 2014

- Oct 1 2014: All newly established companies, and existing companies if they add a Class III device or move sites, add additional sites, must comply to the new GMP.

- Jan 1 2016: All Class III manufacturers must be in compliance.

- Jan 1 2018: All manufacturers must comply.
The guidelines provided details for the supervision departments to follow when they perform onsite inspections and assess inspection results.

They are used for medical device registration onsite verification and issuing manufacturing permit, including (change order and renewal) and other necessary inspections.
INSPECTIONS: DOMESTIC & FOREIGN
CFDA Overseas onsite Inspection 2016

• Team: 73 Nationally accredited inspectors (From national CFDA and provincial CFDA)
  • CFDA provided a 2-month long training session to 73 CFDA GMP inspectors to ensure their expertise in July 2015.
• Purpose of overseas visits
  • self-learning, compliance of GMP to meet China specific requirements of CFDA registered products.
• 2016 Activities
  • CFDA sent 10 teams to overseas medical device manufacturers for on-site inspection. Each time visited multiple sites.
• Target manufacturers
  • High-risk products: implants (stents, orthopedics), sterile etc.
• The major countries: USA, Germany, Japan.
• Major companies: Johnson & Johnson, Boston Scientific, Siemens, Philips, Medtronic, Abbot, Olympus, Stryker etc.
## General Decrees

<table>
<thead>
<tr>
<th>File #</th>
<th>Description</th>
<th>Chinese Version</th>
<th>English Version</th>
<th>Issued Date</th>
</tr>
</thead>
</table>

www.CFDAhotline.com
Thank you!

Grace Fu Palma
CEO, China Med Device, LLC
Ph: 978-390-4453 (US)
Ph: 18201749732 (China)
Email: gpalma@chinameddevice.com
Web: www.ChinaMedDevice.com
Wechat: gracefumed
ISO 13485 & CFDA GMP Quality Control Principles

1. Customer/regulation focus
2. Leadership
3. Total Involvement
4. Process method PDCA
5. Systematic methods of administration
6. Improve effectiveness
7. Decision-making method based on facts
8. The responsibility of outsourcing process
## Inspection Consequence

<table>
<thead>
<tr>
<th>Major Problems</th>
<th>Minor Problems</th>
<th>Inspection Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>Pass</td>
</tr>
<tr>
<td>0</td>
<td>General findings, have no direct impact on product quality</td>
<td>Re-inspect after correction</td>
</tr>
<tr>
<td>≥1</td>
<td>-</td>
<td>Fail</td>
</tr>
<tr>
<td>0</td>
<td>General findings, have direct impact on product quality</td>
<td></td>
</tr>
</tbody>
</table>

**New CFDA GMP**

**IVD, Sterile, Implants, Others**
CFDA GMP Chapter Highlights
Chapter 2 Organization and People Article 5-11

• Establish & maintain the quality management system adapted to the medical device production
• Quality system responsible person should be the separate from administrative management and dedicated as the head of quality management system.
• Professional technical staff, managers and operators should be qualified with product and process requirements of experience, professional & technical knowledge.
Typical Non-conforming Areas
Organization and People

• Have not collected and maintained the relevant laws, regulations and administrative regulations on production and business operation.
• Responsible people (technical, production, quality department) are not familiar with the medical device regulations and the national industry standards.
• Lack of compliance awareness exists in many companies in China. Focus more on profit instead of quality. Quality system at lower priority.
• Lack of staff training. Only received training on how to make products but not on the training of standard operation and quality system.
Typical Non-confirming Example
China GMP Chapter Highlights
Chapter 5 Document Management Article 24-27

- Defined the basic requirements of the quality manual
- Defined the basic requirements of the technical documents
- Document control requirements refinement
- Shelf life of obsolete documents
- Record control requirements refinement (emphasis on traceability, clearly defined record changes)
Typical Non-conforming Example
Document Management

• Obsolete documents at operation site
• Documents not approved in accordance with “Document Control Procedure”
• Record alteration exists
• Record traceability weak, Content incomplete
• The records not reviewed and approved as required
• Prepare documents and records in order to pass the inspection. After the inspection, documents not used. No one pays attention to the significance of these documents in QMS implementation.
Importance of Documentation

Even though documentation system is software, it is the skeleton and the neural central network!
CONTINUE TO REFINE & STANDARDIZE