Regulatory Challenges in China

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Agenda

• China Regulatory Systems
• CFDA Reform and Regulation Framework
• Challenges
China Regulatory Systems

World Registration Map

Medical Device industry is a regulated industry in the world

USA
- Food and Drug Administration (FDA)

China
- China Food and Drug Administration (CFDA)

Canada
- Health Canada

Europe
- European Commission Directorate General Health and Consumers
- European Medicines Agency (EMA)

Australia
- Therapeutic Goods Administration (TGA)

Japan
- Ministry of Health, Labor and Welfare (MHLW)
- National Institute of Health and Nutrition (NIHN)

Korea
- Korea Food and Drug Administration (KFDA)

Brazil
- National Health Surveillance Agency (ANVISA)

Singapore
- Health Sciences Authority (HSA)

China is known as one of the regions with most complicated and strictest medical device regulations in the world.
## China Regulatory Systems

### (Decentralized System)

<table>
<thead>
<tr>
<th><strong>Roles &amp; Responsibility</strong></th>
<th><strong>National</strong></th>
<th><strong>Provincial</strong></th>
<th><strong>City</strong></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Regulation Making</td>
<td>Local Implementation Rule</td>
<td>Local Implementation Rule</td>
</tr>
<tr>
<td></td>
<td>Registration Approval (Class 3 domestic &amp; class 1/2/3 import)</td>
<td>Registration Approval (Class 1/2 domestic)</td>
<td>Manufacture License Approval (Class 1)</td>
</tr>
<tr>
<td></td>
<td>QMS Inspection (Class 1/2/3 import)</td>
<td>Manufacture License Approval (Class 2/3)</td>
<td>Distribution License Approval (Class 2)</td>
</tr>
<tr>
<td></td>
<td>Post Market Administration</td>
<td>Distribution License Approval (Class 3)</td>
<td>Distribution License Approval (Class 2)</td>
</tr>
<tr>
<td></td>
<td>National Standards (GB, YY, WS)</td>
<td>QMS Inspection (Class 2/3 domestic)</td>
<td>QMS inspection (Class 1 domestic)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post Market Administration</td>
<td>Post Market Administration</td>
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<tr>
<td></td>
<td></td>
<td>Local Standard (DB)</td>
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</table>

### Organization

<table>
<thead>
<tr>
<th><strong>National</strong></th>
<th><strong>Provincial</strong></th>
<th><strong>City</strong></th>
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<tbody>
<tr>
<td>CFDA</td>
<td>Provincial FDA</td>
<td>City FDA</td>
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<tr>
<td>CMDE</td>
<td>Government Lab</td>
<td>Health Bureau</td>
</tr>
<tr>
<td>CMDSA</td>
<td>Health Department</td>
<td>Inspection Bureau</td>
</tr>
<tr>
<td>CDR</td>
<td>Standard Administration Department</td>
<td>Industry &amp; Commerce Bureau</td>
</tr>
</tbody>
</table>
China Regulatory Requirement

• Pre-Market Registration Approval
  – Type-testing by CFDA accredited government labs
  – Clinical trials in accredited hospitals
  – Product registration approval/filing by CFDA/Provincial FDA
  – QMS inspection by CFDA and Provincial FDA
  – Manufacture license approval by Provincial FDA/City FDA

• Post-Approval Supervision
  – Adverse Event Reporting (MDR) and re-evaluation
  – Field corrective action (Recall)
  – Device Registries for selected products
  – Inspections of distribution, usage, label, etc.
  – Establishing a system for Unique Device Identification (UDI) and promote its incorporation into Electronic Health Records (EHR)

• Others
  – CFDA standards: National standards (GB) and industry standards (YY)
  – Provincial government standards: Local standards (DB)
  – NHFPC standards: National clinical standards (WS)
  – Etc.

CFDA Reform and Regulation Framework
CFDA Reform

CFDA's Re-Organization

- **Start Time:**
  - March 2013
- **Completion time:**
  - June 2013
- **Major Changes:**
  - CFDA's official level upgraded
  - CFDA's role expanded

Regulation Change

- **Start Time:**
  - March 2014
- **Completion Time:**
  - Level 1: Jun 1st, 2014
  - Level 2: Oct 1st, 2014 (continuing)
  - Level 3: Oct 1st, 2014 (continuing)
- **Major Changes:**
  - Top-down change of whole set of CFDA regulations from level 1 to level 3

Personnel Change

- **Start Time:**
  - March 2013
- **Completion time:**
  - (Continuing)
- **Major Changes:**
  - CFDA Commissioner
  - Head of MD Supervision Dept
  - Head of CMDE

Regulation Framework _ General

**Level 1 (1/1)**
1. Medical Devices Supervision and Administration Ordinance (SC [2014] Order #650)
   [Published on Mar 31st, 2014; Effective on Jun 1st, 2014]

**Level 2 (8/12)**
1. Provisions on Medical Device Registration (CFDA [2014] No. 4) [Published on Jul 30th, 2014; Effective on Oct 1st, 2014]
2. Provisions on IVD Product Registration (CFDA [2014] No. 5) [Published on Jul 30th, 2014; Effective on Oct 1st, 2014]
4. Provisions for Supervision of Medical Device Production (CFDA [2014] No. 7) [Published on Jul 30th, 2014; Effective on Oct 1st, 2014]
6. Provisions on Medical Device Usage Supervision and Administration (Draft for comment)
7. Provisions on Medical Device Adverse Event Monitoring and Re-evaluation(interim) (SFD(2008)No.766)(Published and Effective on Dec 29th, 2008); the new draft for comments will be issued soon
8. Medical Device Classification Rules (Draft for comment)(SYJXGXBH[2013]No.95)
10. Measures for the Supervision of Food and Drug Distribution over the Internet(Draft for comment)
11. Provisions on Medical Device Standard(Draft for comments)(SYJXGXBH No.66 [2014])
12. Provisions on clinical research project by medical and health institutions(GWYF No. 80 (2014 ) )(Published and effective on Oct. 16th, 2014)
Regulation Framework _ General

Updated as of October 31st, 2014

Level 3 (27/38)
1. Good Clinical Practice for Medical Devices (Draft for comment)
2. Good Manufacturing Practice for Medical Devices (Draft for comment) (SYJXG[2009] No. 833) [Published on Dec 16th, 2009; Effective on Nov 1st, 2011]
3. Good Manufacturing Practice for Medical Devices (Draft for comment) (SYJXG[2014] No. 85)
4. Good Supply Practice for Medical Devices (Draft for comment) (SYJXG[2013] No. 96)
5. Good Practices on Quality in Use of Medical Devices (Draft for comment) (SYJXG[2014] No. 51)
6. Class I Medical Device Catalogue (CFDA [2014] No. 8) [Published on May 30th, 2014]
8. Announcement on Implementation of Medical Device Supervision and Administration Ordinance (CFDA [2014] No. 23) [Published on May 30th, 2014]
10. Filing Requirements on Class I Medical Device (CFDA [2014] No. 26) [Published on May 30th, 2014]
11. Registration Approval Operation Specification for Class III Domestic & Import Medical Devices (SYJXG[2014] No. 12) [Published on Sep 10th, 2014; Effective on Oct 1st, 2014]
12. Registration Approval Operation Specification for Class II Domestic Medical Devices (SYJXG[2014] No. 209) [Published on Sep 10th, 2014; Effective on Oct 1st, 2014]
13. Notification on implementing Measures for Supervision and Administration of Medical Devices and IVD Registration (CFDA [2014] No. 144) [Published on Aug 1st, 2014]
15. Medical Device Nomenclature (Draft) for comment (SYJXGBH[2014] No. 41)
18. Technical Guidance Principle for Clinical Evaluation of Medical Devices (Draft for comment) (SYJXGBH No. 46(2014)]

Regulation Framework _ General

Updated as of October 31st, 2014

22. CTS Procedures of Clinical Trials for Medical Devices (Published on September 28th, 2014; Effective on Oct 1st, 2014)
23. Requirement and Instruction for Application Documents of Medical Device Registration and Formats of Approval Prove Documents (CFDA [2014] No. 43) [Published on Sep 10th, 2014; Effective on Oct 1st, 2014]
24. Requirement and Instruction for Application Documents of IVD Registration and Formats of Approval Prove Documents (CFDA [2014] No. 44) [Published on Sep 30th, 2014; Effective on Oct 1st, 2014]
25. CFDA Announcement on Implementing Relevant Issues on GMP for Medical Device (CFDA [2014] No. 15) [Published on Sep 10th, 2014]
26. CFDA’s Notice on Printing and Distributing Provisions for Supervision and Administration of Classification and Grading of Medical Device Manufacturers (SYJXG[2014] No. 234) [2014] [Published and effective on Sep 30th, 2014]
27. Qualification Certification Requirements for Testing Institutions of Medical Devices (Exposure Draft) (SYJXGBH[2014] No. 49)
29. Regulations for Pre-evaluation of Technical Requirements of Medical Device Products by Medical Device Testing Institutions (CFDA [2014] No. 182) [Published on Aug 21st, 2014; Effective on Oct 1st, 2014]
30. Guidance on Medical Device Adverse Event Monitoring (Draft for comment) (SYJXG[2011] No. 425) [Published and effective on Sep. 16th, 2011]
31. Guidance on Medical Device Re-evaluation (Draft for comment)
32. Medical Device Coding Rules (Draft for comment)
33. Notice on Relevant Matters of Implementing Filing for Class I Medical Devices by CFDA General Office (SYJXG[2014] No. 174) [Published on Sep 15th, 2014]
34. Operation Specifications for Review of Quality Management System for Domestic Medical Device Registration (SYJXGBH[2013] No. 53)
35. Notice on Relevant Issues Concerning Medical Device Manufacture Approval (Filing) Issued by Shanghai Municipal Food and Drug Administration (SYJXGBH No. 476[2014]) [Published on Sep 26th, 2014; Effective on Oct. 1st, 2014]
36. CFDA Notification on Issuing the Medical Device List That Shall be Prohibited for Commissioned Manufacture (CFDA Circular No. 18 2014] [Published and effective on Sep 26th, 2014]
37. National Catalog of Medical Devices under Focused Supervision and Administration (SYJXG[2014] No. 235) [2014] [Published and effective on Sep 30th, 2014]
38. Medical Device classification Category (Draft for comments)
Regulation Framework

1 new regulation/4 days
March 31st - October 31st
Covers the entire medical device life cycle

Challenges for Doing Business in China
Challenges _ Authority Perspective

- CFDA shifting pre- and post-market balance to expedite new technologies to market requires ability to gather performance information in real time
- Medical liability environment in disconnected healthcare system makes it difficult to track patients
- Lack of adequate device identification for many devices
  - Device tracking
- Laws governing collection and dissemination of health information
  - i.e. NHFPC’s ‘Notification on Population Health Information Management Measures’
- Lack of registry infrastructure, consistency
- Inability to link information
- Short of regulators, reviewers, QMS inspectors, GCP inspectors

Challenges _ Industry Perspective

1. New regulation transition period:
   - CT will delay new product approval
2. Green channel for innovative new product
   - Faster approval of new product
   - Exposure of patent information
3. CFDA approval timeline
   - Renewal approval is faster
   - New product approval is slower, prolonged by 20%+ for class III
4. Country of origin approval to start a CT
   - Delay import product registration approval
   - Competition of patient, investigator,
5. Clinical trial (CT)
   - CT requirement is less for domestic products comparing with old regulation
   - CT requirement is more for import products comparing with old regulation
   - CTA further delays the start of CT
6. Chinese labeling
   - Date of Manufacture is difficult to be obtained from OEM and contract manufacturer
   - Foreign manufacturers are not ready to provide Chinese label at manufacture site
7. Competent RA professional
   - Nothing would happen without right people
What should RA’s roles be throughout medical device life cycle?

- Messenger
- Follower
- Routineer
- Manual Labor
- Co-worker

Versus

- Communicator
- Innovator
- Improver
- Strategist
- Partner

Challenges _ RA Perspective

RA Mission

- Ensures **On Time Delivery** registration success, which links to the business target
- Seeks for **Efficiency**, and pushes self and others to maximize outcomes
- Drives regulatory **Compliance** across the business
- Collects and analyzes **Intelligence** and incorporates regulatory trends into decision-making processes
Challenges _RA Perspective

RAPS: RA Professional will Bring

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<thead>
<tr>
<th>Science &amp; Technology</th>
<th>Ability</th>
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<tbody>
<tr>
<td></td>
<td>• Scientific, technology understanding</td>
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<td></td>
<td>• Ability to interface with other experts involved throughout product lifecycle</td>
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<td></td>
<td>• Ability to link science, clinical practice, regulation, policy, business</td>
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<tr>
<td></td>
<td>• Strong organizational and communication skills</td>
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<tr>
<td></td>
<td>• Analytical, strong critical thinking skills</td>
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Challenges _RA Perspective

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<thead>
<tr>
<th>Competency Model</th>
<th>Career Path</th>
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<tr>
<td>Core</td>
<td>Managerial</td>
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<td>Project Management</td>
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<td>Time Management</td>
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<td>Emotion Management</td>
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<td>Presentation Skill</td>
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<td>Communication Skill</td>
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<td>Continuous Improvement</td>
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<td>Corporation Skill</td>
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<td>Personal Organization</td>
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<td>Strategic Thinking</td>
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<td>Finance Control</td>
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<td>Good Regulatory Practice</td>
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<td>Development of SOP</td>
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<td>Knowledge of STD</td>
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<td>Leading a successful meeting</td>
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<td>Innovative Problem Solving</td>
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<td>Influence without Authority</td>
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<td>Target Selection</td>
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<td>Leadership Essentials</td>
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<td>Coaching for Results</td>
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<td>Industry Insight</td>
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<td>Regulation Insight</td>
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<td></td>
<td>Consultant</td>
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<td>Specialist</td>
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<td>Principle</td>
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<td>Manager/Supervisor</td>
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<td>VP/Director</td>
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Challenges _ RA Perspective

How to build RA competencies?

- Learning
- Practice

Self

In-job
- Coaching
- Training

External

- Agency
- Academy
- RAPS

Thank you!

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