Innovative Medical Device Development in China: 
An American’s perspectives

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Developing an Industry

1. Enable entrepreneurship
2. Support fundamental research
3. Wait for serendipity
Acquiring an Industry

1. Import foreign manufactured products
2. Copy foreign technology locally
3. Develop novel products internally

Challenges

1. Import foreign manufactured products
   – Adapt for local conditions
   – Prevent dumping inferior products
   – Manage trade balance
Challenges

2. Copy foreign technology locally
   – Avoid dangerous and embarrassing mistakes
   – Monitor indigenous preclinical & clinical studies
   – Protect via non-tariff trade barriers

Cardiac pacemaker: Shaanxi Qinming Medical, founded 1986, Baoji Division of Lepu Medical Technology
Cochlear implant: Nurotron, founded 2006, Hangzhou & Irvine, CA

Challenges

3. Develop novel products internally
   – Pioneer new science and technology
   – Protect intellectual property
   – Design novel clinical trials
   – Harmonize with potential export markets
   – Determine cost-effectiveness
   – Educate caregivers
   – Manage conflicts of interest

CFDA Chapter II The Administration of Medical Devices
Article 7 The State encourages the research and development of new medical devices. "New medical devices" refer to the kind of brand new product varieties which have not been available in the domestic market, or for which the safety, effectiveness and product mechanism have not been recognized domestically.
Patentability

- US & EU require absolute novelty:
  *Any invention, sale, testing or other use in any country constitutes prior art.*

- China encourages and issues patents with minimal search or citation of prior art.

Reimbursement

- US: CMS approval is a huge hurdle and it is almost impossible to sell expensive treatments without it.

- China: Strong tradition of self-payment since collapse of commune health care.
Conflict of Interest

• US: Strict separation of government agencies and regulated industries

• China: Close relations among research institutes, state-owned enterprises and private companies

Regulation

• US FDA: Device approval (21 CFR 820) based on Federal law since 1976

• China SFDA: Operating under trial regulation #883 since 2009
Similar Risk-based Classification Systems

but

• More Class III devices than in US
  – For example, injection devices are class III
• A separate category of high-risk Class III devices whose clinical trials require preapproval
• Inspections vary with class:
  – Class III: CFDA responsible
    (may delegate inspections to provinces)
  – Class II: Provincial FDAs
  – Class I: Municipal level
• Uncertain interpretation and enforcement

China FDA (SFDA)
Interim GMP Regulations
(Jan. 1, 2011)

• Strict product quality control in manufacturing
• Design controls???
• Process validation???

Note:
➢ China still lacks a specific medical device law.
➢ CFDA uses draft and interim policies drawn from drug regulations.
➢ Good Manufacturing Practices ≈ Quality System Requirements
China FDA draft measure (2013):
Fast Track Approval Process of Innovative Medical Devices

- Patented core technology registered in China
- Worldwide pioneering mechanism of action
- Controlled R&D process and documentation

China FDA Medical Device Regulation (MDR, June 1, 2014):
Fine-Tuning and Clarifications

- Contract manufacturing permitted (mostly)
- Reduced & simplified device, manufacturing facility and distributor registration
- Increased GMP, labeling, adverse event reporting & enforcement actions
Recent experience with a novel Class III Medical Device

- Government pressure to file & approve Chinese patents
- Self-defined “standard” - no Design Control documentation
- Biocompatibility testing at pre-approved state facilities
- Components tested instead of finished product
- Clinical trials only at pre-approved institutions
- Formal IDE & study design approval not necessary
- Uncertain potential for export

...to be continued

The Bad Old Days in the U.S.

~50% of medical device problems were caused by poor design rather than malfunction.
1993 Proposed
Good Manufacturing Practices (GMP)
Subpart C. Design Controls

1996 Finalized
1997 Guidance
1998 Effective
1999 Global Harmonized Guidance
ISO 14971 2000
FDA Guide to Inspections

ISO 14971
Risk Management for Medical Devices
ISO 14971 revised 2007

Compliance with FDA Guidance on Design Controls (1997)

Design History File

User Needs

Design Input

Design Process

Design Plan

Review

Verification

Validation

Design Output

Risk Analysis

Medical Device
Integrated Design & Risk Management

- Stakeholder Needs
- Functional Requirements
- Reliability Requirements
- Specifications
  - Test Methods
- Implementation
  - Bill of Materials
- Production Engineering
  - Standard Operating Procedures
- Field Experience
  - Complaints & Returns
  - Adverse Events
- Constraints & Guidance
  - Cause and Effect Analysis (Fishbone Diagrams)
  - Failure Modes & Effects Analysis (FMEA)
  - Fault Tree Analysis
  - Hazards & Critical Control Points (HACCP)

Design Controls are not just a regulation.

They are an effective management tool to avoid costly mistakes and to improve product quality.
Summary & Status

US:
• Long-standing peer-reviewed research system
• Sophisticated (albeit litigious) patent office and courts
• Legacy 510(K) Products
• Process Technical Standards
  \textit{facilitates new product development}

China:
• Political and industrial research priorities
• “Gold rush” patent mentality
• Product Technical Standards
  \textit{how to introduce innovative devices?}
• Quality by Design starting for drugs...