Intelligent Health opportunities in Southern Greater China

8 November 2017
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3. Type your question here
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AGENDA

• Introduction

• Market Overview
  o Hong Kong
  o Taiwan
  o Mainland China

• Q & A
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<tr>
<th>Name</th>
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AUSTRALIAN GOVERNMENT: ASSISTANCE FOR BUSINESS

SAM GUTHRIE
SENIOR TRADE COMMISSIONER
AUSTRADE HONG KONG
ENGAGEMENT ACROSS GREATER CHINA
“GREATER BAY AREA” – HONG KONG, MACAU, GUANGDONG
“GREATER BAY AREA” – HONG KONG, MACAU, GUANGDONG

**Zhaoqing 始慶**
Area: 15,006 sq. km
GDP: USD 30.2 billion
Population: 4.06 M

**Foshan 佛山**
Area: 3,875 sq. km
GDP: USD 125.3 billion
Population: 7.50 M

**Zhongshan 中山**
Area: 1,770 sq. km
GDP: USD 46.4 billion
Population: 3.23 M

**Jiangmen 江門**
Area: 9,554 sq. km
GDP: USD 34.8 billion
Population: 4.54 M

**Zhuhai 珠海**
Area: 1,696 sq. km
GDP: USD 32.3 billion
Population: 1.68 M

**Guangzhou 廣州**
Area: 7,436 sq. km
GDP: USD 284.6 billion
Population: 14.04 M

**Huizhou 惠州**
Area: 11,159 sq. km
GDP: USD 49.5 billion
Population: 4.78 M

**Dongguan 東莞**
Area: 2,512 sq. km
GDP: USD 99.1 billion
Population: 8.25 M

**Shenzhen 深圳**
Area: 2,007 sq. km
GDP: USD 283.0 billion
Population: 11.90 M

**Hong Kong 香港**
Area: 1,104 sq. km
GDP: USD 319.3 billion
Population: 7.37 M

**Macau 澳門**
Area: 29.2 sq. km
GDP: USD 44.7 billion
Population: 0.64 M
TAIWAN PROFILE

TAIWAN
DID YOU KNOW?

- **Population**: 23.5 million
- **GDP (US$B)**: 566.8
- **GDP (US$ per capita)**: 24,027.7
- **Land Size**: 36,000sq km
  (approx. half of Tasmania)
- **Capital**: Taipei
THE HONG KONG MEDICAL DEVICE MARKET SITUATION AND OPPORTUNITIES FOR ENTRANTS

Richard Holloway, Managing Director
Fulcrum MedTech
As growth in developed markets slow, companies are focusing increasingly on emerging markets to fuel future growth.

Source - Euromonitor International
WHY HONG KONG?

**Strengths**
- Upstream supply chain access
- High per capita GDP expenditure
- Well developed hospital sector
- High quality of healthcare provision
- Government commitment to increased spending
- Receptive to advanced medical equipment
- Robust banking, legal and IP systems
- Company opening simplicity
- Low corporation tax rate 16.5%
- Strong compliance culture
- Language

**Weaknesses**
- Small population limits market
- Minimal private sector
- Low implant reimbursement prices
- Lack of private insurance coverage
- Minimal local manufacturing

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WHY HONG KONG?

Opportunities

- The gateway to China (import and export)
- China cross border traffic
- Demographics – ageing population, increasing burden of chronic disease
- Expanding private sector
- Growing wealthy middle class
- High demand for adjunct and consumer medical technology
- Minimal regulatory barriers to entry
- Commercially simple operating environment

Threats

- Regulatory changes underway
- Vulnerable to Mainland China influence
- Potential for political unrest
- Diminishing role as a regional hub
MARKET ENVIRONMENT

• Population 7.5 mio.
  • 16%, 65+

• Healthcare expenditure $US 20 bio. (6% GDP)
  • 45% government funded (bulk of volume)
  • No compulsory private insurance

• Hospitals 51
  • 38 public (Governing body, Hospital Authority (HA))
  • 13 private

• 2017/18 - additional $HK 2 bio. additional HA funding to meet demand
  • Hospital beds
  • OR sessions
  • Emergency surgical services
  • Increased focus on disease prevention
  • Significant capital equipment replacement since 2016/17
THE HONG KONG MEDICAL DEVICE MARKET

$USD mio.

CAGR + 6%

2018 | 2019 | 2020 | 2021

Consumables, $126.1
Diagnostics, $167.9
Dental Products, $37.5
Orthopaedics, $56.6
Patient Aids, $96.4
Other, $192.9

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REGULATORY LANDSCAPE

• Currently voluntary – progressive phase in of mandatory registration.
• Overseen by the Medical Device Control Office (MDCO).
• Device classification matches the EU.
• Leverage of prior approvals possible - Australia, Canada, Europe, Japan and the USA.
REGULATORY LANDSCAPE

Class I Devices

• No registration framework and can not be registered even voluntarily.
REGULATORY LANDSCAPE

Class II, III & IV Devices (Voluntary)

1. Appoint local company to act as a Local Responsible Person (LRP).
2. Demonstrate proof of market approval in AU, CAN, EU, JPN, USA
   - (e.g. CE cert. US FDA 510 (k) approval letter).
3. Submit MDACS application (form GN-05).
4. Appoint local Hong Kong importer.
5. Approvals valid for 5 years.
6. Process typically takes 8 – 12 mths.
REIMBURSEMENT

Private Insurance 55%

Public 45%

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DISTRIBUTION AND ACCESS

- Multiple domestic and international distribution partners -
  - Zuellig Pharma
  - DKSH
  - Auriga Healthcare (LF Asia)
MARKETING – DRIVING DEMAND

Driving Growth

1. Drive Mainland China consumer demand
2. Drive Mainland China consumer demand
3. Drive Mainland China consumer demand
INDUSTRY BODIES

• Hong Kong Medical Device Association
  http://www.medicaldevice.org.hk/en

• Hong Kong Association of Pharmaceutical Industries
  http://www.hkapi.hk
INDUSTRY CALENDAR

• Hong Kong International Medical Devices & Supplies Fair – 07-09 May 2018
SUMMARY

• Small and constrained market.
• Advanced healthcare market.
• Strong demand for new technology.
• Robust legal, finance, compliance and distribution infrastructure.
• Currently minimal regulatory barriers to entry.
• Low implant reimbursement prices.
• The gateway to China.
Incubating Disruptive Medical Technology in Asia

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Fulcrum MedTech - making ideas and innovation a reality by navigating our clients through the challenges and complexities of commercializing disruptive medical technology in the diverse and dynamic markets of Asia.
LEADERSHIP

Fulcrum MedTech

• Managing Director and Founder – Richard Holloway MBA
  - Driving profitability in the medical device and biotech industries for over 25 years.
  - Unique cross functional leadership experience in Asia, The United States and Europe from "startup" through to "Blue Chip" medical device, biotech and pharmaceutical companies with revenues more than $US 550 Million and 400 + people.
  - Corporate experience includes BBraun, Stryker, Orthofix, DKSH and ConvaTec.
  - Strategic focus on the orthopedic, spine, neuro and cardiovascular sectors.
  - 3 time elected Board Director of the HKAPI, (Hong Kong Association of Pharmaceutical Industries) 2009 – 2015.
SOLUTION

Fulcrum MedTech

STRATEGY EXECUTION
Seamless business partnering providing leadership, functional and operational support as required

Agility and responsiveness

STRATEGY OPTIMISATION
Ownership 24/7 to support with tactical adjustments to remain on track

STRATEGY DEVELOPMENT
Bespoke, tailored to the individual needs of our clients, their technology and environment

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TAIWAN'S MEDICAL DEVICE INDUSTRY AND BUSINESS OPPORTUNITIES

DR. CHAO-PIN LEE, DIRECTOR
BIOTECHNOLOGY & PHARMACEUTICAL INDUSTRIES PROMOTION OFFICE (BPIPO)
MINISTRY OF ECONOMIC AFFAIRS
A Glimpse of Taiwan’s Medical Device Industry
Taiwan’s Bio-Industry Grows Continuously

◆ Overall revenue of 9,752 million USD
  - Revenue of 4,380 million USD for medical device, 6.4% growth rate
  - 1,073 medical device companies

Source: Biotechnology White Book, IDB (2017)
Taiwan’s Medical Device Industry Value Chain

Taiwan’s manufacturers have excellent manufacturing capabilities and professional capabilities for key component production and clinical research.

R&D
- Academic Institutions
- Research Organizations (NGO)

Biomedical engineering, chemical, engineering, electromechanical, engineering, life sciences, etc.

ITRI
- Orthopedic surgical device, Miniaturized medical device

MIRDC
- Artificial joint, Surgical instrument, Dental instrument

NHRI
- Biomedical photoelectric device, Interventional medical imaging

PIDC
- Polymeric medical material and processing technology

FRT
- Rehabilitation and nursing medical material

NCSIST
- Medical imaging

Materials Parts
- Plastic, textile, chemical
- Photoelectric precision instrument
- Electronic, semiconductor
- Chemical/Biochemical raw materials
- Metal tools/parts

Product Manufacturing
- Medical treatment equipment
- Medical imaging diagnostic equipment
- In-vitro diagnostic equipment
- High-grade biomedical material product

Sales Services
- Medical device distributors, Hospitals and clinics, Chain stores

Commercialization
Bio-Clusters

Over 100 research-focused companies; 5,000+ graduates/year in life sciences
132 PIC/s GMP facilities; 1.5 hrs travel time from north to south

- Medical Electronics
- Medical Imaging
- Rehabilitation
- Microsurgery Medical Devices
- Medical Implants
- Diagnostics
- Medical Electronics
Opportunities for Collaboration
Taiwan’s Global Leading Industries

- **3C Products**: Notebook, Computer mainboard, Foundry service, Modem, Monitor, Scanner, Keyboard, CD/DVD, Graphic card, Net-connect card, Computing hub, Smart phone
- **Material Engineering Products**: ABS, PU (polyurethane), PPE (polyphenyl ether), and textile products
- **Precision Machinery and Plastic Injection Molding**

**Images:**
- Motherboard
- TSMC
- Precision Metal/Plastic Injection
- Mobile Health
- ASUS Smart Watch
- Medical Monitor
- Endoscope
- MEMS/BioMEMS
- Ultrasound
- Smart Cloth
- Garmin Wrist
- Glucose Testing
- Dental Implant
- DR
- Contact Lens
Potential Areas for Collaboration in Medical Device
~ Prototyping, Manufacturing and Channel

Rapid Prototyping

Manufacturing

Channel

Product Type:
- Plastic Injection
- Precision Metal Machinery
- Bio MEMS
- Nano wire chip design
- Robot

Product Development:
- Concept & Industry Design
- Quality Document, Quality Test
- FDA application plan
- Clinical Trial

Strategic partners into China & south east Asian market
Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO)
Single Contact Window for Taiwan’s Biotech Industry

Global / Domestic Company

Looking for Business Opportunities:
• Products Contract Manufacturing/Marketing
• Investment
• Technology transfer
• Joint venture
• R&D incentives and policy info.
• Others
Example 1 - Rapid Prototyping & Manufacturing

One Israel company with their 3D printing sample looked for

- Plastic injection
- Venture
- FDA regulation service

Result: Small scale production done in 1 month (ready for large scale production)

Company with idea or sample

1. Provide information to BPIPO
2. Found manufacturer in 1 week
3. Discussion on industry design, quality document, manufacture…etc.

Got product!
Example 2 – Manufacturing & Funding

Canadian companies with medical devices in different development stages looked for

- Funding
- Strategic partner with manufacturing capability
- Channel to Asian market

Result: At least 5 companies showed interests in M&A or Joint RD; one company got a manufacture partner, and product is on China market now

- Company provide business plan
- BPIPO identified potential partners and investors
- BPIPO arrange seminar/visiting for business presentation and matching
Thank You for Your Attention

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A DEEPER INSIGHT OF CHINA AND CFDA REGULATION UPDATE

Mike Gu, Managing Director
OSMUNDA - Chinese Device CRO
Total Sales Revenue:

2001 17.9 Billion
2014 256 Billion
Growth: 14.28

China Medical Device Industry

### 2010-2016 China Medical Device Revenue (Billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue</th>
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<tbody>
<tr>
<td>2010</td>
<td>120</td>
</tr>
<tr>
<td>2011</td>
<td>147</td>
</tr>
<tr>
<td>2012</td>
<td>170</td>
</tr>
<tr>
<td>2013</td>
<td>212</td>
</tr>
<tr>
<td>2014</td>
<td>256</td>
</tr>
<tr>
<td>2015</td>
<td>308</td>
</tr>
<tr>
<td>2016</td>
<td>370</td>
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### China Medical Device Industry

<table>
<thead>
<tr>
<th>Area</th>
<th>Characteristic</th>
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<tbody>
<tr>
<td>North</td>
<td>Digital Medical Device such as DR, MRI, Ultrasonic, electron accelerator, Navigation, Bone implantable product etc.</td>
</tr>
<tr>
<td>Eastern</td>
<td>Disposable medical device as infusion set, syringe, IVD etc</td>
</tr>
<tr>
<td>Southern</td>
<td>High-tec medical device such as monitoring, Ultrasonic, MRI, CT, stereotactic radiotherapy etc.</td>
</tr>
<tr>
<td>Total Sales Revenue:</td>
<td>100Billion</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Manufacturers:</td>
<td>2200</td>
</tr>
<tr>
<td>Distributor:</td>
<td>10,000 plus</td>
</tr>
<tr>
<td>CFDA license:</td>
<td>6500 plus</td>
</tr>
<tr>
<td>Listed Company:</td>
<td>20</td>
</tr>
<tr>
<td>Major city:</td>
<td>Shenzhen</td>
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<tr>
<td></td>
<td>Guangzhou</td>
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<th>Product Series:</th>
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<tbody>
<tr>
<td>Monitoring</td>
</tr>
<tr>
<td>Ultrasonic</td>
</tr>
<tr>
<td>MRI CT etc imaging equipment</td>
</tr>
<tr>
<td>IVD</td>
</tr>
<tr>
<td>Stereotacttic radiotherapy</td>
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Top 10 Country with Imported Medical Device Registration Certificate

USA take up about 37%, more than the total amount combining that of Germany and Japan.

Top 10 countries take up 90% of all.

Top 3: EU, USA, East Asia.
China Medical Device Hot Spot

- Liquid biopsy
- POCT
- NGS
- Tumor biomarker

- Implantable
  - Knee joint
  - Hip joint
  - Absorbable material

- Vascular
  - DES
  - Drug coating PTCA
  - Drug coating PTA

- Medical Imaging device
  - PET/CT
  - MRI

- Rehabilitative appliance
  - Robotic-assisted device

- IVD
  - PET/CT
  - MRI

- Hot
1. Registration in country of Origin
2. Having a China Agent
3. Find a experienced CRO company
4. Find a good partner for distribution

Does my device require a Clinical Trial in China for CFDA registration?
Medical Device GMP

New version effective since 2016.6.1
Old version effective since 2004.4.1

Medical Device GCP

New version effective since 2018.8.1
Old version effective since 2004.4.1

Medical Device Classification

New version effective since 2018.8.1
Old version effective since 2009.12.16
CFDA Registration Process-General Flow Chart

Data Collection → Product Technical Requirement → Clinical Trial → Registration Application → Accreditation & Certification
### Dossier to the CFDA

**Dossier Acceptance:**
- **5 working days**

**Dossier Transfer:**
- **3 working days**

Class II: 60 working days  
Class III: 90 working days  
Note: Must be completed within 1 year, otherwise case is rejected

- **60 working days**

- **20 working days**

- **10 working days**

- **60 working days**

- **188 Working days**

**Note:**
1. Time in red is the administration time of CFDA, which cannot be shortened.
2. For innovative product, the CFDA may call for an expert committee review.
3. Supplementary Information Preparation can be accelerated by the Applicant.
201508  Opinions of the State Council on the reform of the review and approval system for pharmaceuticals and medical devices 《国务院关于改革药品医疗器械审评审批制度的意见》

General Office of the CPC Central Committee

General Office of the State Council

20171008  <Opinions on deepening the reform of review and approval system and encouraging the innovation of pharmaceutical and medical devices > 中办 国办印发《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》
20171008

Opinions on deepening the reform of review and approval system and encouraging the innovation of pharmaceutical and medical devices

1. Reform of the management of clinical trials
2. Accelerate the pre-market review and approval
3. Promote drug innovation and generic drug development
4. Strengthen the pharmaceutical and medical device whole life cycle management
5. Improve technical support capability
6. Strengthen organization and Implementation

Clinical site from approval to recording
EC extension and only PI EC approval
Overseas CT acceptance
Strict punish to falsified CT
Green Channel for innovative product
Priority review for urgent product
Orphan drug
MAH
Post market for MAH
Improve the CFDA approval process
Confidential requirement
All involved element scrutiny to ensure truth
Highlights and Trends

1. Policy Support from the Top Administration, especially for domestic devices
2. Permission of private capitals to healthcare
3. National Investment of 130 Billion USD in the next 8 years: Healthcare system
4. Improvement of insurance system
5. Aging society, chronic disease and sub-healthy
6. Home care and wearable devices
7. Incubators, investment and acquisitions
CLINICAL TRIALS
- Class II/III medical device clinical trials
- Clinical trials for IVD reagent
- International Multi-center clinical trials
- Clinical trial protocol design
- Clinical trial monitoring
- Data management and biostatistics
- Clinical trial report writing
- Animal studies for medical devices

CFDA REGISTRATION
- CFDA recording for Class I medical devices and CFDA Registration for Class II/III medical devices
- CFDA registration for IVD reagent
- CFDA Manufacturing License
- CFDA Registration for Imported medical devices

OVERSEA REGISTRATION
- EU CE (MDD, IVDD, PPE, AIMDD)
- US FDA (listing, 510K, PMA)
- Canada HC / Australia TGA
- Japan MHLW / Korea KFDA / Brazil ANVISA

Stock Code: 835575
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