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Strategies for Successful Biomedical Engineering (BME) Industry in Asia

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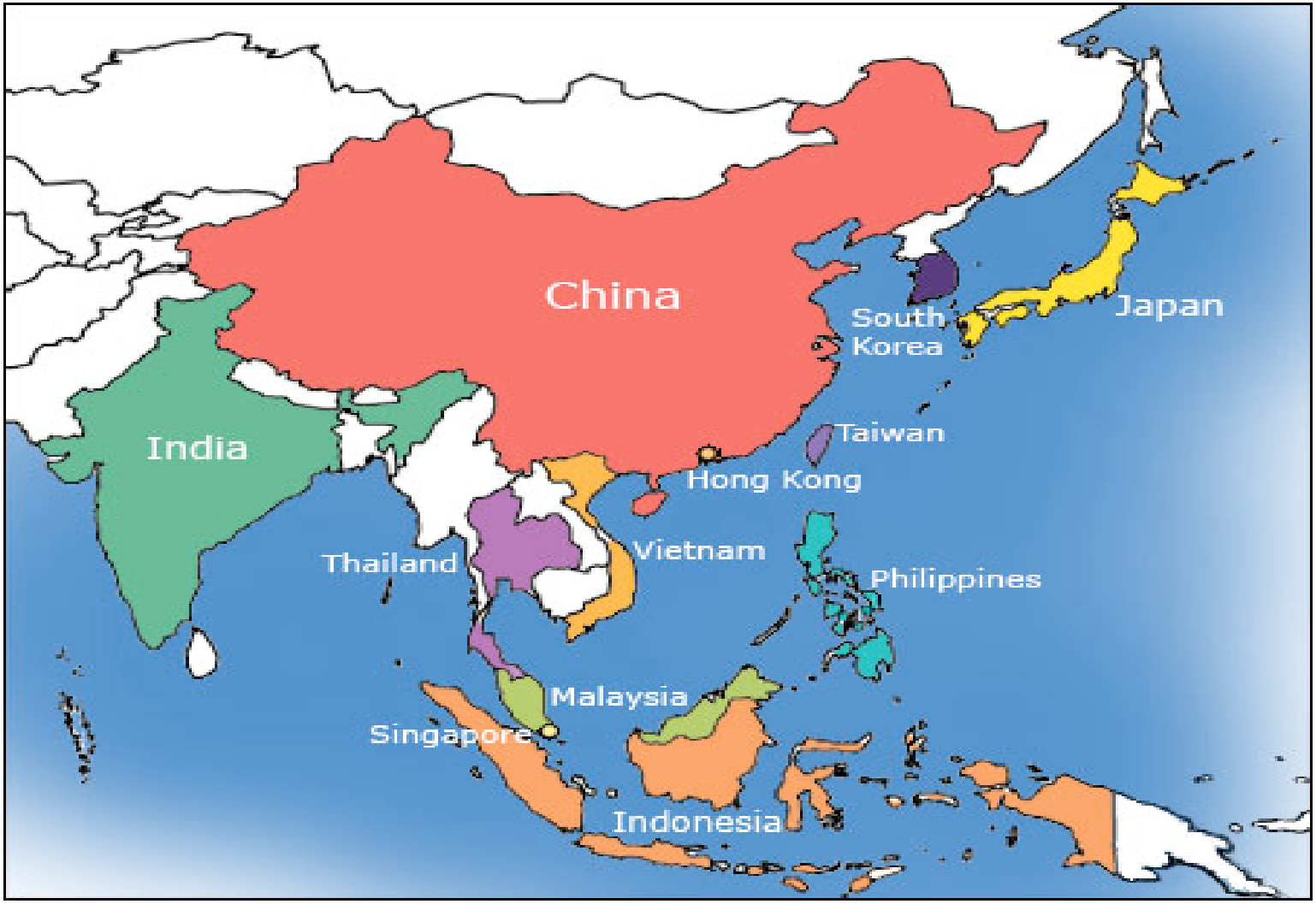
Outline

- Overview the BME Market in Asia
- R&D and Clinical Trials in Asia
- Strategies for BME Development in Asia Countries

Overview of Asia



Source: Pacific Bridge Medical

Demographics

Country	Population (millions)	Population Growth	GDP (PPP)	Per Capita Income (PPP)	Life Expectancy (Years)
China	1,322	0.61%	$10.21 trillion	$7,800	72.88
Hong Kong	7.0	0.56%	$259.1 billion	$37,300	81.68
India	1,130	1.60%	$2.965 trillion	$2,700	68.59
Indonesia	235	1.21%	$948.3 billion	$3,900	70.16
Japan	127	-0.09%	$4.218 trillion	$33,100	82.02
Malaysia	24.8	1.76%	$313.2 billion	$12,800	72.76
Philippines	91	1.76%	$449.8 billion	$5,000	70.51
Singapore	4.55	1.28%	$141.2 billion	$31,400	81.8
South Korea	49	0.39%	$1.196 trillion	$24,500	77.23
Taiwan	23	0.61%	$631.2 billion	$22,600	77.43
Thailand	65	0.66%	$596.5 billion	$9,200	72.55

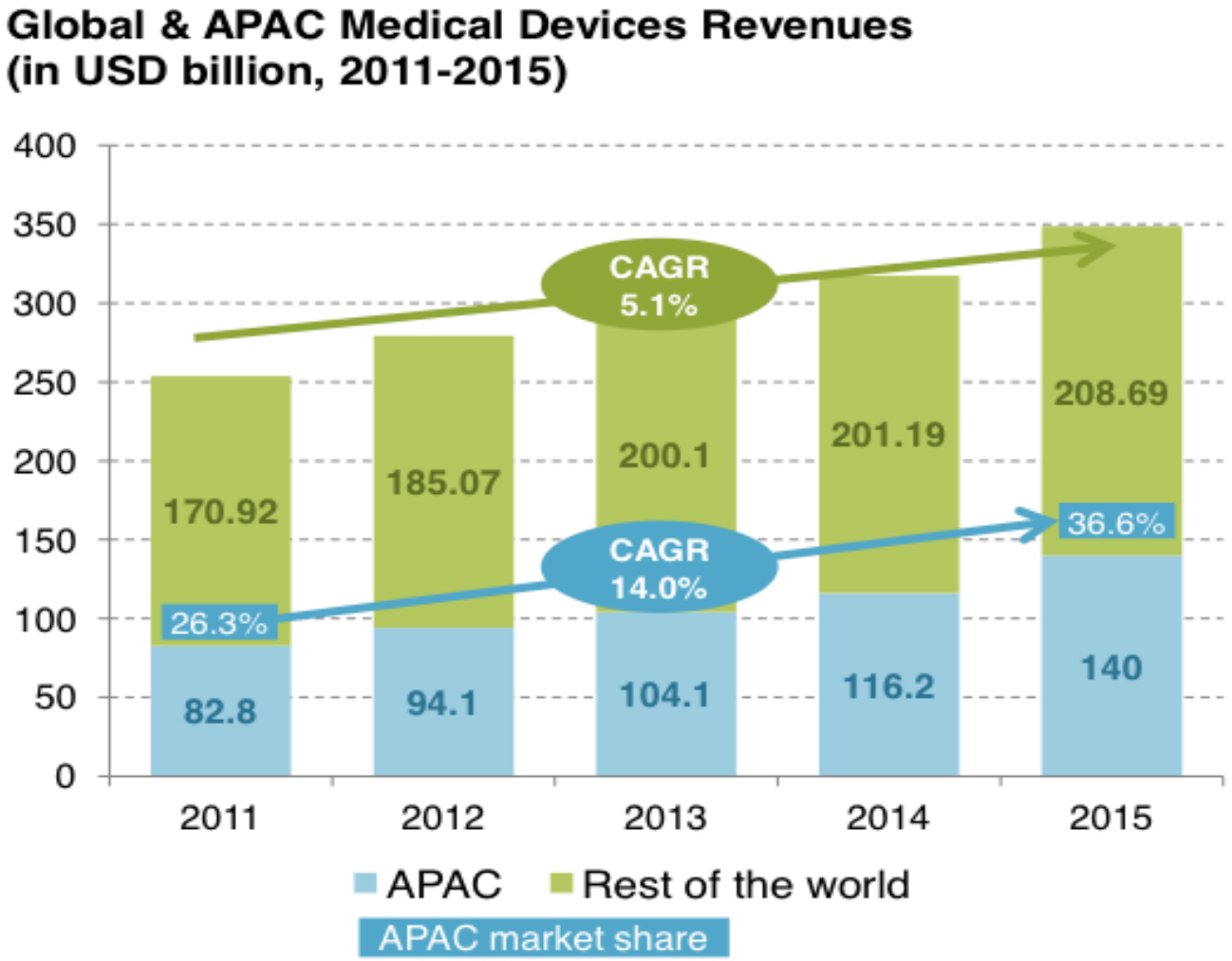
Source: CIA World Fact Book 2006

Asia Health Statistics

	Health expenditure per capita	Health expenditure as % of GDP	Physicians per 1,000 people	Hospital beds per 1,000 people
China	$61	5.6%	1.6	2.5
India	$27	4.8%	0.6	0.9
Indonesia	$30	3.1%	0.1	6.0
Japan	$2,662	7.9%	2.0	14.3
Korea	$705	5.6%	1.6	7.1
Malaysia	$163	3.8%	0.7	1.9
Philippines	$31	3.2%	1.2	1.0
Singapore	$964	4.5%	1.4	2.9
Thailand	$76	3.3%	0.4	2.2
Taiwan	$743	5.6%	7.4	5.7
Vietnam	$26	5.4%	0.5	2.4
USA			2.7	3.4

Source: World Bank, World Development 2006

The Growth Rate
Medical Devices Revenues in Asia

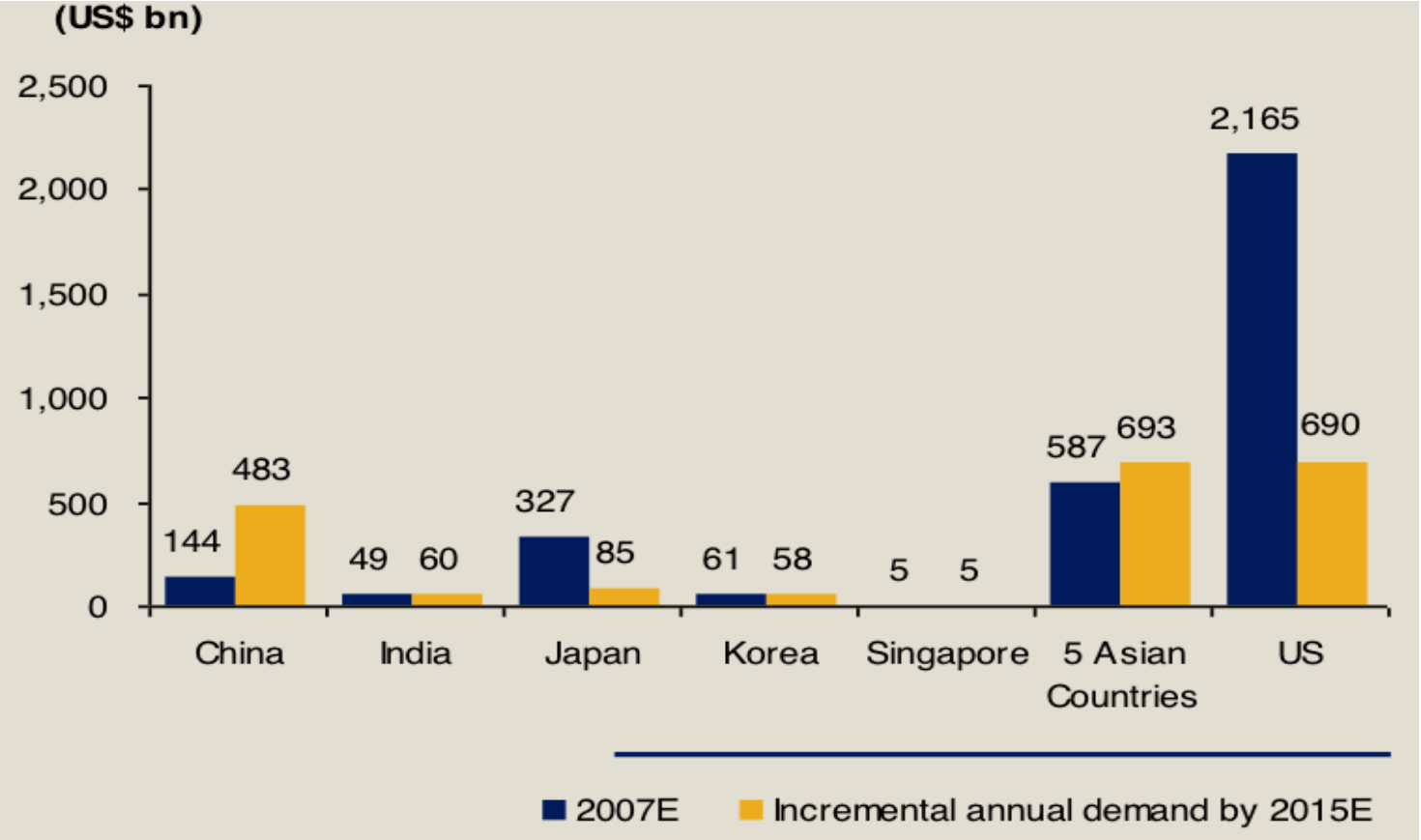


CGAR: Compound Annual Growth Rate

APAC: Asia and Pacific

Source: Frost & Sullivan- Asia Pacific Overall Healthcare Outlook 2012-2015.

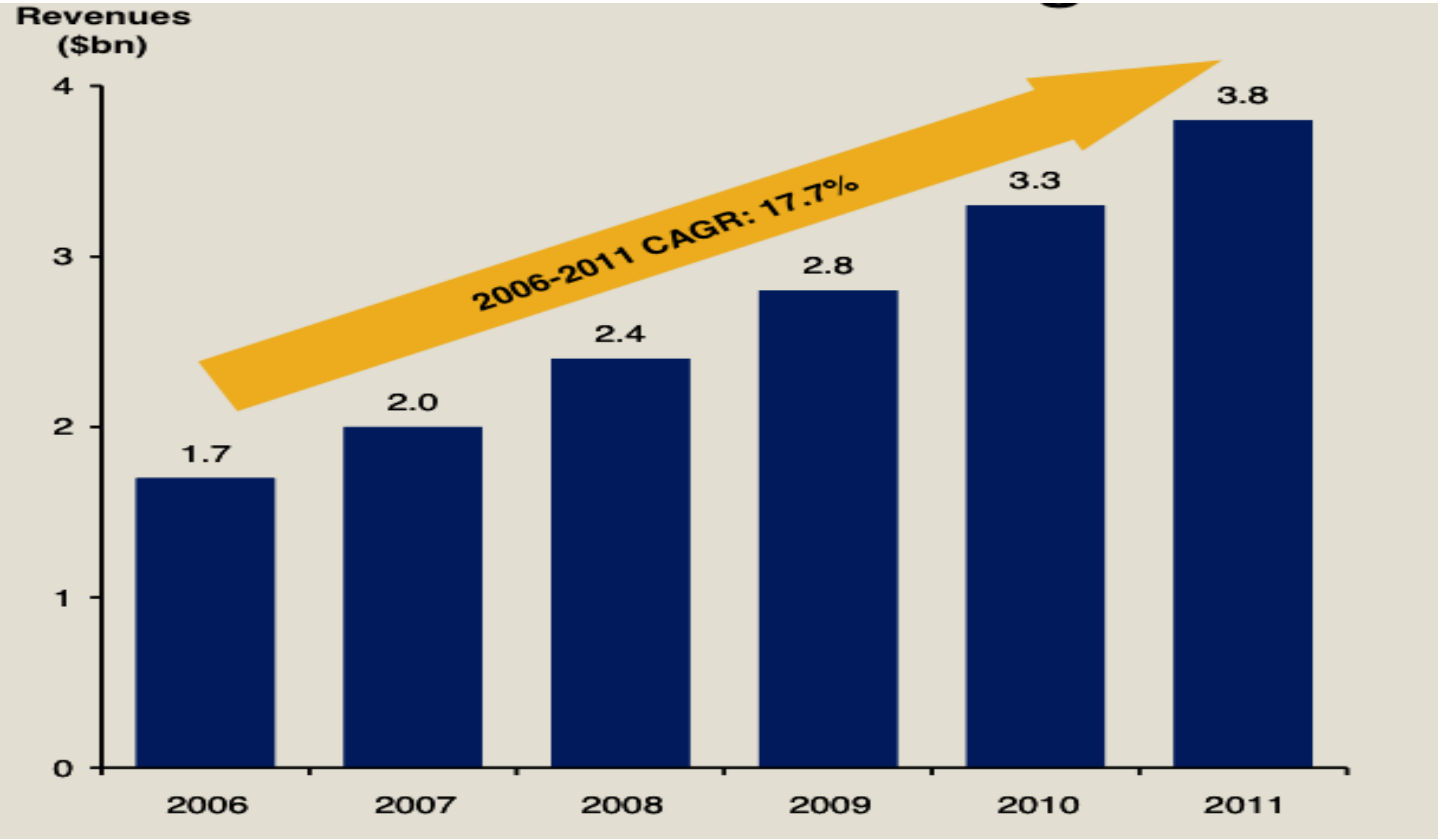
Healthcare Expenditure



-Young populations with increasing disposable income
-Aging population requiring more expensive healthcare treatment

Source: Broker's research report

Medical Outsourcing to Asia

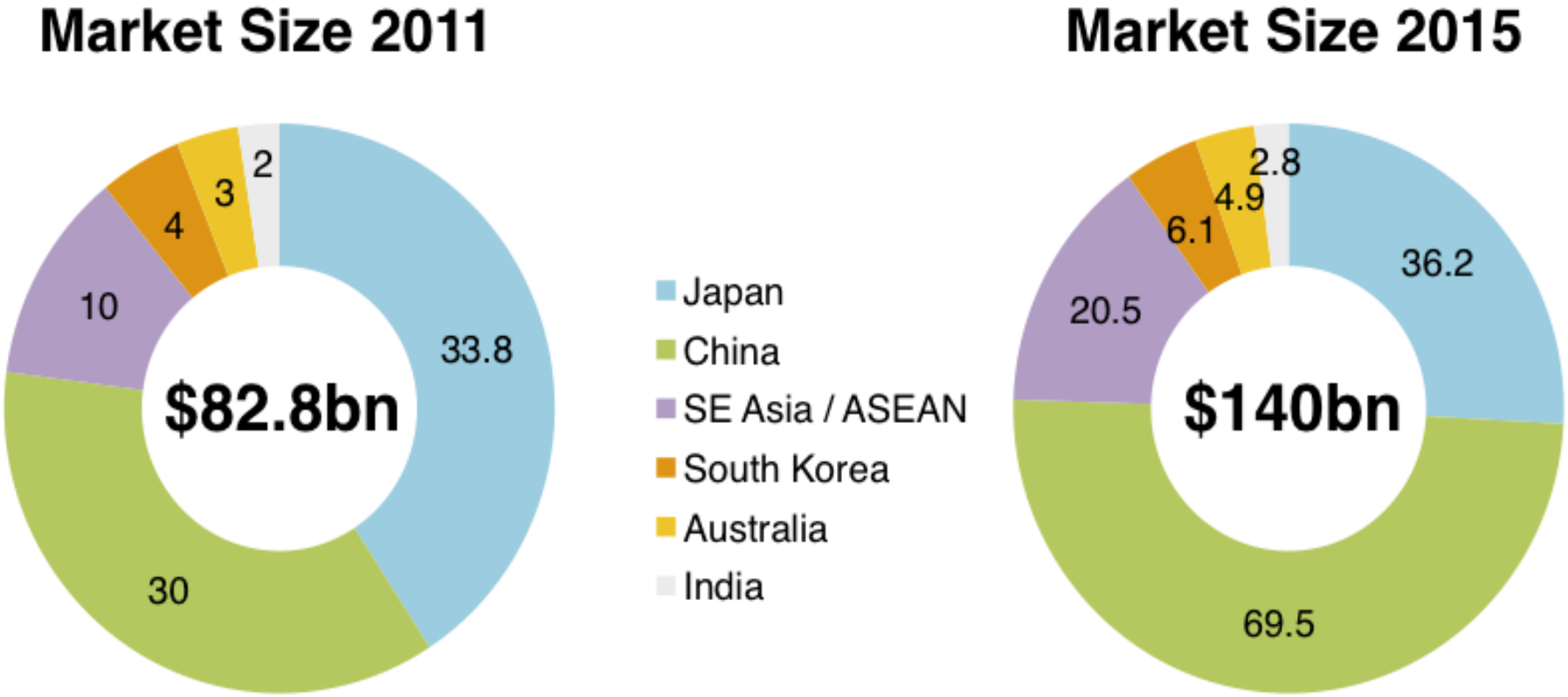


-Increasing contract manufacturing, contract research and medical tourism

Source: Broker's research report

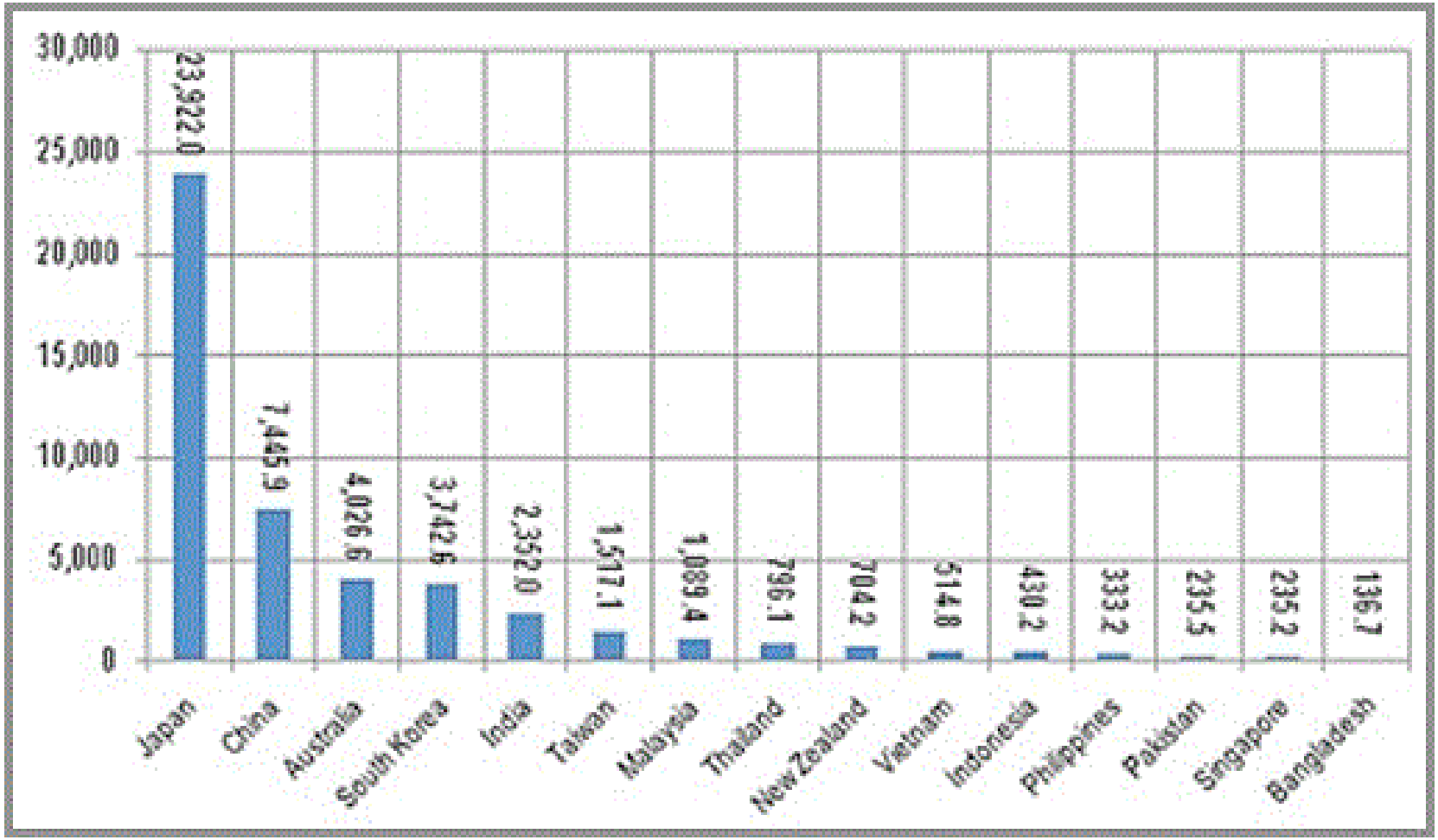
Medical Devices Market Size by Country

~ 60% ↑



Source: Frost & Sullivan- Asia Pacific Overall healthcare Outlook, Espicom, BCC Research (2010), Big Emerging Market Reports 2011

Total Asian Medical Device Market, 2012



Source: Espicom 2012

3 Factors of Growing Market in Asia

Growing aging population

Higher economic growth

Increasing population size.

Percentage of population above 65 years (Asia), 2007-2012

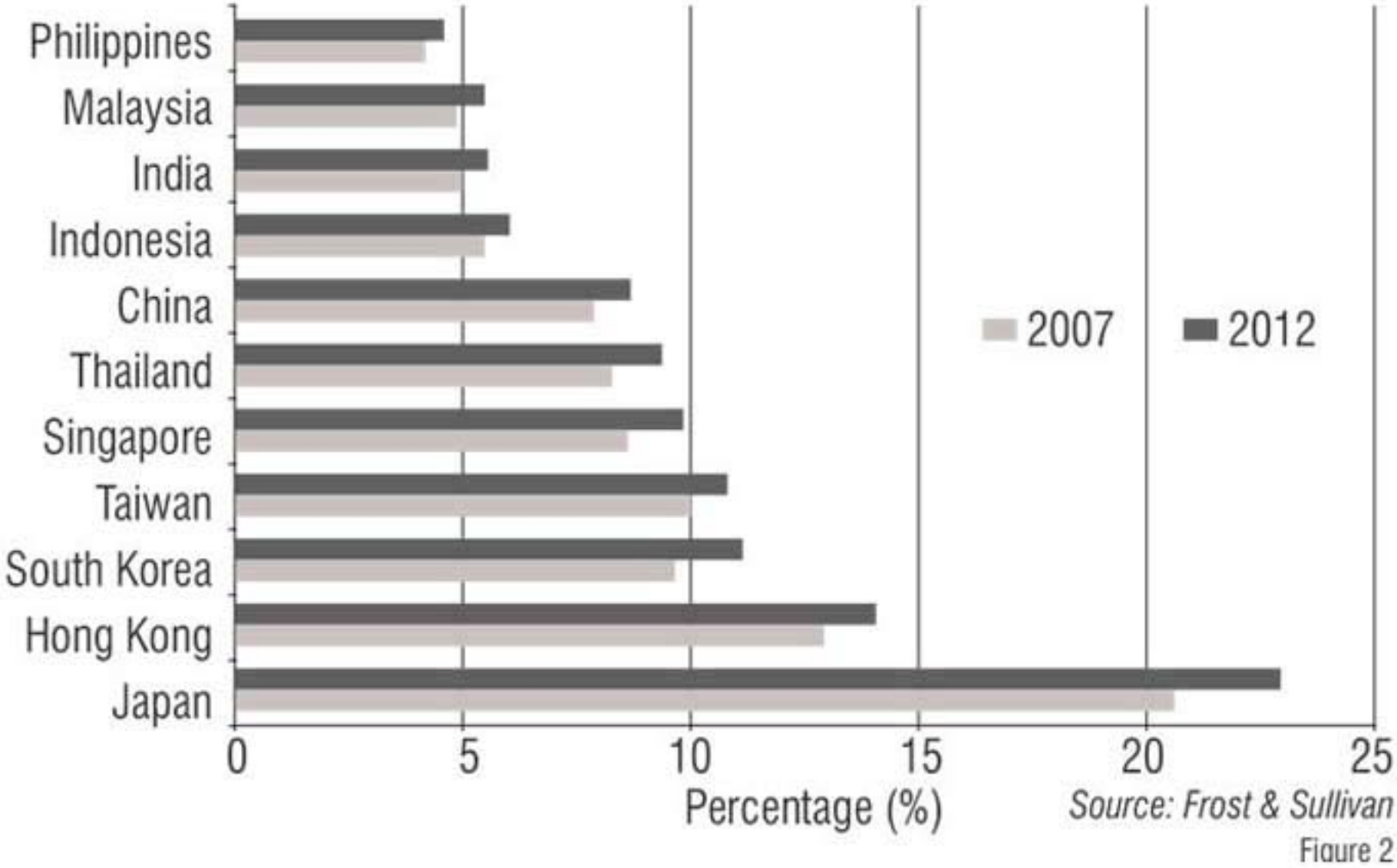


Figure 2

- **R&D and Clinical Trials in Asia**

BME R&D Increase in Asia

- **Focus on two crucial measures:** 1. cost-cutting 2.developing new, innovative and more effective products.
- **China & India being the most popular location:** relative low cost of well-trained science and engineering staff ($2,000 to $10,000 a year)
- **Examples of major R&D firm in Asia:**

  - Stryker: India (joint, spine neurology, endoscopy and imaging)

  - GE Healthcare: China (imaging system)

  - Siemens: Korea (ultrasound and diagnostic technology)

  …….

R&D in Asian Market & Investment Incentives

- Asian R&D center can develop and alter products to meet Asian needs
- Numbers of **R&D parks an industrial development zones** establish by government across Asia.
  - Singapore's Biopolis
  - Taiwan's Kaohsiung Science Park (Medical Device Special Zone)
  - China's Zhangjiang High-Tech Park
- **Intellectual property (IP) protection is one of concern**, especially in China & India. However, now in accordance with World Trade Organization standards.

Outsourcing Medical Device to Asia

Many international medical device companies choose to source or manufacture their devices in Asia.

Relative low labor cost- China, Vietnam, India, Indonesia

Low overhead costs- rent, utilities, component, raw materials, equipment

Improving technical capabilities- capable of producing Class III medical device

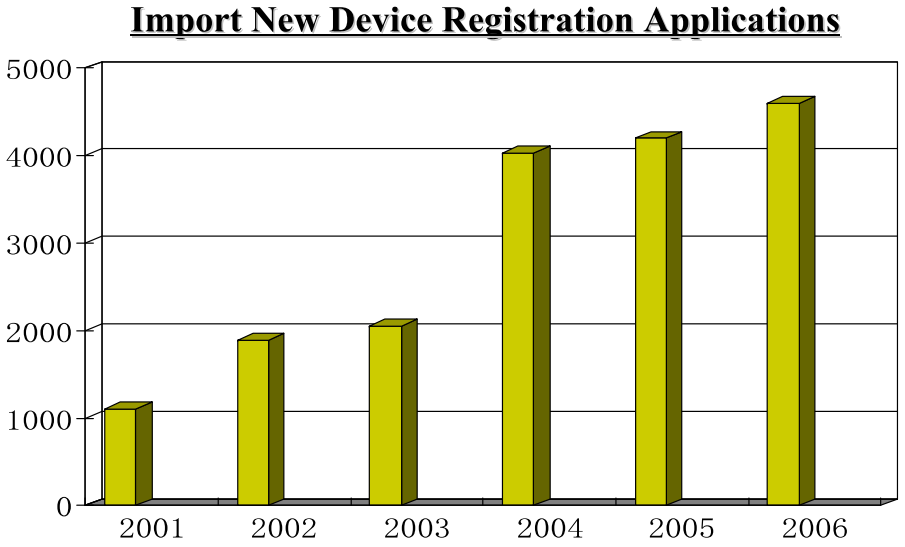
Proliferation of special economic and free trade zones- lower tariffs and duties to foreign companies

Clinical Trials in Asia

- With two-thirds of the world's population, subjects with rare diseases tends to take shorter time than US & Europe
- Clinical trial cost roughly 1/3 in Western countries, except Japan
- India has a large number of local CROs. However, most focus on pharmaceutical than devices.
- The quality of clinical data is still a issue some of countries in this region

Overview of China's Medical Device Markets

- Medical device market is valued at around $30 billion, and is expected to reach $69.5 billion by 2015.
- Annual growth rate of 14 - 15%
- Market capacity of China's medical device industry has been growing year after year
- China has become one of the 10 emerging global medical device markets, Asia's largest market after Japan



Source: Pacific Bridge Medical

Outsourcing Medical Device to China

- Nearly 3,000 medical device manufacturers
- Quickly improving in quality
- GMP are now standard for medical device
- Free trade zone in Shanghai: focus on research and product innovation in the life science
- Recently, the cost increase dramatically- some companies transfer to Vietnam or India.

Focus on Medical Device in China

- Chinese government officials have made the medical device industry an important priority.
- Government increase their funding for product development and medical device research.
- A good case study: drug eluting stent (DES) device.
  - Now, three-quarters of the Chinese DES market is controlled by local Chinese DES firms
  - Foreign companies market share reduce from 85% to 25%
- In 2011, the SFDA issued "Tentative Guidance for the Monitory of Adverse Device Events", ***medical device emergencies must be reported within twenty four hours…***

The Major Strategies to Boost BME Industry Development in China

Priority items to be developed (Medical X-ray, MRI,…)

→ To provide all kinds of incentives to attract major manufactories (GE, Philips, …) to setup branch in China

→ Tax-waive(first 3 years)/reduction (in next 3 year), free land acquired (20 years), stable power & water supply, special area for staffs from abroad,….

→ *All the devices/modules/parts (tube, software, power supplier, TFT, sensor…) should buy from local industries*

→ If there was no such a tech to produce the necessary parts in China, they are obligatory to teach them how to produce the parts/modules; and all tech transfer fee support from government!! (local company has to propose the project → committee → review system)

→ To produce advanced BME product in relative short term without IP infringement!!

→ *In China for China with the most population over the world*

→ Malaysia, Thailand, Vietnam …..

Outsourcing Medical Device to India

- Since the mid-1990s, significant advance take place
- Lower cost of labor than China
- Technical capabilities are improving
- Large population of English-speaking worker
- More than 170 special economic zone: exemption duties and taxes

Focus on Medical Device in India

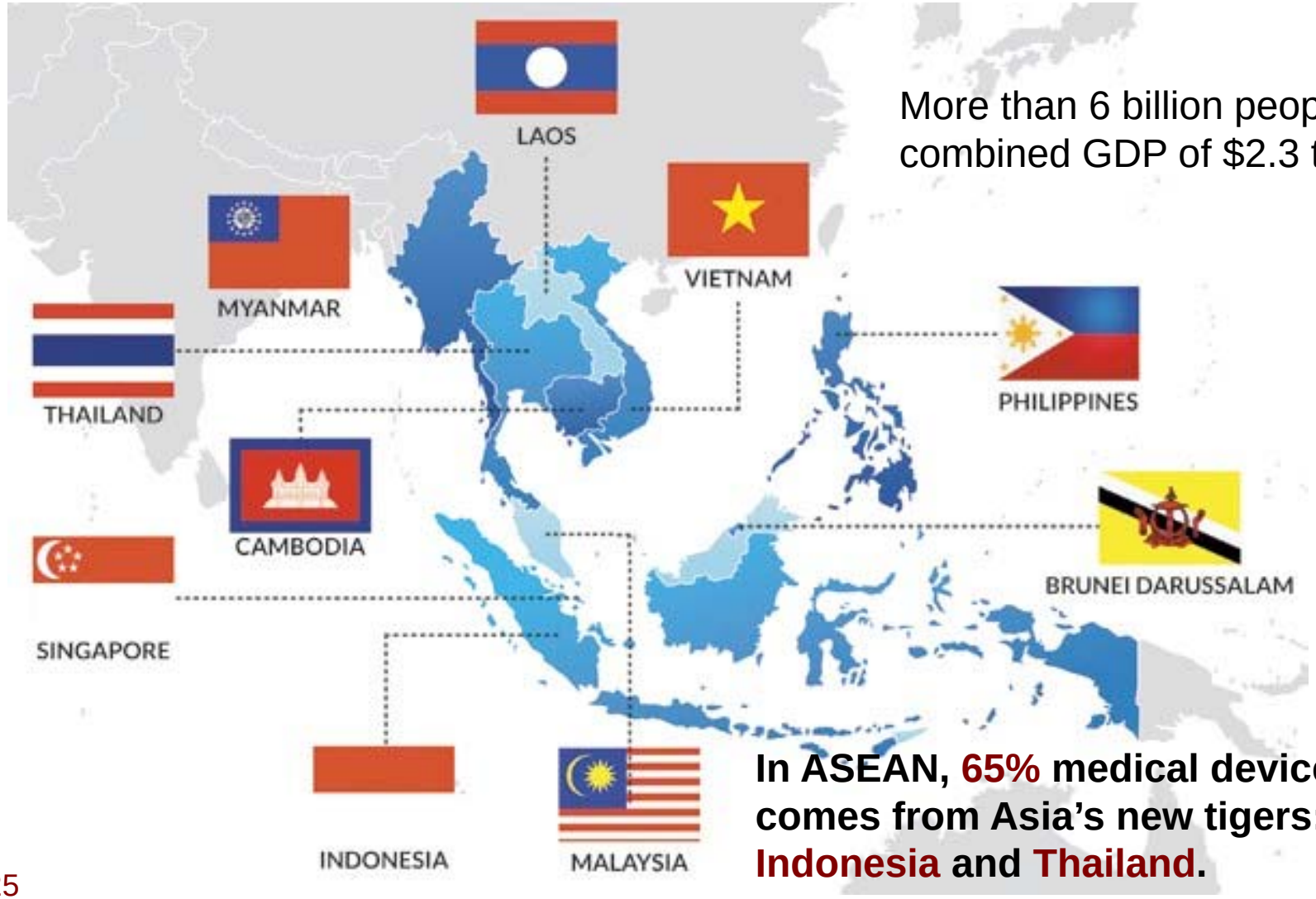
- Medical device market was estimate $3.2 billion in 2011, trailing only Japan, Chia, South Korea in Asia.
- Approximately 72% of medical devices are imported
- Uptick in healthcare spending by private sector
- The Medical Device Bill was introduced in 2012 for ushering in a more comprehensive and structured legal framework for medical device companies operating in India
- Indian medical device regulations are still a work in progress
- **With rapid economic growth & huge population will continue to demand better healthcare services and products.**

Strategies of BME Industry Development in India

Not very strong/solid in manufacture infrastructure

- → Less support to BME industry
- → CROs on Pharmaceutics & Software Development (GVK biomarker data base)
- → It is very flourishing in personal workshop or machine shop
- → To solve problem in certain area and to take job order from internet
- → To setup website to make description what they can do.
- → They all have very good personal skill
- → Government did not have clear policy to boost BME industry due to too much interference factors in politics & religions (multi-racial over 200 tribes no one in domination, more than 40 official languages, different religions & cultures, ….)

Association of Southeast Asian Nation (ASEAN)



More than 6 billion people
combined GDP of $2.3 trillion

In ASEAN, 65% medical device market comes from Asia's new tigers: Malaysia, Indonesia and Thailand.

Focus on Medical Device in Malaysia

- Market is driven by imports, especially high end products
- The Medical Device Act 2012 requires all imported device to be registered by July 2013
- The Medical Device Act 2012 calls for the licensure of all medical device establishment.
- The Medical Device Authority (2012): responsible for enforcing new regulations and promoting the medical device industry in Malaysia.

Outsourcing Medical Device to Malaysia

- Large population, inexpensive land, low wages
- Malaysian Industrial Development Authority: identify medical device as a priority sector for development
- Concentrate in rubber based products- leading in medical gloves and catheters.

Outsourcing Medical Device to Vietnam

- Low-cost alternative to China
- Most focus on low-end products- medical disposables, hospital garments, hospital furniture
- Has a number of industrial parks, export processing zone, and high tech zone
- Enterprises in these zones that export more than 80% of their production may receive corporate two- to eight-year income tax holidays and pay a reduced income tax rate after that period.

Focus on Medical Device in Singapore

- Many large medical device companies manufacture products in Singapore. (good location for sophisticated medical device)
- Because large pool of English speaking scientists, researchers and engineering (human resource)
- Provide robust IP protection
- **Singapore's Economic Development Board** promotes and sustains the country as a global business and investment hub, and offers numerous incentives to companies locating manufacturing operations there
- Provides strong protection for IP rights

Strategies of BME Industry Development in Singapore

To use strength of the countries (banking service, multi-language speaking, multi-racial, relatively public security, …) and to provide all kinds of incentives…

→ to attract the major BME manufactories to setup Asia (Far-Eastern) R&D Center in the city country

→ To cooperate with local research institutes to develop new tech or modules/devices

→ They do not develop a whole set; instead, they play the role as a BME tech provider, to provide a total solution for BME industry demands

→ To sale out the developed tech for value-added product with tech transfer fee and royalty (milestone payment…)

Strategies of BME Industry Development in Korea

Very solid industrial infrastructure and techniques

→ Korea could produce the necessary medical devices by local industry or companies.

→ However, all these companies (although good quality) do not have a reliable trade name (Siemens, Toshiba, Olympus, …) to earn the quality trust from customers

→ To push the small-&-medium entrepreneurs to join to world famous companies (Samsung, Hyundai, Kia, LG….) to organize into a cluster.

→ To sale out the product as the name of the mentioned companies to earn the trust from the customers

→ Government deliver more money to those companies who are willing to join the cluster.

Strategies of BME Industry Development in Japan

Japan has a well-developed BME industry

→ the major challenge is how to keep its edge on the BME product

→ Earth quake happened in high frequency, Nuclear power plant damaged by Tsunami/EQ, high payment for the staff, high production cost….

→ Move the manufactories to lower cost countries but keep R&D in Japan

→ No staff would like to work away from home due to children education….

→ Government help setup Japanese communities abraod (school, Japanese market/restaurant, dormitory, subsidiary….)

Strategies of BME Development in Taiwan

BME Industry is different with the other industry in development:

In other industry would be 3 stages:
R&D → manufacture → product
In the BME development chain would be 5 stages:
R&D → prototype for in-vitro (bio-compatibility test) & animal study (rat, mice, rabbit..) → manufacture → pre-clinical & clinical test (with batch number) → market

In the BME development chain in Taiwan
very good in R&D (Ranking 4th to award USA/EU patent), very good infrastructure and solid strength in every aspects of manufacturing (fine machining, ICT, computer, chemicals, pharmaceutics…), very strong in marketing, but could not develop a global famed BME product

Strategies of BME Development in Taiwan

Must be some of gaps existing in the BEM development chain to make traditional industrial stay away from BME industry

→ In BME industry, from R&D to Product is as-so-called death valley that is money and time cost to go through. Taiwan is a small island. Most of entrepreneurs (small-&-medium) don't like to wait long time without investment coming back.

→ Regulation hurdle

→ Super-incubation Center to fast produce prototype for test or clinical trial, to setup pre-clinical trial and animal center

→ To go clinical trial free..

R&D → Manufactory → Product → Marketing

Raw materials
Knowledge & Innovation
High Value-added Products

Pioneer Tech (Burning Money)
Advanced Tech
High Tech

Low-end Tech (Labor-intensive)

Medical Devices and Products in Taiwan

Before 1990~
(General Health Insurance to go by 1992!!)

After 1995~
Bandage, syringe, catheter, tube, plate & screw…
(Biotech, Sun-Tech., Chitosan….)

Bed-side monitor, biochemical analyzer, glucose-meter, uric acid meter, surgical cloth, TKR-THR, rehabilitation devices, home-care system, devices for handicap people…
(Biocare, Home-med, Med-Tech,….)

Parts and Modules:
Robotics, MRI, X-ray, Ultrasound, CT-scan, Laser, Pacemaker, Endoscope, …

Strength:
Traditional industry, Informatics, Computer and accessories, Electronics, Medical research…

Weakness:
Regulation, Accreditation lab. (Animal Study, Preclinical Study, Pre-marketing Study, Approval & Certificate), Private sector…

Opportunity:
Parts and Modules → Environment → Industry

Threaten:
Mainland China, Korea…

To Develop One Industry (Whole Set) to Boost Others?
→ For instance, MRI to boost TFT, Sensor, Motor, Power Supplier…..
→ HP, Siemens, GE, Philips, Nova…

To Encourage Parts/Modules Industry?
→ BME Service Center
→ Cluster Formation
→ BME Industry

In the past, Taiwan develop different industry all started from service and to form cluster and then to build up the related industry (for example, to help Apple, IBM,…)

International Medical Devices Exhibition

↓

World Medical Parts and Modules Supplier

Design House & Service House

↓

Environment

↓

Assembly

↓

Medical Industry

Strategies of BME Development in Taiwan

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Action Plan for Biotech Industry Development

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- To establish biomedical hubs in Taiwan through incubation of biopharmaceutical and medical device startup companies

Translational Research

- Bridging upstream innovations of discovery research with downstream commercialization of biomed companies

BVC

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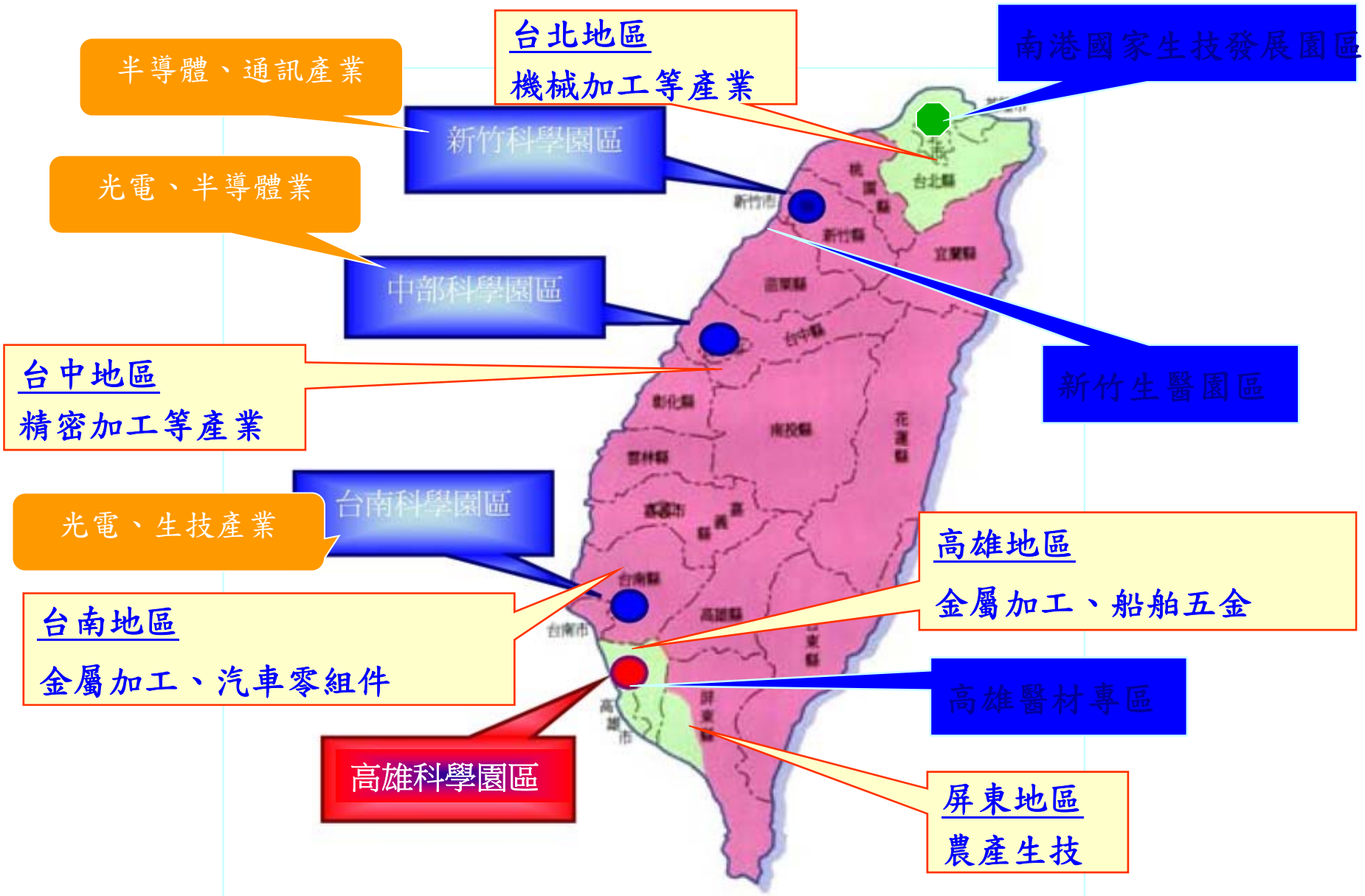
Boosting Biotech to a Trillion NT-Dollar Industry

Taiwan's economic engine: from ICT to Biotech

生技園區及週邊產業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Thanks for your Attention!

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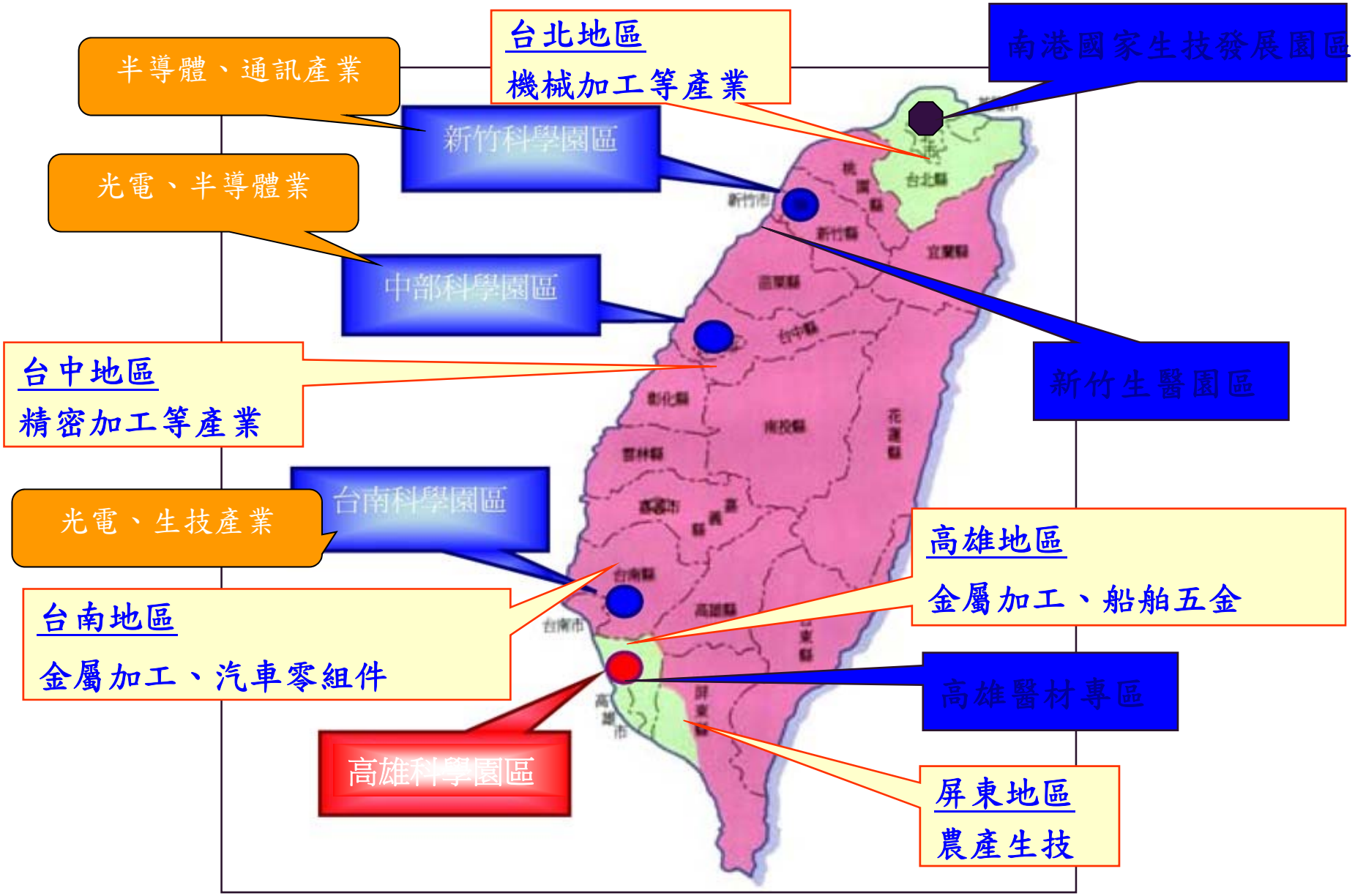
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機械加工等產業
南港國家生技發展園區
新竹科學園區
光電、半導體業
中部科學園區
新竹生醫園區
台中地區
精密加工等產業
台南科學園區
光電、生技產業
高雄地區
金屬加工、船舶五金
台南地區
金屬加工、汽車零組件
高雄醫材專區
高雄科學園區
屏東地區
農產生技

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