



# GROWTH OPPORTUNITIES FOR MEDICAL DEVICE OUTSOURCING IN MALAYSIA

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## What is Outsourcing ..... Wikipedia's definition



**Outsourcing is the contracting out of a business process to a third party. Sometimes it involves transferring employees and assets to the third party. It includes both foreign and domestic contracting and sometimes includes offshoring or relocating a business function to another country.**

“entrusting an outside firm with the responsibility of delivering quality products based on clear specific standards and **sponsoring** their growth opportunities.”

## Why do Companies Outsource?

- Cost reason— profits, market forces, end of PLC
- New business opportunities
- Capacity overflow
- Synergistic reasons – commonality in technology, engineering skills and infrastructure
- Risk mitigation
- Flexibility – business cycles
- Resources constraints – capital, labour, land and others
- Human capital skills and capabilities
- Shared services
- Diversification
- Competitive strategy
- Market knowledge— agents, distributors and 3<sup>rd</sup> party

## Industry Segmentation – Widely practice

- ✓ Purchasing
- ✓ Logistics
- ✓ R&D and Rapid engineering services
- ✓ Manufacturing Operations
- ✓ Service management
- ✓ Human resources
- ✓ Finance / Accounting
- ✓ Sales and marketing
- ✓ Training
- ✓ Legal Processes
- ✓ IT

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

## Definition of Medical Devices: ISO 13485 :2003

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of :

- diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or a physiological process,
- Supporting for sustaining life,
- Control of conception,
- Disinfection of medical devices
- Providing in vitro examination of specimens derived from the human body,

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

## General outlook of medical device industry.....

- Robust to cyclical swings.....some are recession proof
- Large segment is disposal single use – stable - growing demand
- Increasing expenditure in global healthcare and per capita spending.
- Increasing in population growth
- Increasing life expectancy / increasing aging population > 65 yrs
- Growth in number of hospitals, beds, physicians
- High entry barriers with increasing compliance regulation
- Strong brand loyalty
- Good margins
- Employs - low to high technology
- Generally long product life cycle

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

**Question :**

**Is the Medical Device Industry an attractive industry to invest ?**

YES ?

NO ?

MAYBE ?

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

## Question:

Are the Growth Opportunities in MY conducive to attract companies to outsource or encourage local entrepreneurs to be outsource partners?

YES ?

NO ?

MAYBE ?



## What do companies wanting to Offshore / outsource generally look for.....

- Cost
- Manpower availability
- Critical mass / High Volumes manufacturing
- Market access
- Industry cluster
- Technology clusters
- Government incentives
- Integrated infrastructure
- JV partners with available infrastructure and resources
- Material sources
- Competent clinical and test labs
- Others

Eg: Teleflex – 5 sites in Mexico and 3 O/S partners in China

Others : Covedien, JnJ, BS, KC, Baxter, Cardinal

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

Let's look at nature of existing industries in MY

- Highly segmented base – Orthopedics / other implants, surgical instruments, critical care device, diagnostic devices, hospital and medical equipment, medical consumables, electro mechanical devices, analytical test devices and others
- Govern by different product standards and classification
- Employs diverse manufacturing technologies – lacking critical mass
- Clustered ?
- Revenue generation approximately Rm13b.

# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

## Teleflex experience

Started as a results of un-forecasted demand increase resulting in various capacity constraints – tooling, machinery, direct labour hiring and space

Alternatives considered :

- Be selective with the customers based on GM%.
- Stretching delivery lead times – potentially high noise level
- OEM product from third party – mainly off shore to mainland Chinese companies. Conducted numerous supplier audits and feasibilities. Numerous issues related to compliance and controls.
- Review local SME – challenges in all areas with regards to implementation and compliances to QMS.

Decision was to go with local partner.

# How we got started

## Vendor selection

- Minimum ISO 9001 and ideally 13485
- Ready infrastructure – class 100 K and below cleanroom
- Proximity to site
- Strategic fit to core business – leverage current vendor base on molding, extrusion, blow molding and related technologies to product.
- Proven track record.....as current supplier performance
- Financial track record
- Management commitment
- Risk assumption
- Long term goal and aspirations of vendor

# How we got started continue....

## Contract Agreement

- 2 years minimum contract commitment .....
- Provide semi finished raw material and component
- Machinery and test equipment support
- Maintenance support for Teleflex owned machinery
- Direct labour incubation, training and development before going live.
- Management support – production / quality and engineering change control.
- Cost model = direct labour cost + allocated overhead cost + margin %.
- Support initial investment and inflationary cost increases
- Key matrix tracking, performance incentive and penalty clause.
- Environment, safety and health compliance -
- Non compete clause

# How we got started continue.....

## Implementation and management

- Task force – key resources and subject matter expert
- Clear communication and escalation process
- Training and development and on boarding process
- Major QMS matrixes implementation
- Capacity and volume determination
- Incremental volume from 1 – 3 shifts
- Differentiate work orders for effective traceability and segregation
- Management support – production, quality and maintenance engineering
- Structured meetings

**How do you think we fared with all the preparation ?**

Why.....



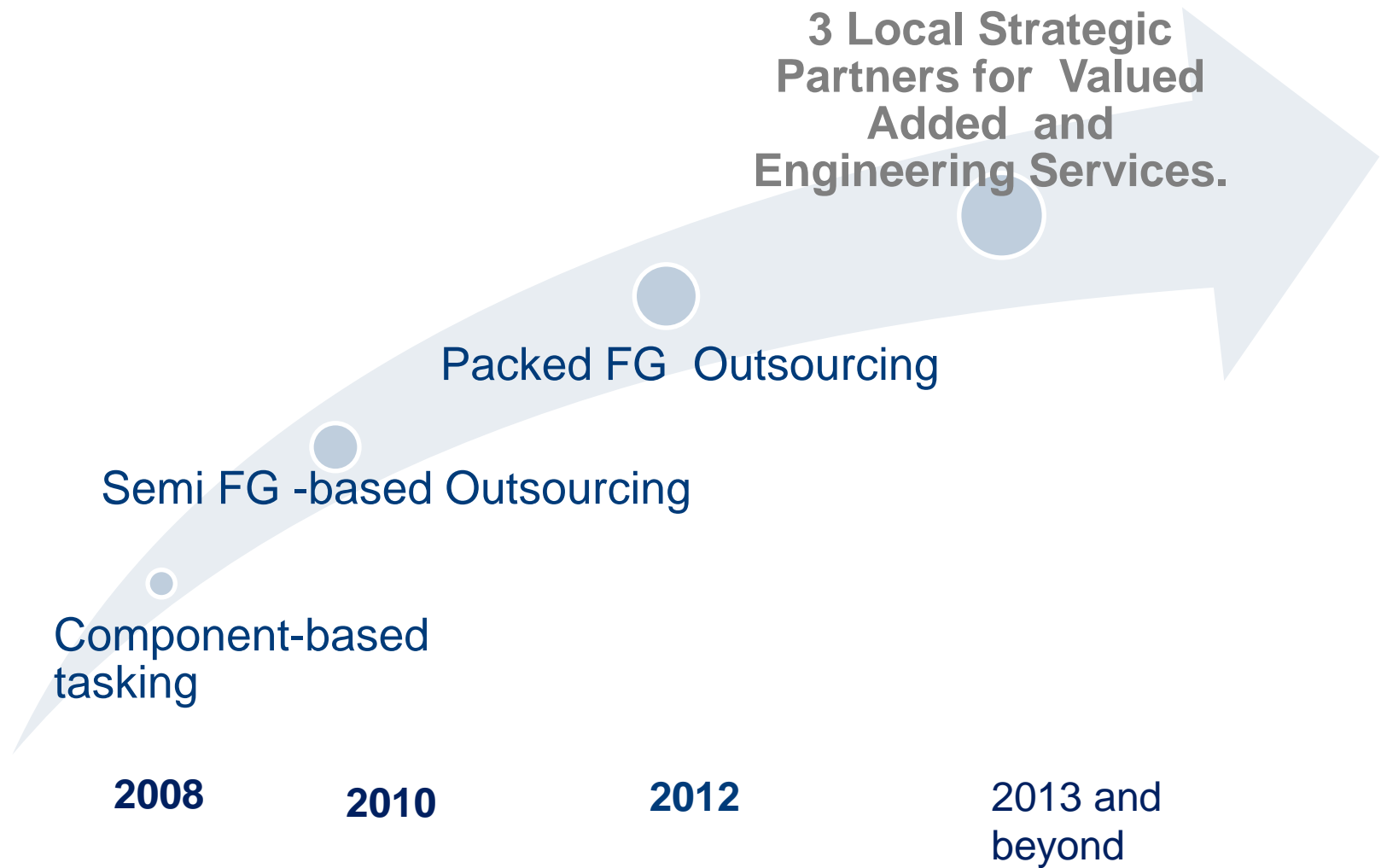


## Major issues faced

- Direct labour turnover and talent management
- Breakdown in communication transparency / Blame game
- Quality issues - lacking real time problem identification and solving
- Inexperience supervision and management control
- Cost overruns – low productivity and high scrap
- Pressure to perform – dysfunctional results
- Partner's commitment – in QMS, production and quality engineering very poor

HOWEVER .....

# The Evolution Process



# Is there Growth Opportunities in MY for Medical Device Outsourcing.....

## Summary – Yes

- The right Medical device companies that can be connected to the existing eco system and production technologies.
- Infrastructure availability – critical showcase
- Commitment to drive effective implementation of QMS and strong adherence to compliance
- Technology base over labour intensive.
- Government support
- Continuous nurturing, support and investment in talent development
- Right cost model

Thank you for your attention