Risk Mitigation and Singapore's Supply Base

Susan Mucha
Powell-Mucha Consulting, Inc.
smucha@powell-muchaconsulting.com

ABSTRACT
This presentation examines critical concerns that original equipment manufacturers (OEMs) in the medical industry have about outsourcing, in general, and offshore sourcing specifically. It will also provide examples of ways Singapore's educational/technical infrastructure and supply base are addressing these specific areas.

INTRODUCTION
Medical device OEMs have outsourced manufacturing for decades. Typically it is a choice driven by either the improved financial performance that outsourcing can drive or the ability to access technical and manufacturing expertise not resident in an OEM's internal resources.

This presentation will focuses on:

- Risks in outsourcing
- Key medical OEM concerns and strategies
- The hidden cost equation
- Changing medical industry dynamics
- Low cost labor market evolution
- The Singapore solution in addressing costs and risks.

RISKS IN OUTSOURCING
Outsourcing does involve both risks and tradeoffs. The largest risk is the supplier's ability to consistently produce quality product that complies with regulatory requirements. An added concern can be loss of control. For example, internal design teams may not have as close a working relationship with a supplier's team as they would with an internal production team. This can result in mistakes in new product development at the supplier or missed opportunities for incorporating manufacturability or testability improvement suggestions by the engineering team if the two groups do not find a way to work closely together.

Another concern can be loss of scheduling flexibility and the ability to prioritize project activities. Most suppliers have frozen production windows and may not be able to respond as rapidly to unanticipated demand changes as an internal production team. As a result, there can be short-term inability to meet demand.

Another factor can be mismatch between a supplier's capabilities and the OEM's needs over time for geographic build site options, technology or range of services. Finally, there can be concerns about supplier financial viability or even the supplier's commitment to its business model over time. For example, in a recession it is not usual for companies who prefer high volume projects to be willing to lower volume work simply to fill underutilized capacity. As demand increases, smaller projects either see prices rise or are asked to leave.

When sourcing is done offshore, the list of potential risks often includes:

- Ability of supplier to meet product quality/regulatory requirements
  - Ability of supplier to maintain configuration control/material quality
  - Ability of supplier to meet the product's technical requirements
  - Ability of supplier to meet cost reduction targets without impacting quality or reliability
- IP protection
- Ability of supplier to support new product development
- Ability to communicate with the supplier's program management or engineering team
- Hidden cost surprises
- Ability of supplier to meet variable demand
- Ability of supplier to provide adequate post manufacturing support.

KEY MEDICAL OEM CONCERNS AND STRATEGY

Powell-Mucha Consulting, Inc. conducted interviews with several senior medical OEM sourcing and engineering executives to better understand current perceived risks. While the interviewees acknowledged all risks were present, they prioritized the top risks in offshore sourcing as follows:

- Ability of supplier to meet product quality/regulatory requirements
  - Ability of supplier to maintain configuration control/material quality
  - Ability of supplier to meet the product's technical requirements
  - Ability of supplier to meet cost reduction targets without impacting quality or reliability
- IP protection
- Ability of supplier to support new product development
- Hidden cost surprises
- Ability of supplier to meet variable demand.

Product quality was considered the top concern by all interviewees. In terms of configuration control and material quality, the concerns related to both the ability of the supply to comply with the approved vendor list and the potential issues that could arise when available material composition in the build site region varied from the material specified in another region.

IP protection was listed as a key concern, but considered more of a business issue than an issue that should be addressed by the sourcing team. The ability of product development teams to work at a distance with suppliers was also a major concern.

In terms of strategies to mitigate these risks, the interviewees took a fairly hands-on approach. Audits were done at all potential suppliers and often the OEM's international purchasing office (IPO) would continue to re-audit periodically. The interviewee's answers on whether or not industry-specific quality certifications such as ISO 13485 or compliance with FDA Quality System Regulations (QSR) 21 CFR Part 820 ranged from "all suppliers must have ISO 13485 certification" to "it is generally required but exceptions are made for strategic suppliers" to "use of our own quality system is required."

Other risk mitigation strategies included using product development firms or their IPO personnel in the build site region to manage the product development process with the suppliers. Source inspection was used during the new product introduction process.

When adding suppliers, some firms used a strategy of midstream processing, where the new supplier did only partial product assembly until proven as a reliable supplier. In some cases, 100% incoming inspection of product built by new suppliers was done for a set period of time.

Manufacturing agreements with clear performance requirements were also cited as a way to mitigate risk.

The interesting dynamic in the strategies listed is that it is a mix of efficient and inefficient supply chain management strategies. While audits, 100% inspection, onsite source inspection and driving adoption of a unique quality management system mitigate risk, they also increase cost. While they are far less costly than a product recall would be, it is important to consider this type of cost in evaluating whether or not sourcing in a given low cost labor region really saves money.

THE HIDDEN COST EQUATION

Within a given unit price, it is easy to understand the measurable costs such as the bill of materials, assembly labor and logistics costs. Supplier profit margins are also easy to understand. However, the cost of inefficiency can be very difficult to measure because it exists both in supplier overhead and OEM overhead. Once measurable cost has been reduced as far as it can be reduced, the only two areas for cost reduction is the waste attributed to inefficient working relationships and the supplier's profit margin. Figure 1 shows some of the areas of potential waste that drive these hidden costs.

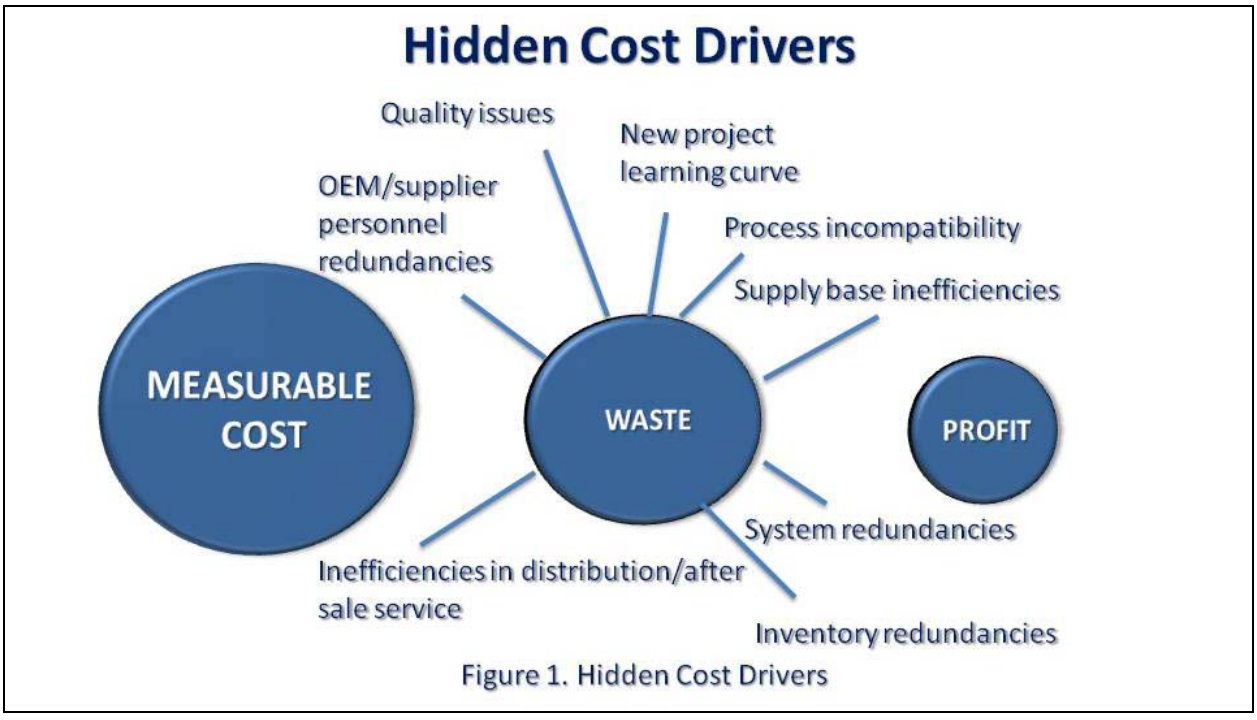

Figure 1. Hidden Cost Drivers

CHANGING MEDICAL INDUSTRY DYNAMICS

To understand true costs of a given sourcing choice, it is also necessary to understand likely medical industry trends. The medical device industry faces a number of challenges including:

- Increased regulatory scrutiny
- Continuing pressure to reduce costs
- Economic crisis driving increased concerns about supplier solvency and/or long-term business model commitment
- Changes in demand patterns
- Global economy opening up new markets
- Technological convergence
    - Miniaturization/communication
    - Electronics being added to non-electronic products
    - Greater sustainability challenges.

The challenge for medical OEMs is finding a way to continue to reduce cost without impacting quality or reliability. However, challenges such as increased regulatory scrutiny, changes in demand patterns, the need to rethink manufacturing strategy to support new markets and the need to develop products which may incorporate technologies in which the OEM does not have internal expertise suggest that migrating production to suppliers in emerging labor markets may not represent the most cost effective solution.

LOW COST LABOR MARKET EVOLUTION

Low cost labor markets tend to evolve from emerging regions where low cost, low skilled labor is used for easy-to-source projects with lower quality requirements, to established low cost labor regions with a mix of automation and labor, and finally to mature low cost regions where cost competitiveness is derived from a combination of productivity enhancements in a highly skilled workforce balanced with access to lower cost regions. Figure 2 illustrates the advantages and disadvantages of these types of low cost labor markets.

Figure 2. Evolution of Low Cost Labor Markets

In terms of examples of each type of labor market, a country such as Vietnam represents an emerging low cost labor market, China is an established low cost labor market and Singapore represents a mature low cost labor market. While emerging and established regions offer potential for cost reduction, they may be lacking in support for schedule flexibility or product development support for new technologies. Comparatively, a mature labor market such as Singapore offers a supply base which can tap a highly skilled workforce for complex projects and source in emerging and established low cost labor regions for projects with less complexity.

THE SINGAPORE SOLUTION IN ADDRESSING COSTS AND RISKS

Singapore has become a regional hub for medical manufacturing. According to Singapore's Economic Development Board (EDB), as part of Singapore's biomedical sciences sector, the medical technology industry doubled its manufacturing output from S$1.5 billion in the year 2000 to about S$3 billion in the year 2008. Over the same period, its manpower base also doubled from about 4,000 to more than 8,200 last year. By the year 2015, the medical technology sector targets to achieve S$5 billion in manufacturing output.

Today, Singapore is a global leader in medical technology manufacturing and accounts for 10% of the world's contact lens production, half of the world's thermal cyclers and more than 50% of the world's microarray production. EDB statistics show that Singapore has emerged as a choice location in Asia for more than 25 global medical technology companies manufacturing high value-added products. More than 30 leading biomedical sciences companies, including the top ten global medtech companies, have located their regional and international headquarters in Singapore.

There are a number of reasons for this success including:

- Ability of OEMs to one-stop shop within the region
- Good supply base infrastructure
- Public-private partnerships for improvements in technology and supplier capabilities
- Business friendly environment
- Logistics simplicity.

Ability to One-Stop Shop

While Singapore's mature manufacturing environment can be viewed as a labor cost driver, this maturity factor has also created a larger pool of multinational suppliers able to support the entire product life cycle with quality systems and program management methodologies comparable in scope to those found in the United States or Europe. The multi-functional skill level of the workforce enables companies to staff more efficiently than their emerging labor market counterparts, while Singapore's overall costs of doing business remain lower than the United States or Europe. And, in many cases, suppliers have multiple manufacturing sites, which allow them to direct labor-intensive work to lower-cost regions, while keeping processes which require more highly skilled personnel in Singapore.

Good Supply Base Infrastructure

Singapore's supply base advantages include:

- A large number of suppliers with key medical quality certifications and familiarity with US, Asia and European regulatory requirements
- Robust continuous improvement methodologies in place
- Mature program management model/excellent English skills
- High mix, variable demand part of many suppliers' business models
- Product development support (design firms plus suppliers with robust NPI capabilities)

- Low employee turnover
- Highly ethical management teams
- Strong IP protection discipline.

Public-Private Partnerships
Government support of initiatives designed to provide regional supply base capability enhancement, as well as overall industry R&D objectives, also help drive competitive cost. These programs encourage suppliers to more aggressively invest in new or enhanced capabilities by offsetting a large portion of the cost either through direct reimbursement, leveraged economies of scale via consortia or tax credits. Customers benefit from efficiencies generated by the enhanced capabilities, yet supply base overhead costs remain competitive as a result of the cost offsets.

For example, the Singapore Institute of Manufacturing Technology (SIMTech), a research institute under Singapore's Agency for Science, Technology and Research (A*STAR) launched the Medtech Manufacturing Consortium in October 2009. The 26-member consortium reinforces local industry capabilities and establishes medical technology R&D platforms for technology and knowledge transfer by exploiting the results of R&D collaboration with the research institutes, value chain partners and OEMs.

Focused areas of R&D collaboration will include:
- Forming technology for precision forming of medical devices and medical equipment components of polymeric, metallic and ceramic materials for use in safety needles, lenses, polymer-based microfluidic chips for DNA analysis and medical diagnostic applications
- Surface finishing to anodise and polish surgical materials for good corrosion protection, bio-inertness, anti-sticking and durability
- Carbon coatings surface finishing for implantable parts to increase biocompatibility and mechanical performance of metal parts used as implants
- Flexible and conformal technologies for wearable medical electronics and sensors
- Micro-laser welding to join dissimilar materials where heat sensitivity can be a problem
- Mass finishing of small medical components by abrasive flow machining where processing of complex internal passage is inaccessible by conventional methods.

Training has also been addressed. The Workforce Skills Qualifications Graduate Diploma in MedTech Manufacturing is a training program developed by the Singapore Workforce Development Agency in collaboration with SIMTech. This program aims to equip existing engineers and technical specialists with the requisite knowledge and skills in the latest medical device regulations and manufacturing technology to support the emerging medical technology manufacturing sector in Singapore, as well as to facilitate the entry of new talents into the industry.

Business Friendly Environment
Ease of doing business is another factor which helps eliminate hidden costs. Singapore's legal system is based on British Common Law and English is the official language of business. Singapore's commitment to Intellectual property (IP) protection is very robust. This simplifies contract negotiations, patent filings and IP protection enforcement, and ensures timely and accurate communication with suppliers.

Import/export issues are simplified as well through Free Trade Agreements which support multiple country manufacturing strategies, as well as market entry with minimal tariffs.

Supplier identification support is also available and this can be a significant benefit to sourcing teams with specialized supplier needs. While it is relatively easy to find contract manufacturers and suppliers of common custom components such as injection molded plastics or metal stamping, finding component or subassembly suppliers with ISO 13485 certification, the ability to work with high-mix, variable-demand projects or the ability to procure and work with specialized, medical-grade materials, can be a challenge in many lower-cost labor markets.

International Enterprise (IE) Singapore assists Singapore-based suppliers in expanding to new markets by introducing them to multinational OEMs seeking new suppliers. IE Singapore's supply base search and matchmaking services make sourcing hard-to-find commodities much less of a challenge. OEMs can submit their specifications for supplier capabilities to an IE Singapore representative and the agency will develop a list of compatible suppliers. With offices in more than 30 cities worldwide including London, Frankfurt, New York and Los Angeles, IE Singapore officers will also set up meetings with the short-listed suppliers chosen by the OEM's sourcing team, so that the team can visit and/or audit the selected companies within a single visit. IE Singapore's staff includes engineers, which helps ensure that the agency's supplier recommendations are in line with the OEM's specific technical capability requirements. In some cases, arranged visits may include side trips to satellite facilities in lower-cost labor markets such as Indonesia, Malaysia, Vietnam or China.

The agency also organizes trade missions for Singapore suppliers to various countries to provide a localized "first look" to sourcing teams wishing to explore options prior to travelling to a supplier facility. Finally, IE Singapore teams with other trade promotion agencies and associations to create focused supply base matchmaking events and conferences to allow OEMs to schedule trips that combine relevant educational opportunities with pre-arranged supplier tours.
Such programs help lower costs of supplier identification and qualification on both the supplier and customer side of the equation. Niche suppliers minimize their marketing costs, while OEMs with complex needs can consolidate their regional audits and tours into one or two focused trips.

Logistics Simplicity
Singapore also offers a range of logistics support options. Movements of materials and finished goods in and out of the country and payment transfers are governed by easy-to-understand regulations and efficient systems. This contributes to predictable costs and cycle times.

CONCLUSION
Achieving competitive cost in an industry as demanding as medical device manufacturing requires a robust sourcing strategy that analyzes all elements of the cost equation. Labor cost is one factor, but the cost reductions achievable through suppliers who meet their responsibilities for robust quality, responsiveness and adequate technical support must also be considered. Singapore's mix of a high service, multinational supply base and strong public-private partnerships offers a breadth of solutions worth exploring.

REFERENCE
[1] Mucha, S.E., "Finding the Right Formula," Medical Product Outsourcing, January/February 2010, pp. 82-85.