A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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COVID-19 Impact at Forefront Medical Technology

As this is written, Forefront Medical Technology has fully recovered from the operational impact of COVID-19 in its Singapore and China operations. Unfortunately, COVID-19 is now impacting the rest of the world.

While there are still some logistics challenges as shipping services resume, Forefront's facilities in Singapore; Changzhou, China; and Xiamen, China are at full staffing levels and working diligently to eliminate any backlogs caused by the delayed start-up schedule following the Lunar New Year holiday.

Communities around the world now face the operational disruption associated with reducing

COVID-19 cases in Changzhou for 24 days and no new confirmed COVID-19 cases in Xiamen for 28 days.

Forefront continues to take full precautionary measures with its staff. All employees returning to facilities are tested for COVID-19 and placed in quarantine until test results are returned. Procedures are in place to ensure a safe and healthy environment for all staff members and the products they manufacture.

The planning staff continues to monitor the supply chain to ensure that any issues are identified early and rectified quickly. Production staff is cross-trained, providing the ability

A Timeline of COVID-19 Operational Impact at Forefront Medical Technology

Jan 31

- Singapore facility opens (91% staffing)
- China Lunar New Year holiday extended to Feb. 10

Feb 1

- China Customs Office Open
- Xiamen, China facility opens (40% staffing)
- Changzhou, China facility opened on Feb. 13

Eob 17

- Singapore facility working normally
- Xiamen facility at 75% staffing
- Changzhou facility at 40% staffing

Feb 24

- Singapore facility working normally
- Xiamen facility at 95% staffing
- Changzhou facility at 65% staffing, tooling staff

returns

Mar 2

- Singapore facility working normally
- Xiamen facility working normally
 Changzhou
- Changzho facility at 85% staffing

Mar 9

- Singapore facility working normally
- Xiamen facility working normally
- Changzhou facility working normally

Forefront's China operations were able to resume production at full staffing levels within six weeks of the Lunar New Year shutdown. Employees were fully tested before being to allowed to return to work.

new COVID-19 infections and the uncertainty associated with how long this disruption may need to occur. The embedded graphic illustrates the timeline associated with Forefront's return to full operational status in a country that was fighting a significant outbreak. Hopefully, it will serve as a positive note in terms of the speed of operational recovery possible once new cases of the virus start to drop. As of March 12th there have been no new confirmed

to shift workers within the production facility to address changes in requirements rapidly. The Business Development and Customer Service team have been regularly communicating with customers on project status. In short, there is a return to normalcy occurring within the regions in which Forefront operates and our team is prepared to address any challenges associated with demand variation driven by COVID-19 in the rest of the world.



Regional Flexibility in a Changing World

Medical product manufacturers have been under cost pressure for a long time. The industry has a dual challenge in that cost pressures drive manufacturing in lower cost countries, while the regulatory environment drives a need to place manufacturing in regions where there is an established supply chain of companies with the required quality system certifications, internal processes and experienced personnel to manufacture in product compliance with the regulatory environment of those products' end market. Trade policies may further influence location choices.

Supply chain disruption doesn't pick favorites. While the COVID-19 pandemic created havoc in China and the rest of Asia before infecting the rest of the of world, the 2009 H1N1 infection disrupted production in Mexico. Natural disasters and long-term strikes in shipping

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New Product

Development

Product Concept

& Realization

Electronics.

Electrical,

software.

metal parts

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Quality

IQ/OQ/PQ

Concept to Commercialization

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Rapid

Prototyping

Drug

Infusion

Set

(

Assembly

Manual



Forefront's geographic reach provides its customers with regional support and choice in manufacturing build sites.

Reinforced

Silicone Tube

0

Sterilization

EtO

ports have also created surprise supply chain disruption at a regional level in many parts of the world. In short, every region has a

LSR Cuff

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Production Resources

Cleanroom

Facilities

potential for supply disruption and the best protection is choosing suppliers able to offer some flexibility in build site locations.

Forefront Medical Technology is headquartered in Singapore and has manufacturing locations in Singapore, China and the U.K. Forefront uses a regional hub strategy that combines the best of Singapore's business advantages and skilled technical workforce while tapping China's lower labor cost and logistics advantages. In addition to being globally headquartered in Singapore, this location also includes their Engineering Design Center, micro molding, specialty catheters, rapid prototyping, product development and tooling fabrication for complex molds. Its two manufacturing facilities are located in China. The facility in Xiamen, PRC is primarily

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Plastic &

LSR Tooling

In-house

tool room &

design team

Insert Mold

Micro Mold

2k Mold

Stack Mold

0

Molding

Capabilities

Injection

Extrusion

Injection Blow

Extrusion Blow

Wide Range

of Materials

0

Packaging

Rigid Blister

Soft Blister



Forefront's Singapore Facility offers Engineering and Logistics Advantages

The World Bank's "Doing Business" survey ranks Singapore number two for ease of doing business in a survey that measures a variety of activities including trading across borders, enforcing contracts, obtaining credit and paying taxes. Singapore ranks fourth globally and first in the region for institutional protection of intellectual property in The World Economic Forum's Global Competitiveness Report. English is the official language of business and its legal system is based on English Common Law.

More importantly, Singapore serves as a regional medtech R&D hub within Asia. According to the Singapore Economic Development Board, more than 30 global medical technical companies are carrying out research and development efforts related to technology and product development in Singapore. The diversity of Singapore's population has made it an excellent option for clinical trials, as study participants can be recruited from a broad base of races and ethnicities. This can be particularly important when differences in patient physical characteristics may require adjustments to a design. Additionally, this strong focus on the medical sector helps ensure that companies pursuing product development there have a local supply chain with the appropriate regulatory registrations and product quality standards.

Singapore also has a track record of supporting its supply chain with public-private partnerships designed to increase overall supplier competitiveness in world markets. For example, Forefront Medical Technology received a grant to create an Engineering Design Center focused on identification and commercialization of advanced manufacturing technologies.

In addition to its headquarters, Forefront Medical Technology also has an Engineering Design Center plus micro molding, specialty catheter production, rapid prototyping, product development and tooling fabrication for complex molds located in Singapore. The Engineering Design Center's capabilities include product development



Above, a high speed, automated assembly line at Forefront Medical Technology's Singapore facility.

engineering for precision-engineered and electromechanical products. Software development engineering is also available. The Singapore manufacturing facility is focused on advanced technology products such as implantables, tissue fasteners and micro-molded devices or parts. It is also a good solution for smaller footprint pharma devices such as implantable drug delivery systems. Facility capabilities include rapid prototyping (SLS) systems, molding, and mechanical and electromechanical assembly. While Singapore's labor costs are higher than those of China, Forefront's expertise in production automation contributes to increased cost competitiveness by significantly reducing manpower as projects increase in volume.

Singapore's business advantages do not decrease there. Singapore has 20 implemented free trade agreements (FTAs) with 31 trading partners, including the U.S. and the E.U. While, the criteria for classifying a product as Singapore origin may vary slightly by FTA and will require a separate process for each agreement, most products will qualify as Singapore origin under multiple FTAs, provided the product's HS code transforms during the final assembly and packaging process and there is at least 25 percent regional value

content from Singapore. The Singapore Free Trade Agreement with the U.S. (SGFTA) also qualifies it as a "designated country" under the Trade Agreements Act of 1979 (TAA). As a result, products qualifying as Singapore origin under SGFTA can be sold as TAA-compliant, which can be important for products sold to U.S. government entities such as the Veteran's Administration. Products made entirely in China are not TAA-compliant.

Forefront is not simply expert in product development and manufacturing. It also supports lowest total cost of ownership logistics strategies, helping customers migrate their existing supply chains to competitively-priced, qualified regional suppliers and optimize shipment of finished goods to customers' preferred delivery points.

From product development to a best cost logistics strategy, Forefront Medical Technology's Singapore facility offers a comprehensive end-to-end commercialization solution.



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Forefront Medical Technology focuses exclusively on the medical device industry and thoroughly understands the needs of this market. As a specialty contract manufacturer with a focus in disposable diagnostic, drug infusion and medical device systems, Forefront Medical has extensive expertise with injection molding, extrusion, assembly and packaging of specialty medical disposable devices. In addition, Forefront Medical Technology's technical expertise extends into collaborative product design and development, rapid SLS prototyping, in-house tool making and isolated clean rooms for manufacturing, assembly and packaging. Capabilities also include sterilization and global logistics to provide one integrated source for the total supply chain. This world class supplier has the expertise to custom design a new product... or redesign the current one...from a conceptual drawing into a completely manufactured, packaged and sterilized product, ready for global shipment.

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Regional Flexibility

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focused on production for export to other regions. The facility in Jiangsu, PRC facilitates and supports customers requiring a source of domestic production for the China market as well as for export, with an economic proximity to their R&D centers in Shanghai. Its U.S. Technical Center provides support in a convenient time zone to its U.S. customer base. Additionally, it maintains an ownership stake in Arrow Medical Limited, a U.K. medical contract manufacturer specializing in textiles, RF

welding, silicon injection moulding and cleanroom assembly. This provides a manufacturing footprint within the U.K.



Above, Forefront's vertically-integrated capabilities include extrusion.

when close proximity to the U.K. or Europe is desired. Arrow Medical maintains three ISO Class 7 (US Fed Std

10,000) clean room assembly facilities for the assembly of single use devices and other Class 2 and Class 3 products for use in anaesthesia, emergency and cardiac treatments. Two additional clean room facilities are dedicated to High Consistency Rubber (HCR) and liquid silicone rubber (LSR) moulding and RF welding, respectively.

Forefront's combination of a robust new product introduction strategy, multiple build site options, level of vertical integration, regulatory expertise and compliance track

record, and logistics expertise, make it an excellence choice when redundancy in operational locations is desired.