Singapore: Innovative Medtech Hub Combined with World Class Contract Manufacturing

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In the medical industry, hubs of innovation aren't created overnight. They are cultivated over time, when policymakers, institutions, medical device makers and suppliers collaborate to create an environment with the right infrastructure to support innovation. If you study areas of the world with a high concentration of medical innovation, you'll find seven things:

- Business-friendly government policies
- Significant regional investment by larger medical device manufacturers
- Access to funding
- Strong educational and research infrastructure
- Availability of qualified personnel
- World class supply chain
- Optimal logistics.

Singapore's medtech community has all those elements. This whitepaper looks at how these elements are driving rapid innovation in COVID-related invitro device (IVD) technology.

Singapore Medtech Community Overview

According to the Singapore Economic Development Board (EDB), Singapore is home to more than 60 multinational medtech companies undertaking a range of activities from regional headquarters and manufacturing to research and development. Its medtech manufacturing sector produces a diverse range of medical technology products from implantable pacemakers to contact lenses and life science instruments for global markets. Medical device manufacturers are successfully leveraging Singapore's strong design and engineering capabilities, base of automation suppliers and high quality assurance standards to undertake the manufacturing of high-value medical products.

Singapore's network of top universities, research institutions and innovative start-ups are also key to driving innovation. There are 25 R&D centers established by multinational medical device companies and a local pool of over 220 medtech start-ups and small-medium enterprises. Sixty percent of the world's microarrays and one third of the world's thermal cyclers and mass spectrometers are manufactured in Singapore.

The R&D Center presence drives a strong end-to-end infrastructure ranging from product design to product optimization and validation. 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'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.

Ensuring a World Class Supply Chain

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, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, has leveraged government support in its efforts to support local universities and medtech innovators in commercializing products related to COVID-19.

In 2020, government agency Enterprise Singapore identified a shortage of IVD test kit manufacturing capability and established grant funding for suppliers willing to invest in added capabilities. Forefront was able to utilize this funding to offset a portion of the costs of its investment in adding capability for manufacturing and handling of reagents. As a result, it has been able to support multiple startup project development efforts for both Singapore-based initiatives and regional activities.

These projects included:

- An Indonesian medtech funded saliva-based test kit for a rapid testing and mobile digital passporting exploration project. This project helps create "new normal" solutions for a Covid-endemic world.
- A local university's initiative focused on a set of kits incorporating serological testing for both single and multiple strains of Covid Neutralizing Antibodies identification, slated for the local and regional markets.
- Commercializing a Singapore and US university-collaborated invention for a point-of-care serological test kit that can be used for rapid detection of Covid Neutralizing Antibodies, as well as other disease identification in the future.
- A locally-developed Antibody Rapid Test (ART) Kit using locally developed reagents and manufacturing solutions.

Forefront Medical's combination of design engineering and manufacturing expertise is helping in each of these projects. While the commercialization effort blends the expertise of scientists and commercial partner engineering teams focused on the product technologies, ergonomics and overall ease of use, Forefront's team helps ensure the design is manufacturable and achieving its cost objectives.

For example, Forefront partnered with a local supplier and provided prototype micro molding parts for a test kit that needs a 10-micron gap to shear saliva for a better test sample.

In another example, Forefront is injection molding cuvettes and closures, preparing reagent and sealing the kits into pouches, then preparing final packages for safe shipping and storage at customer's warehouses.

Forefront also uses its well-equipped chemistry lab to perform incoming and QC tests of completed test kits and provide documentation consistent with its customers' regulatory requirements.

Forefront's Approach to Product Development

The robustness of a contract manufacturer's process for supporting the commercialization of new product or a smooth transfer of work has direct impact on time to market, quality and cost. When this development effort is managed by a single supplier instead of in silos at multiple suppliers, it ensures that all opportunities for reducing cost and ensuring optimum quality are considered.

In new product development, Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. A customer specification is then developed and market inputs are collected.

On the custom parts side of the equation, once the customer specification is approved, 3D CAD models are developed and analyzed. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began.

To help shorten product development cycles, Forefront Medical also maintains a database of approved materials which includes a full range of medical-grade polymers. While the best material will vary depending on application, cost considerations and desired functionality, the product development team is often able to recommend pre-approved materials choices to reduce product development time. Using materials that have previously been tested and approved within the regulatory environments associated with the product can cut 4-5 months from a product development cycle.

On the electromechanical side of the equation, Forefront's design team provides electronics design and PCB layout, as well as software development services. Mechanical and packaging design can also be supported. Prototyping and validation are also provided.

Design for manufacturability (DFM) recommendations are made on both sides of the equation. Tooling and assembly lines are optimized for efficiency. Prior to tooling fabrication, simulation software is used to ensure the tooling design will achieve the desired cost and quality targets.

As part of the new product introduction (NPI) effort, Forefront collaborates with its customers on identifying any needed suppliers; risk management; machine, tools and process validation; product bio-compatibility and stability validation; sterilization validation including sealing integrity; and packaging ship testing.

Forefront also operates a U.S. Technical Center to make it easier for U.S. customers to communicate with personnel in a time zone convenient to their normal work schedule. Forefront's management team, program management team and engineering team are fluent in English and multiple Chinese dialects, ensuring that project discussions are fully understood at all levels of the manufacturing process.

Regulatory Support

One of the most costly aspects of medical device manufacturing is meeting the regulatory requirements of different markets. Often, the cost driver isn't in established systems, but instead in the regulatory requirements learning curve found in new markets. Working with a contract manufacturer capable of supporting a global device marketing strategy in terms of validation testing and quality infrastructure saves time and improves economies of scale. When silos are eliminated by having one contract manufacturer manage this element of the product development process, the timeline and overall process efficiency is optimized.

In addition to money saved by selecting a manufacturing partner with regulatory expertise and the appropriate quality system registrations, there may also be efficiencies found in their relationships with regulatory agencies. Contract manufacturers who regularly work with the agencies relevant to your products represent a known supplier to those agencies and understand the best contacts for addressing any issues that may arise. Forefront Medical has a dedicated Regulatory Affairs team whose responsibilities include product registration and CE marking; maintenance of the Device History Record (DHR) and technical file; biocompatibility testing; validation and support sterilization; updates on regulations and communication of new/revised regulations; and intellectual property protection. Forefront's design team provides software verification and validation per industry standards. The team can provide services in electromagnetic compatibility (EMC) testing as per IEC60601 and software life cycle development/documentation as per IEC62304.

All Forefront Medical facilities are registered to ISO: 13485:2016. All facilities are also compliant to MDD 93/42/EC which is the Medical Devices Directive for European Community, MHLW Japan's Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169, ISO 15378 which is focused on primary packaging materials for medicinal products. All facilities are FDA and Japan registered as foreign contract manufacturers. Its JiangSu, China facility currently holds an FDA Establishment Registration and Class 2 Product Registered (510k), as well as China FDA (CFDA).

Singapore's medtech hub is continually developing innovative products. And Singapore's business-friendly strategies continue to ensure the growth of a world class supply base. From product development to a best cost logistics strategy, Forefront Medical Technology's Singapore facility offers a comprehensive end-to-end commercialization solution for both device makers in this region and in other parts of the world.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. JiangSu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China and Farmington, CT USA are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices, electromechanical devices and other specialty products. Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complemented by class 10K clean rooms for assembly.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485:2016 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

Visit http://forefrontmedical.com/ to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: http://forefrontmedical.com/contact-us/, email us at: appl_dev@forefrontmedicaltechnology.com, or call +1 (860) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).