

On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

Fourth Quarter 2021

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Forefront Supports Singapore's Hub of Innovation

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



Forefront has supported multiple IVD-related startup project development efforts for both Singapore-based initiatives and regional activities.

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The Year in Review: Enhancing Our Ability to Navigate the New Normal

This year demonstrated that while vaccines and therapeutics were a good step forward in the fight against COVID, the virus' ability to mutate ensured it would continue to represent a threat for a long time to come. The result has been migration to a new normal of workplace preventative measures and supply chain/logistics constraints. Many of the issues present this year will likely continue well into 2022.

Here at Forefront Medical, we've seen these challenges as a signal to evolve our business model, focusing on ways to reduce unnecessary cost while increasing throughput. For example, our Singapore team applied Lean Six Sigma



Walter Tarca

techniques to improve throughput by 50 percent on a project experiencing spikes in demand, which lowered shipping costs. We can't change the unanticipated increases in demand that our customers are experiencing as their markets normalize. Nor can we reduce shipping lead-time. However, we can improve the speed at which raw material is transformed into finished goods in our factory. To that end, we've put Six Sigma Green Belt training in place in all our facilities, ensuring we have teams with enhanced problem solving skills and core tools to lead this continuous improvement focus.

Over the last two years, we've supported a number of rapid product development efforts related to COVID. That has driven home the need for increasing the checks and balances we apply in our new product introduction (NPI)

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Innovation

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- Availability of qualified personnel
- World class supply chain
- Optimal logistics.

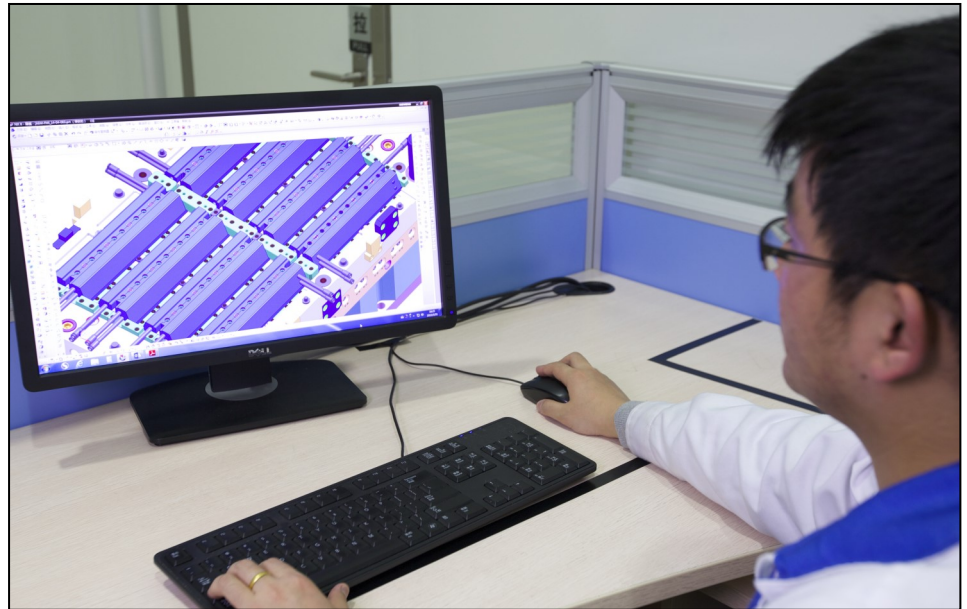
Singapore's medtech community has all those elements and that is driving rapid innovation in COVID-related invitro device (IVD) technology.

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



Forefront Medical's engineering team can collaborate in product development or just work to optimize manufacturability, depending on customer requirements.

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 trans-

forms 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 has

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Reflections on 2021

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process. Our team's Safe Launch process helps address the need to balance the speed and quality equation. The Safe Launch audit process provides a gap analysis on commercial run readiness which leads to development of an action plan. Once all the gaps are closed and pre-defined critical customer and product requirements are met, the team exits Safe Launch and begins normal production.

Finally, we've continued investments in capabilities expansion and our Singapore Technical Centre. The Centre was

supported in part by a Singapore government Enterprise Development Grant. We've built on last year's investments by adding capability in automation, IVD technology and microbore extrusion, including automated handling of reagents and assays to support manufacturing of consumables for IVD devices. Additive manufacturing (3D printing) capabilities have also been enhanced. Elsewhere in the newsletter we discuss some of the innovative projects these enhancements are supporting.

We can't change the external constraints that we and the rest of the manufacturing world find ourselves dealing with right now. However, we can improve the way we operate to mitigate the impact of external challenges.

We move into 2022 recognizing that it will likely be a year of continuing challenges. That said, our team's focus on improving our internal efficiencies in 2021 and our planning to build on those successes in the coming year, make us optimistic about our ability to continue to effectively mitigate the challenges this new normal brings in 2022.

I'd like to wish everyone a happy holiday season and a healthy and prosperous 2022.

Walter Tarca
President

Innovation

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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.

The expertise of Singapore's medical hub of innovation combined with a high quality supply base, make it an excellent venue for medical product development and manufacturing.



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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.

USA: Business Development & Technical Sales Office

Farmington, CT 06034-1234
 Phone: (860)-830-4637
www.forefrontmedical.com

Arrow Medical's Isolation Gown Helps in COVID Mitigation

Forefront Medical's UK subsidiary company, Arrow Medical Limited, was appointed to supply personal protective equipment (PPE) to Birmingham Hospitals in the UK. The company is now mass producing isolation gowns in its Kington, UK facility.

The gowns have set-in sleeves, adjustable neck sizes and welded seams in areas most at risk of exposure. They are available in boxes of 30 in blue in sizes from small to x-large. Custom box counts are available. They are CE marked ISO EN 13795.





The multi-layer structure of this fabric (SMMS) offers a unique combination of strength and



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microbial barrier properties. Tear strength is a key feature in comparison with standard single-layer, non-woven materials and it also offers good drapeability and softness. It is also non-leaching, non-linting and odorless.

<p>Benefits</p> <ul style="list-style-type: none"> • Single use • Latex free • Anti-static • Fire resistant • Low linting 	<p>4 LAYER POLYPROPYLENE</p> 	<p>ADJUSTABLE NECKLINE</p> 
	<p>SONIC BONDED SEAMS</p> 	<p>KNITTED ELASTICATED CUFFS</p> 