

On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

Third Quarter 2020

Volume 5, Issue 3

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Helping COVID-19 Related Products Get to Market

Around the world, companies and research institutions are developing products used in the fight against COVID-19. In Singapore, Forefront Medical Technology is helping to commercialize these efforts.

The contract manufacturer is currently supporting five coronavirus-related projects including a test kit and nasal swabs.

In 2018, Forefront Medical began expanding its Singapore research & development and manufacturing capabilities, increasing automation capabilities, adding cleanroom capacity, and growing its employee talent pool. This has positioned it well to partner with Singapore's R&D community and associated medical device manufacturers in developing products supporting COVID-19 mitigation efforts.

Test kit and swab manufacturing represents two of the COVID-19 related projects Forefront Medical is currently supporting. Its robust project processes combined with state-of-the-art infrastructure are helping its team work on accelerated timelines to support the demand for these critical COVID-19 mitigation supplies.

Test Kit Manufacturing

Forefront's investment in cleanroom capacity, and its manufacturing automation and quality management competencies made it a logical choice for commercialization of a test kit developed by a company in Singapore. Automated equipment mixes and fills reagents in one clean



Forefront's previous investment in expanding clean rooms in its Singapore facility has helped ensure available capacity for rapid production ramp-up.

room, while a separate room is used to fill the positive controls in a biohazard safety cabinet. The reagents are then packaged into test kits and shipped.

While the speed requirements of this project meant that Forefront Medical built its manufacturing solution around specifications developed entirely by its customer, its regulatory team did support a concurrent validation, registration and regulatory process.

Swab Manufacturing

Forefront Medical is also one of the companies selected by the National University of Singapore to manufacture nasopharyngeal swabs for COVID-19 testing.

The initial design uses additive manufacturing for speed, although Forefront is concurrently developing tooling for an injection molded version, to be introduced later this year. The project started in May 2020 and the Company shipped 1 million 3D printed swabs in July 2020, which have passed all acceptance tests.



A Robust Process for Product Commercialization

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. In the case of COVID-19 related production, this combination of manufacturing expertise and process discipline enables fast production starts without sacrificing necessary checks and balances.

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. In the abbreviated product development process for the swab manufacturing project, where Forefront's team was working to specifications provided by the National University of Singapore, the DDP process has helped ensure that all necessary information was transferred and that all key project milestones were incorporated in the DDP. That said, Forefront Medical's full DDP process is designed to provide whatever level of engineering and product development support a customer may desire.

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 begin.

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



Forefront Medical's team is expert at developing scalable automation.

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. 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

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Product Commercialization

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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 MDR 2017/745 which is the Medical Devices Directive for European Community, MHLW Japan's Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169. 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 National Medical Products Administration (NMPA).

The Forefront Medical Advantage

While the COVID-19 projects discussed earlier illustrate Forefront Medical's abil-



Production operators in one of Forefront Medical's Singapore clean rooms.

ity to pivot and support rapid launch of COVID-19 related products, this vertically-integrated contract manufacturer has the capabilities to support a broad range of medical products from single use to electromechanical devices.

Forefront Medical Technology's Singapore

Engineering Design Center supports micro molding, specialty catheter production, rapid prototyping, product development and tooling fabrication for complex molds. The Engineering Design Center's capabilities include product development 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, where Forefront also has manufacturing facilities, Forefront's expertise in production automation contributes to increased Singapore manufacturing cost competitiveness by significantly reducing manpower as projects increase in volume.



Additive manufacturing, also referred to as SLS rapid prototyping or 3D printing has played an important role in the first phase of swab 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.

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Singapore Deputy Prime Minister Visits Forefront Medical

Forefront Medical Technology was honored to host Singapore's Deputy Prime Minister Heng Swee Keat for a visit to its Singapore manufacturing facility in August. Forefront's senior management team showed DPM Heng the various medical devices manufactured in the facility, along with recent investments in an in-vitro diagnostic (IVD) laboratory and the extrusion of specialty medical tubings. He also met some of the new staff hired who bring additional medtech skills to the company.

The Singapore government's business-



(L-R) Forefront Medical Technology (FMT) President Walter Tarca, FMT Group Operations Director Jay Cheng, FMT Independent Director Ng Cher Yan, FMT CFO Gan Ying Hui and DPM Heng Swee Keat.

friendly approach improves the ability of Forefront Medical Technology to drive innovation and continuous improve-

ments. This, in turn, helps build new sustainable revenue streams which can create additional job opportunities and a brighter shared future within the region.

In addition to DPM Heng, representatives from Singapore's Ministry of Finance, Enterprise Singapore and @PMO were also part of the visit.

The Straits Times article covering the visit and highlighting a

new Singapore business support initiative can be read [here](#).