Case Study: Forefront Medical Technology Helps COVID-19 Related Products Get to Market

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Around the world, companies and research institutions are developing products used in the fight against COVID-19. In Singapore, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, 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. This whitepaper looks at two of the projects it is currently supporting and the infrastructure that it enables the Company to robustly support these types of time sensitive product development and manufacturing efforts.

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 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 (NUS) 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 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

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described earlier in this whitepaper, where Forefront's team was working to specifications provided by NUS, 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 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. 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 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

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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 these projects illustrate Forefront Medical's ability 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.

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 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, complimented 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) 255-7610 (Europe and America's) / +86 21 6062 7177 (Asia).

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