Is Mexico the Right Fit For Your Medical Product?

Is Mexico the Right Fit for Your Medical Product?

November 11, 2023

Developing an optimized manufacturing strategy requires more than just evaluating the manufacturing competencies of potential contract manufacturing partners. It also requires evaluating the benefits of regions in terms of manufacturing and logistics cost.

In this whitepaper, Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, discusses some advantages of the flexible, global manufacturing solution its new facility in Mexico provides customers.

Logistics Simplicity

Asia offers some of the lowest cost options for manufacturing even when logistics cost is considered. For products sold within Asia, logistics is relatively simple. However, for products sold in North America, the transit time factor in logistics can slow responses to changes in demand and create a longer pipeline of finished goods inventory. In those cases, Mexico offers the best blend of manufacturing cost and logistics simplicity.

Medical manufacturing is well-established in Mexico's border regions. Forefront Medical selected Juarez, Mexico for its location because it offers the shortest transit time to a major US city, international airport, rail and U.S. interstates. El Paso has three sterilization facilities capable of gamma and/or ethylene oxide (EO) sterilization. An EO sterilization facility is also available at the adjacent port of entry in Santa Teresa, New Mexico.

Depending on border crossing/customs wait times, products with no sterilization requirement leaving a Juarez factory can be on a U.S. interstate heading towards their end destination in as little as 24 hours.

The El Paso/Juarez borderplex's logistical benefits include:

- Quick access to the I-10 (East-West) and I-25 (North-South) interstate corridors
- Access to five international bridges and the Union Pacific and BNSF rail lines
- A variety of warehousing and distribution services
- Choice in customs and logistics services
- Access to a large free trade zone on the U.S. side and multiple regional free trade agreements on the Mexico side.

This speed of transit can help OEMs support unpredictable spikes in demand as well as reduce the levels of finished goods inventories kept as a just-in-case measure against products with lengthy transit time.

Experienced Industrial Base

According to Bio Juarez, an advocacy group for the region's biomedical manufacturing base, there are over 30 factories in the El Paso/Juarez borderplex producing Class I, II and III medical devices. Over 40,000 people work in the medical device industry in the region.

Some examples of devices manufactured in the El Paso/Juárez region:

- Catheter-based devices
- Orthopedic supports
- Minimally invasive surgical equipment
- Aortic and thoracic stents
- Diagnostic imaging equipment
- Surgery kits
- Electronic PCBA for medical devices
- Pressure belts
- Respiratory devices
- Ophthalmic devices
- Electronic and mechanical infusion pumps.

The result is a labor market with executives, managers and production workers highly experienced in the rigorous requirements associated with manufacturing medical devices, making easier to hire experienced personnel and maintain high workforce standards.

Convenience

Supplier sourcing teams often have challenging schedules. Offshore suppliers add complexity since cost and length of travel time often translate to supplier audits that take a week or more. Comparatively, a visit to a Juarez, Mexico facility more closely resembles a U.S. business trip. Air travel can occur entirely within the U.S. El Paso and Juarez are in the Mountain Time zone, minimizing the time zone differences travellers within the U.S. otherwise face. Given that border transit time from a U.S. hotel to the factory is often less than 20 minutes, U.S. hotel stays are an option. Juarez also has a variety of hotel chain options for visitors preferring to stay on the Mexico side of the border.

The result is lower travel-related costs for supply chain audits, shorter trips and greater scheduling flexibility.

The Advantages of Mexico and Forefront Medical's Global Solution

Forefront Medical announced the addition of a manufacturing facility in Juarez, Mexico in Oct. 2023. The 68,000 sq.ft. facility is minutes from the U.S./Mexico border. Facility fit-up is in progress and production qualification is scheduled for the middle part of 2024. Capabilities will include injection molding, extrusion, clean room assembly and packaging, and automated high volume production.

The addition of its Mexican facility gives its North American customers a nearshore solution that leverages its vertically integrated capabilities in facilities around the world including Singapore, China and the U.K.

Forefront's approach to contract manufacturing provides its customers with superior quality solutions through proven processes and expertise. Its ability to leverage vertically-integrated solutions and team expertise in low cost labor regions helps enhance its nearshore solutions in terms of cost and capabilities.

When either product design assistance or redesign for cost reduction is involved, Forefront's design engineering group works under a Design Development Plan (DDP) process designed to assess customer requirements and define a detailed product specification. The customer specification reflects both

customer and market inputs. This two-pronged approach of pulling information from the customer combined with studying the market helps ensure the initial specification adequately identifies all critical requirements. The customer specification provides a written document that aligns the teams in a shared vision.

Once the customer specification is approved, 3D CAD models are developed and analyzed to test assumptions related to the design and manufacturing process. Tooling performance and throughput assumptions are tested via software modeling. Design reviews which include functional analysis and risk evaluation are completed. After the customer's team approves the design, prototyping and verification begin. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial. Use of rapid prototyping technologies ensures that the customer team is able to see and handle a prototype as an additional check and balance in the process.

Forefront's Safe Launch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process.

Areas audited include:

- Material receiving and incoming inspection
- Material storage conditions and security
- Work order issuing
- Material issuing and accountability
- Set-up, line clearance and first article inspection
- Production record of good vs. scrap
- Production run with 100% inspection on critical points
- Work order closure to determine if actual quantity aligns with system quantity.

The output of this audit process is a gap analysis on commercial run readiness which leads to development of an action plan. Data collection is used to determine if critical defects are detected. 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.

In developing each Safe Launch™ Plan, Forefront's team and the customer's team collaborate to assess potential defect opportunities and define a list of requirements that help prevent defects from occurring. Forefront's team then develops a control plan with checks and balances to prevent defects from occurring where possible, plus inspects CTQ elements to ensure only defect-free product leaves the factory.

Forefront Medical's manufacturing capabilities, when its global operations are considered, include Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems, injection and blow molding, extrusion, metal fabrication, electromechanical assembly, and clean room assembly capabilities.

Six Sigma Green Belt training is in place in all Forefront facilities, creating teams with enhanced problem solving skills to lead continuous improvement focus in each facility. The core tools used to drive this process include:

- 7S Workplace Organization
- Poka Yoke mistake proofing technique
- 8D systematic approach problem solving methodology
- Risk management & Process Failure Modes and Effects Analysis (PFMEA)
- Statistical process control.

Forefront Medical's team also has significant experience in supply chain realignment to reduce logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure.

This combination of expertise, well-defined processes, vertically-integrated facilities, ability to leverage engineering resources in low cost markets and a global manufacturing footprint provides customers with choice in product manufacturing technology options and build site locations while ensuring consistency and similar quality among facilities.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with five manufacturing 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. Arrow Medical, Kington, Herefordshire, UK, is now a part of the Forefront global capability, specializing in wound care products. A facility in Juarez, Mexico is opening in 2024. Regional Business Development offices are located in Farmington, CT USA; Kington, Herefordshire, UK; and Shanghai, China, and 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, 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) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).