

Who We Are



We are a global strategic contract manufacturer of custom, high-quality silicone and thermoplastic components, subassemblies, and devices.

For more than 75 years, Flexan has been trusted to deliver manufacturing solutions for the top medical device companies. We have achieved our reputation by investing in innovation, talent, and infrastructure to provide end-to-end manufacturing services across the supply chain utilizing the best technical expertise in the industry.

With locations across the globe, Flexan has the pedigree medical device companies are looking for to accelerate manufacturing transfer projects by leveraging our infrastructure and experience.



Contact

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Values & Benefits



To support our customers with manufacturing transfers, we serve a diverse range of markets and applications. Our decades of proven experience in custom components and devices include a wide range of medical device technologies, allowing us to extend our capabilities in an expanding global market. Our manufacturing capabilities include:

- Silicone expertise in Extrusion, Molding, Automated Assembly, and Sterile Packaging
- Thermoplastic expertise in Extrusion, Injection Molding, Insert Molding, Overmolding, Tipping, Device Manufacturing & Assembly
- Design and Development of Specialty Catheters and Vascular Access Devices
- Assembly, Kitting, and Packaging Solutions

Over the last 20 years, Flexan has executed over 25 successful transfers. Our Flexacution manufacturing model has been certified in our QMS procedures. These were developed specifically for manufacturing transfers. These procedures help shape our project plan, define our engagement with our customers, and set the tempo from the start of the project through final validation and launch. Thanks to partnerships with key customers over the years, we've gained a tremendous amount of collaborative experience and are capable of successfully completing projects. Our transfer process is the culmination of years of experience and learnings and has stood the test of time through extensive audits.

Flexan has a global presence, and our manufacturing locations include:

- Lincolnshire, IL
- Chicago, IL
- Salt Lake City, UT
- Jiangsu Province, China
- Juárez, Mexico (Coming Q3 2023)

Keys to Successful Manufacturing Transfer



Manufacturing Strategy

The right manufacturing strategy delineates what the best solution is from the start. Flexan's Flexacution method begins with customer engagement and needs assessment based upon manufacturing requirements. Specifically for manufacturing transfers, this process begins with a cross-functional team assessing all actors required to build a successful plan.



Process Excellence

Flexan ensures that all of our manufacturing, assembly, and packaging processes are superior. Exceeding expectations for our employee's safety and customer's product quality is our number one objective. We ensure that our clean rooms are state-of-the-art and that our processes are compliant while driving efficiency. A good transfer program incorporates training systems that provide confidence that the exchange of knowledge is not lost.



Project Management

Establishing strong professional relationships at all functions within each organization (e.g., commercial, technical, operations/logistics, etc.) is the most critical requirement in establishing a true collaborative partnership. Documenting clear project expectations up-front (cost, timeline, responsibilities, etc.) is also crucial in avoiding confusion and delay. Larger-scale transfer programs usually require establishing a dedicated "Tiger" team to eliminate distractions.



Engineering and Quality Systems

In the device-manufacturing space, change is constant, and patient safety/regulatory compliance risks are ever-present. Given this reality, both FDA & ISO Quality System requirements mandate risk analysis and risk mitigation throughout the development process. A robust contract review performed by the CMO is the most effective way of meeting customer standards and requirements.



Supply Chain Capabilities

You want a partner who can be resourceful and cost-conscious. Flexan has established partnerships with key vendors and manufacturers and maintains a global procurement team, to ensure projects stay on track.

Manufacturing Transfers Benefits

Outsourcing decisions are driven by the continuous pursuit of maximum value by branded manufacturers: cost competitiveness and know-how matched by high-quality standards. This trend can be articulated in five critical factors of make-or-buy decisions.



Scalability



Cost Saving



Vertical Integration



Quality



Technology Know-How

Contact Flexan today for your next Manufacturing Transfer Project at 224-543-0003 or visit [Flexan.com](https://www.flexan.com)

