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Successfully Navigating A Manufacturing Transfer During Global Disruptions

By Mike Huiras, Flexan

Throughout the COVID-19 pandemic and into post-pandemic operation, medical device contract manufacturing organizations (CMOs) have had to refine their operations with greater agility and flexibility. Not only have customer needs evolved in terms of both volume and customization, but traditional industry challenges (e.g., demanding development timelines) have compounded with emerging or worsening difficulties (e.g., supply chain complications).

Manufacturing transfer — here specifically, relevant to custom silicone and thermoplastic components, sub-assemblies, and devices — is at the heart of these challenges. As medical device OEMs have narrowed their strategic focus to core competencies, innovation, and global market expansion, demand has grown for CMO partners with proven capability to operate in a global regulatory and quality environment. Moreover, OEMs require partners with an operational model adaptable to the modern industry's technical requirements and unpredictability.

A CMO's experience and ability should encompass all iterations of manufacturing transfer. The two most common are new product development, wherein the customer is developing a product and intends to outsource its manufacture, and the transfer of an existing, on-market product. In this latter scenario, the customer may be manufacturing internally, working with another CMO and seeking to end that relationship, or wishes to add an additional CMO to support large volume. The challenges in working with each type of customer vary.

"Flexacution" Smooths Transfer and Manufacture

Flexacution is more than a tag line. It is Flexan's business model: design > develop > deliver. Flexan's SOPs and processes have been crafted to provide customers with maximum flexibility during manufacturing transfer, regardless of the transfer type.

In the design phase, our commercial responsibility is to identify opportunities that fit our capabilities and strengths, allowing us to provide a solution to each customer that meets or exceeds their expectations. It is vital to qualify and understand exactly what each customer is looking for — where they want to be at the end of the collaboration — up front.

While it is important to always strive to build capabilities in service of one's customers, it is equally important for a CMO to avoid stepping too far outside itself from a technical standpoint (i.e., in terms of timelines, process and product quality, and regulatory adherence). Once we progress through the quotation and negotiation, and have been awarded the business, Flexan follows a seven-stage phase gap approach to develop any new product. This approach is standard at all four of our sites, from Lincolnshire, IL, to Suzhou (Jiangsu Province), China.

At this stage gate, called contract review, the development phase begins. The relationship transitions to a development program and enters our quality management system. At that point, we have a cross-functional review with the customer, during which all information the customer has shared is both validated and documented as part of development: quality assurance, regulatory requirements, new product engineering, manufacturing and secondary operations, manufacturing cost and customer service, etc.

This due diligence ensures we understand what the program will entail (e.g., whether it involves two SKUs or 100 SKUs), which dictates the resources and planning necessary to successfully execute manufacturing transfer. Depending on the product, the material, and the customer's projected volume, up-front work for the transfer could involve the development of fixtures or the acquisition of new capital equipment.

In new product development, the customer owns the device history file: fit, form, and function, as well as regulatory filings. If Flexan is part of early-stage discussion and development, we provide guidance on design for manufacturability. For example, in the case of a catheter, the customer may want a particular type of fluid flow and prevention of backflow. We can help design that tip, how the holes are formed relevant to that component's manufacturability. The same applies to material selection: we might provide advice regarding what might be easier to manufacture — depending on the customer's fit/form/function design goal, but they ultimately are responsible for biocompatibility, functionality, and the impact, if any, of sterilization.

As with most CMOs, Flexan is typically not designing the device in new product development and driving the entire NPD timeline, but we remain a critical part of the go-to-market timeline. Cost often is perceived as a key outsourcing concern, but it rarely ranks above a CMO's speed, quality, and expertise. Still, project speed is impacted by numerous factors

throughout the development cycle, including product class, clinical trial requirements, and planned global distribution.

When Flexan qualifies transfer of an existing product, we thoroughly examine the transfer (e.g., the product's design and manufacturability) to confirm we are a proper fit for the project. Once we determine we are aligned with the customer relevant to end goals and timelines, focus shifts to inventory management, supply chain, and regulatory filings. The key aim throughout is to ensure manufacturing is not interrupted, that the customer is not facing a window of time where no partner is supplying product.

Depending on the situation and timeline, it often is prudent to explore, during a transfer, whether opportunities exist to alter product design into something easier or more cost-effective to manufacture. For example, can we develop a manufacturing process that reduces the labor necessary, achieving a better price point for our customers? Manufacturing transfers are inherently costly, so providing optimal return on that investment is critical.

Driving each step is clear communication and transparency. Within a smaller project (e.g., just a few SKUs) Flexan's project engineer owns that communication. We establish the cadence of communication and frequency of cross-functional reviews up front with each customer. That said, Flexan's internal teams meet twice a month to review all programs, keeping us grounded and aware of every customer's current and upcoming needs, from new equipment to a change in the inspection process. Issues inevitably arise in any project; the key is communicating quickly and having a plan to resolve those issues.

Flexan's Unmatched Experience and Expertise

Flexan has delivered custom CMO services for more than 70 years and has more than 30 years' experience completing successful project transfers in the high-quality silicon/thermoplastic components, sub-assemblies, and devices space. The majority of our business is medical device-related, serving mostly multinational organizations, but includes smaller and emerging device makers, as well.

Accordingly, our processes must be able to seamlessly accommodate various requests. Consider that, within large OEMs, significant variability can exist between stipulations and goals for different products. For example, a recent large OEM customer required Flexan to document a considerable amount of information during development — a practice we typically do not begin until process validation. However, because of the customer's quality system requirements, they wanted some history on the development process, and we had to be flexible to adapt to their needs.

Additionally, Flexan serves a broad swath of market segments. One of the largest categories we support is vascular access (manufacturers of full devices for dilators, sheaths, introducers, catheters, peripherally inserted central catheter [PICC] lines, etc.) — most of which comprises thermoplastics. We support implantable devices, such as cardiac rhythm management, neuromodulation devices, and women's incontinence devices implanted in vivo, as well, many of which are silicone components. Some go inside the devices and serve as seals or grommets, as well as other functional and/or protective (i.e., from body fluids) roles.

In terms of volume, Flexan manufactures SKUs in volumes ranging from 20,000 units (though sometimes as low as 5,000 units) to millions of units. While we focus our services on being a low- to medium-volume manufacturer, the reality of dealing with fully finished devices or portfolio products demands that we offer the flexibility and range to support low, medium, and high volumes.

Final Thoughts

Flexacution was a part of Flexan's business before COVID-19, but issues resultant of the pandemic reinforced the necessity of having such a system in place. Improving execution, learning, tweaking processes — it is a continual and ongoing exercise. Accordingly, we have a solution for any issue that may arise during manufacturing transfer.

For example, early in one of our programs with a large OEM, part of the manufacturing process did not match the print, a common occurrence when OEMs manufacture internally, because they sometimes do not update component prints to record adjustments to their processes. When Flexan contracts with an OEM, we have to follow the print to the letter, even if it does not meet their current process output. This experience forced us to develop a more robust, thorough review of the print.

This dedication to continuous improvement and process discipline derives from our experience. The importance

of setting precise expectations, understanding the work streams, and building a mutually agreed upon project plan up front cannot be overstated. Device development and manufacturing transfer always will reveal technical surprises, but surprises as a result of inadequate communication or supply chain disruption can be minimized or eliminated through transparency and effective collaboration.

In that same vein, OEMs working with a CMO partner are well-served by appointing a project leader with leadership-supported control over the project. One of the most common timeline disruptions is the holding pattern that results when a project leader is waiting for a response from individuals in quality or regulatory because the project is not a priority for those teams or individuals. These delays cost time and money. Similarly, transparency and open communication are two-way streets: a CMO operates better when expectations are clearly set and an appropriate sense of urgency is conveyed relevant to specific tasks.

To learn more, contact the author and visit us at flexan.com.

About The Author

Mike Huiras has been Vice President of Sales and Marketing at Flexan since 2016. Mike began his career with Helen Curtis/Unilever as a sales representative for the consumer products division. He then joined Abbott in the Diagnostic and Molecular Diagnostics divisions, where he spent 23 years in several sales and marketing leadership roles supporting global product development, new ventures, and international commercial operations. Most recently, Mike served as the Senior Director of Global Marketing for Abbott Molecular. He holds a Bachelor of Business Administration from Loyola University of Chicago.

About Flexan

Founded in 1946, Flexan has been delivering custom contract manufacturing solutions for over 70 years. Today we stand out as medtech custom manufacturing leaders, solidified by a leadership team with more than 120 years of combined medical device industry experience. With four locations across the globe and over 2,000 SKUs, Flexan has the pedigree medical device companies are looking for in a custom contract manufacturer.

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