Effective Communication Drives Successful Manufacturing Transfers and Productive CMO Relationships

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The relationship between a medical device OEM and its contract manufacturing organization (CMO) thrives or fails based on communication. Whether remote or face to face, these communications must involve the appropriate individuals or teams, be substantiated with relevant data wherever possible, and remain untainted by ambiguity or uncertainty.

This is true when production of the device transfers directly to the CMO without change, as well as when design for manufacturability (DFM) is required. Often, DFM is necessary to some extent, even when the OEM does not believe so; for example, alternative raw materials may need to be sourced to meet greater production numbers, records relevant to the original product design may be missing, or changes may be advisable to make manufacturing more cost-effective. Accordingly, a CMO with applicable DFM expertise and the resources to foster effective communication throughout the relationship is an invaluable partner.

While lift-and-shift scenarios—wherein manufacturing is moved from one site to another without product or manufacturing process redesign—are ideal, they are also a rarity. Consider that many legacy products have been manufactured for years and, during that time, records, drawings, prints, and/or tooling have not been updated. The OEM is often working from knowledge shared among its personnel, as opposed to a meticulously documented formula, and they are hesitant to make changes that could fail.

Although the quality of the product and fit, form, and function meet the requirements, the existing manufacturing process documentation may not always be recorded in the standard operating procedures (SOPs) or work instructions, or the latest technologies may not have been incorporated to facilitate process improvements. Disseminating the product on a global scale may require the OEM to implement more robust quality systems or align with more stringent, recently adopted production standards applicable in the target markets. As such, it may be financially viable or necessary from a regulatory standpoint to alter the product, but not every OEM or CMO can undertake the challenge of filling in the gaps with relevant knowledge and documentation. In addition, that partner may not want to commit (or invest in) resources if the task lies outside its core competencies.

Thus, contract manufacturers are tasked with replicating the OEM's requirements while adapting to changes both external (e.g., supply chain) and internal (e.g., undocumented processes or material changes). They must support customers across two distinct phases. First is beginning production as soon as possible using the OEM's available plans and materials. Second is validating, in parallel, new resources (e.g., personnel), updated processes, or alternate materials to meet new (or newly applicable to that manufacturer) standards. To achieve this, communication between partners must be prompt and precise. To ensure that the requirements for the transfer are clearly understood across all functions, Flexan has established two quality procedures

and a transfer checklist to help build an effective project plan.

How Flexan Facilitates Manufacture Transfers

During product or production-line transfer, numerous people and resources enter and exit the process at various points. During the COVID-19 pandemic and into the post-pandemic era, as organizations rely increasingly on remote discussion rather than face-to-face meetings, managing all these moving parts can be a struggle. However, when a customer can make their key people available (e.g., project managers, engineering, and QA leads, etc.) to engage in real time with Flexan's functional heads who understand their pain points, the collaboration progresses much more smoothly.

As a contract manufacturer, Flexan supports our customers by prioritizing such communication. We meet weekly to discuss high-level topics, assembling project/program managers and department heads from each side to address topics like delivery, quality, and current issues. Then, we segue into smaller groups to discuss issues like documentation and records. This structure ensures that everyone involved understands constraints the same way and comprehends how Flexan can provide additional resources to handle problems or tasks.

Still, we often find that, when a customer decides to transfer a project, they have already reassigned their resources based on the misconception that their team is no longer needed. The customer team gets smaller and smaller as the transfer progresses, making it difficult to access those individuals. Flexan offers the expertise in transfer, as well as depth of experience in troubleshooting design and validation, to fill this vacuum and preserve the customer's timeline (sometimes to the extent that we manage the customer's scheduling) by identifying roadblocks and proposing solutions.

In addition to communications between OEM and CMO project teams, Flexan can help customers expedite their internal decision-making processes by providing information and context conducive to a speedy, well-informed resolution. For example, a recent customer needed to change materials but was wary of the delay that would be imposed by the lengthy testing process (in this case, from four to six months) to validate the material. Consider that a customer may work regularly with one of several well-known medtech silicone manufacturers or suppliers but has no established connection with the others. We were able to provide that customer with historical data from other, similar applications showing an alternative material's equivalent performance, inspiring greater confidence in their decision to change while continuing the transfer process in parallel.

The same logic applies to manufacturing equipment, from machines to tooling. Expanding production may necessitate a shift from dedicated to multiple machines, mitigating risk by introducing flexibility, redundancy, and room for further expansion. Flexan's multiple sites across the globe ensure redundant

manufacturing equipment and processes, enabling us to commit resources to accomplish validation of new equipment in parallel with existing manufacturing activities. This way, delays do not plague a common-sense move to machinery or tooling that could cut, for example, several steps from the manufacturing process, and, in some cases, reduce the amount of material wasted during production, resulting in tangible cost savings.

FINAL THOUGHTS

Experience and expertise are inadequate unless they are passed along through effective communication. As the pandemic has waned, Flexan has embraced the opportunity to reintroduce in-person interactions, combining them with remote contact to strike a balance of convenience and clarity with our customers. We believe a group of people in a room together typically are much more impactful and powerful than an assemblage of individuals on a conference call, where one or two people tend to dominate the conversation. In-person discussions are cross-functional, open, and more transparent.

We welcome the opportunity to walk customers through our facilities, from the cleanrooms to the production lines, allowing them to observe the effectiveness of process flow in person, rather than via a remote tour. A remote, online tour diminishes the effectiveness of this exercise because customers cannot experience our culture, see our personnel in action, or have questions answered immediately.

Complications are common when transferring manufacturing from one facility to another, and many organizations realize they lack the internal expertise and/or resources to accomplish transfer quickly and precisely, leading them to search for robust partners who can take over with little to no downtime. Flexan's commitment to our customers promises full access to dedicated resources and broad expertise. We are adept in bridging gaps caused by lost or tribal knowledge and adapting processes or documentation to meet modern standards across the globe.

We work hard to keep communication transparent and effective by striving for understanding and seeking accountability from all stakeholders. In short, a trusted partnership is our most valuable asset. Contact us to learn more about how we can help you bring your device or device component to market.

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

About The Author

Bob Khin is the Plant Manager at Flexan's facility in Lincolnshire, IL. Bob began his career as a design/manufacturing engineer in the automotive Industry, progressing to Director of Engineering/CI. He later worked as Director of Quality and Head of Operations in the Appliance and Aerospace/Defense industries. For the past 15 years, he's been involved in the design, CI, and manufacture of orthopedic implants and surgical devices, working for companies such as Zimmer, Depuy, Biomet, Medtronic, Paragon, and more. Bob holds a B.S. in Mechanical Engineering from the Illinois Institute of Technology and an MBA.

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.