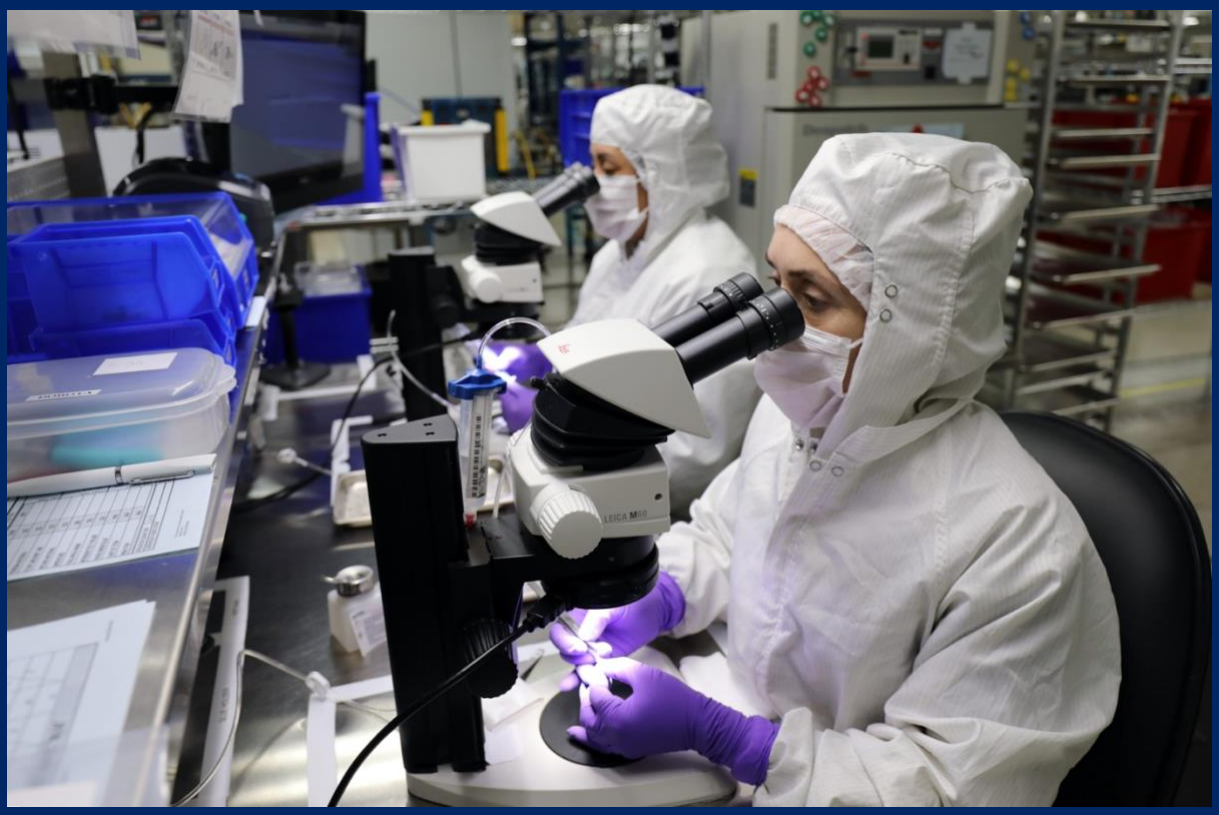

Manufacturing Transfer Requires Cross-Functional Leadership, Resources, and Open Communication

By Harold Sant, FLEXAN

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When a manufacturing consolidation strategy emerged for a top-30 medical device manufacturer (OEM), they found themselves presented with the challenge of needing to close a legacy facility. Rather than transferring the critical manufacturing operations of a Class-III industry-leading implantable device to another location, the OEM decided to explore their outsourcing options.

It was imperative for the OEM to find a partner that could support its high-mix/low-volume portfolio and comply with the stringent requirements for Class-III implantable device manufacturing. The scope of this operation was complex – the OEM would be transferring more than 125 implantable Class-III custom silicone implantable components to a tightly controlled production environment while ensuring continuity of supply and quality standards. And the aggressive timeline would require an experienced partner with a track record of success and an unparalleled commitment to partnership with detailed project management experience. Lastly, a failed attempt to outsource some of the operations several years earlier created significant concerns for senior leadership.

Flexan – an Illinois-based CM specializing in custom manufacturing solutions for high-precision silicone, rubber, and thermoplastic components and devices – was selected by the OEM for a transfer project with visibility across the organization including their Board of Directors. The OEM based this decision upon Flexan's highly experienced engineering and technical teams, its deep quality assurance and regulatory (QA/RA) expertise for supporting process validation and regulatory reporting, as well as its disciplined Project Management approach for large project transfers. Flexan was also willing to co-invest in the capital equipment, resources, and time required to meet the customer's deadline and to make this large-scale project a success.

DISCIPLINED AND CREATIVE PROJECT MANAGEMENT

The first step in the process required alignment between the parties for the full scope of the project. This included understanding the project priorities and team member roles, along with clarifying expectations on how challenges would be escalated and resolved. All known and potential risks were discussed at the earliest stages to establish both realistic expectations and to develop contingency plans if challenges were unable to be resolved.

Flexan created a dedicated, cross-functional team to manage the project. Led by the Program Manager, the team consisted of Engineering, Supply Chain, Operations, Finance, and Quality personnel, with frequent senior

management support. Routine meetings with the OEM reviewed project requirements, production updates, raised team member concerns, and established clear accountability for open items.

An efficient process was established to review, align, and approve each component and device with full compliance with all Design History File (DHF) requirements. Quality Assurance representatives worked directly with the OEM's Quality team to ensure that all quality and regulatory requirements were being met, especially within the context of the project's tight timeline. This engagement helped both parties drive efficiencies to streamline the rigor of regulatory review and approval, saving considerable time and resources.

Flexan was also responsible for installing and validating a complex, state-of-the-art proprietary manufacturing system developed by the OEM – another challenge to an already aggressive timeline. Drawing from its technical expertise in equipment and software validation, a team was assembled to conduct a risk assessment, develop software requirements, and propose a validation solution to the OEM. Flexan succeeded in transferring and validating the customer-owned equipment and supporting software without slowing down the project timeline or impacting their supply chain.

Employing comprehensive Contract Review and Manufacturing Transfer checklists ensured that all project and product requirements were properly documented and transferred. Structuring efficient parallel documentation, review, and approval processes quickly streamlined the validation complexity. Validation times were shortened from five weeks to two, and the documentation reporting review process was shortened from seven days to one.

Over the duration of the project, Flexan transferred and validated more than 20 unique pieces of equipment and over 200 molds, along with duplicating all fixtures and inspection equipment. Components were successfully transferred to Flexan's production team, allowing them to supply two OEM plants simultaneously as they transferred assembly operations without interruption.

SUMMARY

As with any project of this scale, unexpected surprises can derail a project with significant financial and operational implications. Flexan's detailed Project Management process was crucial in providing a quick identification of challenges, rapid response to those challenges, and quick development of an action plans for resolution. This disciplined approach quickly mitigated unexpected challenges and minimized the disruption to the timeline. By the end of the project, Flexan had validated:

- 31 subassemblies
- 26 extrusion part numbers
- 65 molded part numbers
- 15 special process part numbers
- 70+ backup molds and fixtures

Flexan thrives on challenging, large-scale, complex projects. The company has a demonstrated ability and experience to utilize its entire technical organization to develop cost-effective processes for projects of any scale. Key capabilities Flexan brings to any project include:

• Integrated Quality Assurance throughout the phase-gate project plan, with metrics and gates to identify issues early on, to minimize additional cost and delay.

• Commitment to work with multiple customer sites and functional/leadership structures to ensure that project goals are met.

• Dedicated personnel and processes to effectively resource a project and to achieve tasks per the commitments of the project timeline.

• Experience in proactively designing a clear, methodical, and robust design control process to prevent last-minute challenges prior to production.

• History of effectively managing the logistics for raw material, supplies, and equipment to manage to the timeline.

"Flexan was a great partner as we transferred complex, implantable medical device manufacturing and assembly operations out of our facility," stated an OEM senior program manager who worked closely with the Flexan team. "What impressed me the most throughout the project was the management team's dedicated involvement throughout the project, everybody's 'can do' attitude, their ability to develop creative solutions, and how they met all our high-quality expectations."

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

About The Author

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About Flexan

Founded in 1946 and based in Chicago, 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, as well as the capability to provide products from molded components to final packaged full assemblies, Flexan has the pedigree medical device companies are looking for in a custom contract manufacturer.