4 BEST PRACTICES TO MITIGATE RISK IN MANFACTURING TRANSFERS

If you're considering a manufacturing transfer, you may be losing sleep over all the things that could go wrong: cost overruns, schedule slips, or quality issues, to name a few. Missteps anywhere in the process can make the difference between meeting or missing your timeline and budget.

Medical device companies can mitigate the inherent risks associated with manufacturing transfers by choosing a contract manufacturing organization that understands how critical it is to execute programs on time and on budget. The people you partner with can make or break your manufacturing transfer. Choosing an experienced partner with skilled teams and robust processes and procedures in place to manage risk can ensure a smooth transfer and give you peace of mind.

As a contract manufacturing organization with decades of experience, Viant has handled manufacturing transfers for hundreds of customers—from startups to the world's largest medical device companies. We've dedicated resources to developing a world-class methodology for manufacturing transfers, training our staff, and nurturing a culture of continuous improvement.

For medical device companies wondering what to look for in a manufacturing partner, this white paper will share 4 best practices to mitigate risk for a successful manufacturing transfer.

1. DEDICATED SKILL SETS
2. DEFINED PHASE-GATE PROCESS
3. COMPREHENSIVE RISK MANAGEMENT SYSTEM
4. ROBUST 3P EVENTS

#1: TEAM WITH DEDICATED SKILL SETS

EXPERIENCE MAKES A DIFFERENCE

When planning a manufacturing transfer, look for an experienced partner with a solid track record of success. An experienced, well-trained team can drive the process forward. Skilled team members can proactively identify and take action to mitigate risks that could lead to schedule slips and cost overruns.

> ***《 Viant Program Managers are very customer focused and act as an extension of our team. 》***
>
> Viant customer | single-use device in regenerative medicine space

Seasoned team members also have a deep understanding of quality requirements from the FDA, from the customer, and from their own internal quality system. Knowing the do's and don'ts is what makes an experienced Program Manager stand out.

At Viant, our dedicated team of manufacturing transfer experts includes:

- Program Managers who are certified Project Management Professionals (PMPs), responsible for planning and monitoring projects, interfacing with customers, and actively advocating for the customer
- Dedicated engineering managers who lead technical teams of manufacturing, quality, and packaging engineers that execute projects and ensure timelines are met
- Specialized engineering teams that can "parachute in" to address critical issues

Working with a contract manufacturing organization that is passionate about manufacturing transfers and has been around the block a few times gives you confidence that your project is in good hands.

REAL-LIFE EXAMPLE

Viria Carmona, PMP | Program Manager, Viant

Viria has a bachelor's degree in industrial engineering and is a certified Project Management Professional (PMP). She is currently spearheading the transfer of a large medical technology company's 2 new coronary angioplasty devices from a U.S. Viant facility to our low-cost manufacturing facility in Costa Rica.

Viria says the most important element of program management is effective communication with internal and external stakeholders. Her role is to be her customer's advocate and to serve as a bridge between Viant and the customer.

As Program Manager, Viria takes ownership of the project and drives it through Viant's stage-gate process, leading the cross-functional team and managing every detail so her customers can focus on their core business.

#2: DEFINED PHASE-GATE PROCESS

PLAN AND MANAGE THE DETAILS

Benjamin Franklin said, "When you fail to plan, you are planning to fail." That certainly goes for complex manufacturing transfers. Without a comprehensive plan, you can run into issues with cost, schedule, supply chain, quality, and more.

> ***《 Knowing Viant has so many controls in place inspires confidence. 》***
>
> Viant customer | surgical device for cellulite treatment

At Viant, we've developed a defined, gated process for each of the 4 phases: Planning, Documentation, Validation, and Transfer. An activity matrix for each phase defines specific inputs, outputs (deliverables), and owners (who's responsible) for each item. Itemized templates for activities from procurement and financials to risk management and lessons learned help our Program Managers to closely track the details and keep our customers informed every step of the way.

Our Program Managers take fierce ownership of this gated process. They're relentless in overseeing the details and holding their teams accountable for ensuring that all tasks are completed. But they also have a vision for the "big picture" and understand how each item on the matrix plays a critical role in ensuring the project's overall success.

High-level review and oversight is also important to keep projects on track. Our Program Managers have support from our leadership team, which provides direction throughout the process and helps to resolve any roadblocks that could slow the team's momentum.

With a robust system in place to plan and manage the details in each phase, you can have confidence up front that nothing will slip through the cracks.

REAL-LIFE EXAMPLE

A medical device startup that had just received FDA approval for a novel surgical device was eager to get to the Transfer phase so it could ramp up production. In the Planning phase, Viant spearheaded a 3P event that identified a safety issue that would have caused major problems in the manufacturing line. Identifying and resolving the problem before the Transfer phase eliminated the chance of injury on the line and mitigated the impact of a launch schedule slip.

#3: COMPREHENSIVE RISK MANAGEMENT SYSTEM

PROACTIVE VS REACTIVE APPROACH

Risk management is the key to successful manufacturing transfers. Without a rigorous process to identify and manage risk, you could be blindsided by any of a wide range of issues that could cause your schedule to slip and your costs to escalate.

Customers don't expect us to predict the rain, but they do expect us to build an ark.

Any company can react to issues that have already occurred. At Viant, we strive to avoid those issues by taking a proactive approach. Risk management is part of our culture. It's a closely defined, tightly managed process.

We've developed a detailed methodology that helps us to identify and manage short-term as well as long-term risk. Our team brainstorms potential issues, assesses impact and probability, plans mitigations (to prevent risk) and contingencies (back-up plans), and tracks the status of each potential risk. Risk management is also a key part of our monthly review meetings with leadership. Our Program Managers on the ground have the support and guidance of our most experienced executives to ensure no stone is left unturned.

With a comprehensive risk management system, you ensure that there are no surprises in the manufacturing transfer process.

REAL-LIFE EXAMPLE

Viant was working with a customer to transfer a surgical device for the treatment of benign prostatic hyperplasia (BPH). The Viant team identified the potential risk of delayed delivery of materials (molded components, tubing, wire harnesses) that could delay the Validation phase.

- Mitigation: Viant implemented periodic system checks and manual inventory checks to ensure adequate material levels.
- Contingency: At the recommendation of the Viant team, the customer ordered materials in advance to provide a buffer.

These measures avoided weeks of schedule delay and cost overruns.

#4: ROBUST 3P EVENTS

IDENTIFY AND ELIMINATE WASTE

> ***I can't imagine anyone doing a transfer without first going through the 3P process.***
>
> Viant customer | implantable device used in reconstructive surgery

Not every manufacturing transfer project warrants a 3P (Production Preparation Process) event. But for a startup or a mature manufacturing line that has not already been subject to a Lean process, a 3P event can be a valuable tool for helping the team to visualize and analyze the manufacturing process. 3P events can identify opportunities for:

- Improved safety
- Improved efficiency
- Reduced operating costs
- Optimized equipment for projected volume
- Optimized staffing levels and training needs

At Viant, assessing the value of conducting a 3P event is a mandatory part of Phase 1, Planning. If deployed, 3P teams include staff from Viant and the customer, as well as key suppliers. Participants can include cross-functional staff members from engineering, quality, operations, supply chain, or business development, to name a few.

To facilitate and conduct an event, we construct a "3P arena" with U-shaped seating, multiple projectors, prepared components and devices, process flow charts, and floor-to-ceiling white boards. The most valuable output of a 3P event is the construction of a physical mock-up that allows the team to take a hands-on approach to the design of the line and directly interact with the proposed solution.

If product design is not finalized, coupling a 3P event with a Design for Manufacturability (DFM) event can significantly amplify the results of the 3P event.

Robust 3P events can help you meet your requirements in the most efficient way, resulting in the highest-quality product at the lowest cost.

REAL-LIFE EXAMPLE

A surgical device company had a goal of decreasing its manufacturing cycle time from 309 minutes to 120 minutes per unit. Before the transfer, Viant held a 3P event that identified opportunities to implement improvements such as continuous flow process and a volume ramp-up manufacturing strategy that reduced cycle time by 37%.

WHEN SHOULD I CONSIDER A MANUFACTURING TRANSFER?

Consider a manufacturing transfer when you:

- Want to lower manufacturing costs
- Want to reduce labor costs
- Need additional manufacturing and assembly capabilities
- Need more manufacturing capacity
- Want to improve quality
- Need additional staff or specialized skill sets
- Need additional infrastructure (eg, clean rooms)

CONCLUSION

We understand that the stakes are high when you're considering a manufacturing transfer.

Risk management begins before any contracts are signed, when you choose a contract manufacturing organization. Chose a partner with a proven track record of success in managing transfers on time and within budget, and the infrastructure in place to ensure you meet your goals.

Medical device companies can mitigate risk by choosing a partner that has:

1. Dedicated skill sets
2. Defined phase-gate process
3. Comprehensive risk management system
4. Robust 3P events

At Viant, our culture of continuous improvement means we are continually enhancing and shaping our manufacturing transfer process to ensure that our capabilities can meet our customers' growing needs for more–and more complex–manufacturing transfers.

ABOUT VIANT

At Viant, we focus on providing end-to-end solutions for medical device OEMs. Our deep materials expertise–combined with our experience in engineering, manufacturing, assembly, packaging, and sterilization–allows us to bring our customers' healthcare solutions to market. We have facilities across the U.S. and around the world, including low-cost facilities in Costa Rica, China, Mexico, and Puerto Rico. Visit Viant at viantmedical.com.

VIANT™
WE'RE IN IT FOR LIFE.