

# 4 BEST PRACTICES TO MITIGATE RISK IN MANUFACTURING TRANSFERS



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*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, Vention Medical 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

“Vention Program Managers are very customer focused and act as an extension of our team.”

Vention customer | single-use device  
in regenerative medicine space

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.

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 Vention, 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  
Vention Medical



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

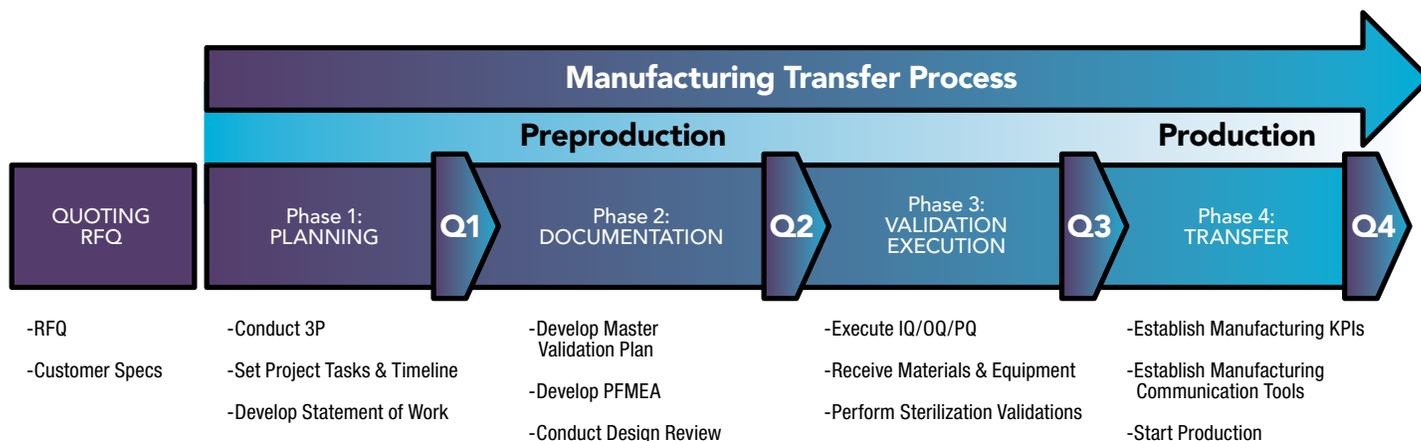
medical technology company's 2 new coronary angioplasty devices from a Vention design & development facility to our low-cost manufacturing facility in Costa Rica.

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 Vention and the customer.

As Program Manager, Viria takes ownership of the project and drives it through Vention'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



“Knowing Vention has so many controls in place inspires confidence.”

Vention customer | surgical device for cellulite treatment

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.

At Vention, 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, Vention 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

“Vention customers do not expect our program managers to forecast the rain, but they do expect us to plan ahead and build an Ark.”

- Dan Croteau | CEO, Vention Medical

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.

Any company can react to issues that have already occurred. At Vention, 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*

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

- Mitigation: Vention implemented periodic system checks and manual inventory checks to ensure adequate material levels.
- Contingency: At the recommendation of the Vention 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.”

Vention 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 Vention, assessing the value of conducting a 3P event is a mandatory part of Phase 1, Planning. If deployed, 3P teams include staff from Vention 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.

#### 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, Vention 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%.



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.

## WHEN SHOULD I CONSIDER A MANUFACTURING TRANSFER?

Consider a manufacturing transfer when you:

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

## 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. Choose 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 Vention Medical, our culture of continuous improvement means we are continually enhancing and shaping our manufacturing transfer process to ensure that our capabilities can meet our customer's growing needs for more—and more complex—manufacturing transfers.

**Mary Jo Sysko** has nearly 15

years of experience in the medical device and aerospace industries.

As Vention's Senior Director of Program Management, she leads the Transfer Program Manager team

and is responsible for continuous improvement of manufacturing transfer processes and procedures. She is a certified Project Management Professional (PMP) and has a bachelor's degree in mechanical engineering as well as an MBA.



## ABOUT VENTION MEDICAL

Vention Medical is a global integrated solutions partner with more than 30 years of experience in design, engineering, and manufacturing of complex medical devices and components. Vention Medical specializes in components and services used in interventional and minimally invasive surgical products including catheters, balloons, extrusions, polyimide and composite tubing, heat shrink tubing, braid-reinforced shafts, cleanroom injection molding, and finished device assembly and packaging. Visit Vention at [ventionmedical.com](http://ventionmedical.com).