Cardiac Rhythm Management & Neuromodulation

Integer®

4 Phases to Successful Manufacturing Transfers

Flawlessly executed manufacturing transfers of medical components and device assemblies are not only critical to support continued growth strategies, but paramount to sustaining the competitive edge in today's globalized medical industry. Central to ensuring successful manufacturing transfers, the disciplined rigor associated with adhering to a defined Manufacturing Transfer Procedure executed by an actively engaged Transfer Team, held accountable by functional leadership, is the key to realizing step-change improvements in project milestone conformance, better than budgeted performance, and enhanced communications to all key audiences.

Introduction

In today's medical device market, there are compelling reasons for medical device OEMs to consider transferring the manufacturing or assembly of a product from one site (a sending site) to another (a receiving site):

- To add capacity
- To optimize manufacturing costs
- To improve capabilities
- To locate closer to customers or to suppliers
- To re-allocate investments to other parts of the business

Successfully executing manufacturing transfers requires attention to process discipline and rigorous adherence to defined procedures. Based on our experiences, adhering to an established Manufacturing Transfer Procedure (MTP) has been key to driving significant improvements in transfer project performance metrics:

- Project milestone delivery conformance increased by 75%
- Financial adherence to the approved budget improved by 66%
- Communication effectiveness amongst all stakeholders was enhanced by 50%

This paper provides an overview of Integer's 4-Phased Manufacturing Transfer Procedure and the integration of the procedure deployment into the overall success criteria evidenced across the cadence of manufacturing transfers executed over the last four years.

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Michael has managed product and technology transfer projects for over 30 years. His team has supported the development of and ongoing refinement of Integer's Manufacturing Transfer Procedure.

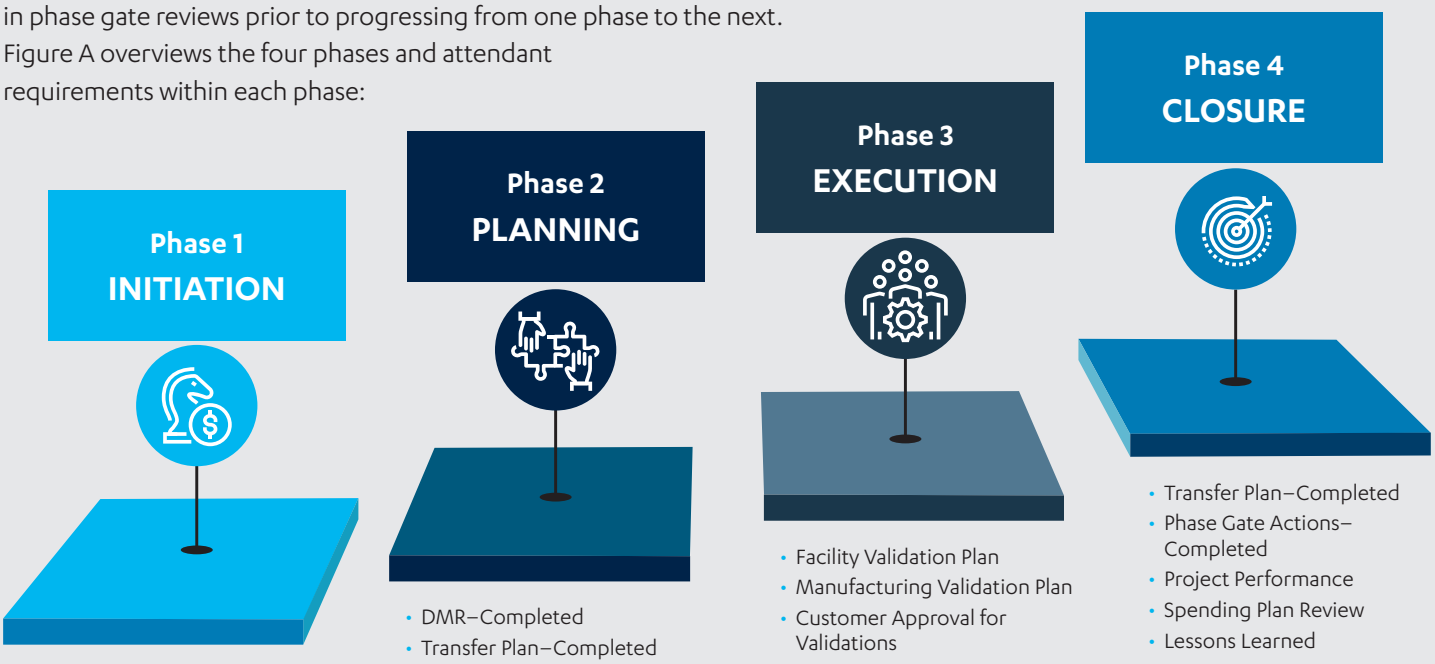
Procedure Adoption

At Integer, the adoption of the 4-Phased Manufacturing Transfer Procedure (4MTP) has been instrumental in optimizing the methodology used and resulting executions of the transfers of production released components and devices. The basis for this procedure was developed from extensive reviews of lessons learned from previously executed transfer projects, done on an ad hoc basis with no over-arching governance. The lack of a standardized procedure and accompanying governance was recognized as a leading indicator for projects that were often poorly defined and prone to scope-creep, under-resourcing, and indicative of minimal customer engagement. Following the adoption of 4MTP, we quickly recognized the beneficial impact as project charters were established with very clear scope statements; project plans were documented and rigorously protected; early and frequent risk reviews were held throughout the projects and time-bound actions were assigned with clear accountabilities; and, senior leadership oversight ensured the sustained adherence to procedures and to disciplined project management practices.

To be clear, manufacturing transfers are distinctly different than design transfers. The Manufacturing Transfer Process (MTP) is not a replacement for or reformulation of a Product Development Process (PDP). Whereas the PDP provides the guidance for developing a new product from inception to commercialization between a development site (sending) and a manufacturing site (receiving), the MTP applies to production released components or devices where the design transfer package is complete and the Device Master Record (DMR) and Design History File (DHF) are already established at the sending site. The paramount goal of the MTP, then, is to re-establish the proof of safety and effectiveness of the transferred product in its new manufacturing location (receiving site) with a revised Device Master Record and Design History File established.

4 PHASES OF THE MANUFACTURING PROCEDURE

Integer's 4MTP consists of four distinct phases, each with a comprehensive set of required actions that must be completed and subsequently assessed for compliance and conformance in phase gate reviews prior to progressing from one phase to the next. Figure A overviews the four phases and attendant requirements within each phase:



- Business Case
- Approved Spending Plan
- Project Charter
- Customer Communication Plan
- Quality & Regulatory Plan
- Supplier Change Mgmt Plan
- DMR Draft
- Transfer Plan–Draft
- Communication Plan

- DMR–Completed
- Transfer Plan–Completed
- Quality & Regulatory Plan–Completed
- Facility Master Validation Plan
- Manufacturing Validation Plan
- PFMEA–Completed

- Facility Validation Plan
- Manufacturing Validation Plan
- Customer Approval for Validations
- Regulatory Filing Updates

- Transfer Plan–Completed
- Phase Gate Actions–Completed
- Project Performance
- Spending Plan Review
- Lessons Learned

Figure A: Integer's 4MTP Phasing and Phase Gate Requirements

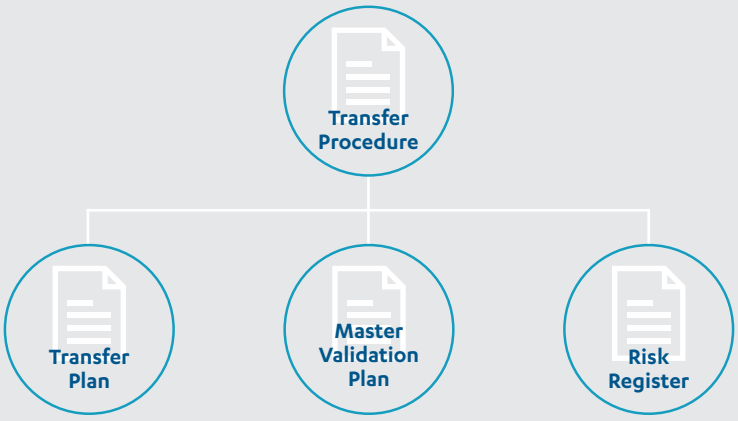
Required Governance

The premise of 4MTP is the adherence, by the designated cross-functional Transfer Team, to the procedural requirements for each of the phases. Responsibility for adhering to the 4MTP is ascribed to the designated Transfer Project Manager who, along with the Transfer Team, is accountable to a Steering Committee comprised of senior functional leaders representing both sending and receiving sites. In fact, a valued ex officio member of the Steering Committee may be a Customer representative as another way to further solidify the engagement and recognition of inputs needed to support the Customer's regulatory submission requirements associated with a product manufacturing site change. Stage Gate Reviews are scheduled at appropriate intervals, dependent on the completion of the prescribed actions in the phase. These Gate Reviews provide a forum for the Steering Committee to confirm, via objective evidence provided by the Transfer Team, that the required actions have been satisfactorily completed. The Steering Committee is responsible for approving the progression of the project to the next stage or reverting the project to the current stage with clarity on the gaps observed.

FIVE FACTORS TO SECURE SUCCESS

While the adoption of 4MPT is critical, it is just one of five factors that we have found that assure the likelihood of complete success of the Manufacturing Transfer:

1. **Leverage experienced project managers and project management tools to drive a flawless execution**
   a. Adhere to the defined project governance model and procedures
   b. Develop a statistically sound validation strategy
   c. Support the Customer through regulatory submission
2. **Build an effective Project Team**
   a. Develop effective partnerships between the sending and receiving sites
   b. Include the Customer as part of the team
   c. Assess required skill sets
   d. Define clear roles and responsibilities, inspire motivation, and hold one another accountable for completing assigned tasks
   e. Celebrate success through recognition
3. **Follow a standardized, template-supported Manufacturing Transfer Process Procedure which includes**
   a. Assessing the original product Device Master Record and remediating any gaps
   b. Developing a detailed project plan outlining all transfer activities
   c. Executing the Master Validation Plan
   d. Assessing manufacturing readiness
4. **Assess risks throughout the project and develop robust mitigation plans**
   a. Ensure appropriate communication of risks to key stakeholders, escalating requests for support of corrective action plans
   b. Classify risks by process step, functional area, and level or severity of impact
   c. Use a Risk Register tool to capture and make visible all of the identified risks and corresponding mitigation actions and owners
5. **Demonstrate that the transferred process Key Performance Indicators (KPIs) are at or exceeding the planned targets**
   a. Validate the baseline KPIs for the process to be transferred
   b. Develop a KPI dashboard and monitor transferred process performance at the new site
   c. Sustain the culture of continuous improvement



In closing

Manufacturing transfers are a reality for many medical component and device OEMs. Successfully executing such transfers becomes table stakes to ensuring sustainability of long term performance. At Integer, we have adopted a 4-Phase Manufacturing Transfer Procedure that provides the rigor and governance to assure consistent and repeatable successes. As a result of implementing the procedure and rigorously holding ourselves accountable to following it, we have realized improved project milestone delivery conformances, better than budgeted performance, and enhanced communications to all key audiences.

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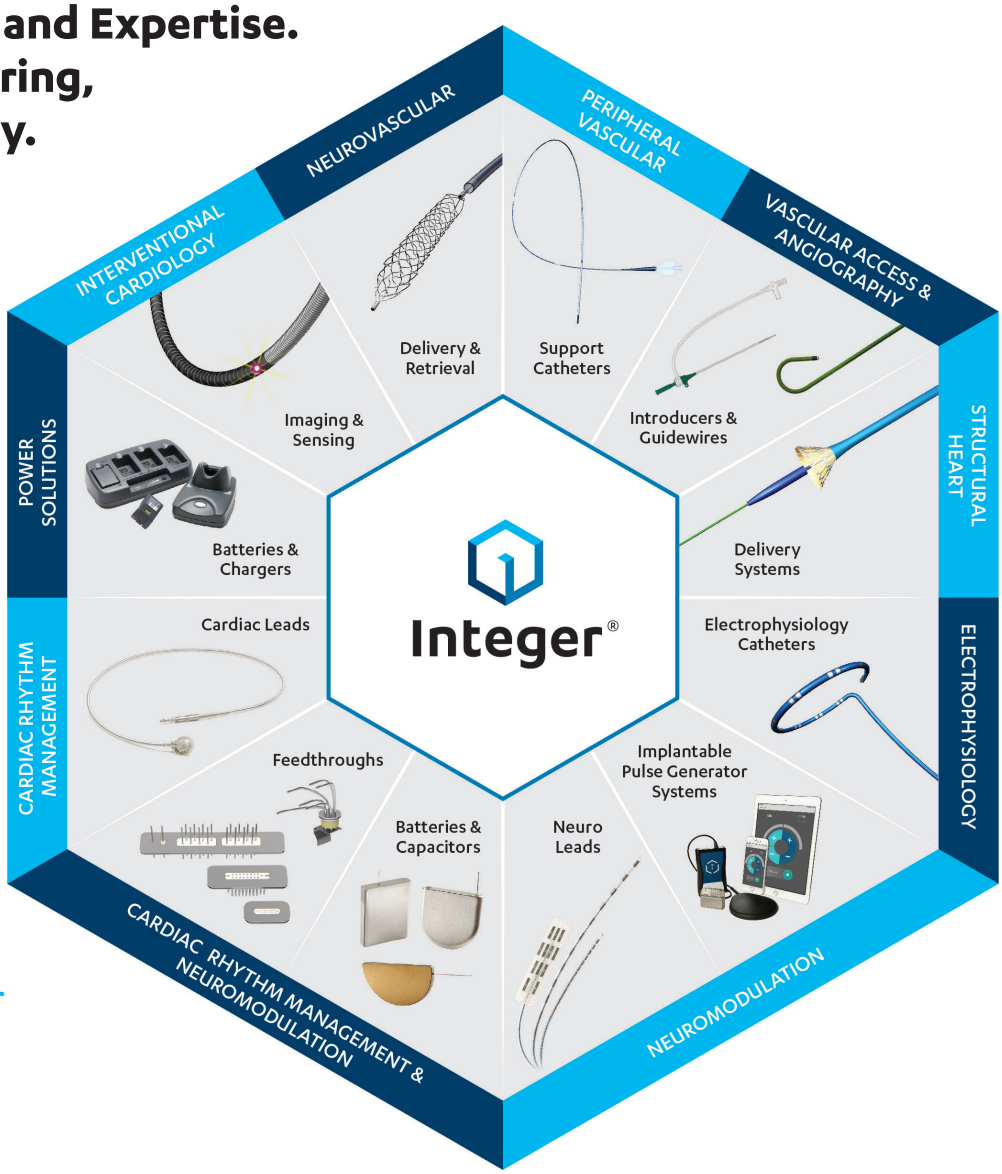
> Let's Start a Project Together



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