Five Tips for Smoothing the Transition from Design to Manufacture

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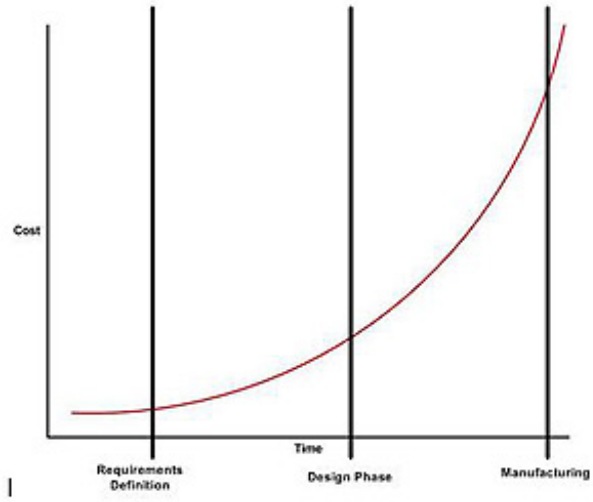
In the fiercely competitive medical device and instrumentation industry, speeding time to market is important to edge out competitors and begin generating revenue for products that often carry long and expensive research and development cycles. Pushing products through the development lifecycle is essential for distinct market presence.

A common obstacle to a successful market launch is the transition of medical products from design to manufacture, with issues often leading to unnecessary costs and significant delays. Several tips and techniques can be implemented to smooth the transition from the product development stage to full-scale production, and ensure products are delivered to market on time and on budget.

1. Start Early

The first and perhaps most important tip to smooth the transition from design to manufacturing is to start early. Making changes to the product design once the handoff to manufacturing has occurred will only create additional costs and time delays. The “cost of change” increases asymptomatically as the product development cycle time increases. (See Figure 1)



Cost of Change
During Product Development
Figure 1

Managing the “cost of change” also means making sure that the product requirements are solid before the design activities begin. This is paramount to

reducing the risks associated with product changes during the development cycle. Further, making manufacturing a priority during the design process by involving production and quality control personnel as well as key vendors will help avoid additional design revisions at later stages. While change is inevitable, focusing the right resources early can minimize the probability of major change downstream in the development cycle or during manufacturing.

2. Assemble Cross-Functional Teams

Forming and utilizing cross-functional teams, comprised of mechanical, electrical, compliance, systems, manufacturing, and quality engineers, can also smooth the transition from design to manufacture. The team should include members of the supply chain, like buyers and planners, as well as suppliers, program managers, marketing personnel, and industrial design and human factor experts.

Members of these teams must bring to bear a broad knowledge base. Combining their diverse skill sets and areas of expertise enables a holistic approach to device manufacturing and the regulatory approval process. Together, they devise well-defined goals and objectives for each phase of development that minimize manufacturing obstacles and ensure devices and instrumentation adhere to U.S. Food and Drug Administration (FDA) and European Union (EU) regulations.

Cross-functional team members can work closely together to review product requirements, address technical risks, and manage instrument costs. Reducing development cycles to shorten time to market requires assembling the experts and cross-functional teams early to ensure manufacturability, serviceability, reliability, and a manageable supply chain.

The team environment is an important ingredient for a successful design to manufacturing product transition. Recognizing that team dynamics (the principles of “Forming-Storming-Norming-Performing” or FSNP) play an important role in the efficiency of any multi disciplined team project is essential. Team members and vendors who are familiar with each other and have been through previous successful transitions can accelerate the process.

It should be noted that there are tradeoffs between moving through product development and transition to manufacturing too quickly, and bringing a superior product to market. Moving too rapidly can result in a product that may require redesign to address manufacturability, serviceability and reliability, while going too slow could mean lost opportunities. The clear definition of desired product performance parameters with the rapid execution of a proven medical product development process, utilizing an experienced cross functional team is what leads to a successful transition.

For example, an OEM developing a clinical chemistry analyzer paid the price for not assembling a cross-functional team at the outset of the project. The OEM developed the chemistry and assay protocol needed to perform the in-vitro diagnostic tests on the bench and commissioned a contract design firm to develop an instrument to automate the process. When the company began transitioning the product to

manufacturing, however, it became apparent that the assay protocol required additional functionality that was incompatible with the hardware. As a result, the product was never brought to market. By involving both the development and hardware design teams prior to the transition process, the OEM could have saved an enormous amount of time and money and produced a commercially viable and potentially profitable product.

3. Rely on a Proven Process

Developing and continually tweaking the process used for transitioning products from design to manufacture will create a solid method for getting medical devices and instruments to market on time and within budget. Over the past 30 years, we have honed a proven process for moving medical devices and instrumentation to production.

First, for a smooth handoff to manufacturing, planning for transition must begin in the product development stage well before the software and system verification and validation efforts have been completed.

A manufacturing test plan and detailed test specifications should be developed to include system level testing, sub-assembly testing, and spare part testing. To verify conformance with instrument system requirements and further ensure a smooth transition to manufacturing, a system acceptance test procedure should also be used.

Once the test requirements are complete, specific test equipment should be designed and tested using the prototype system. Data from this testing can be used to finalize test parameters and verify the design of the test equipment. The instrument’s on-board test capabilities can be utilized by end users in the field, eliminating the need for custom field test equipment.

During the pilot-build phase, the manufacturing team should begin developing detailed instructions for instrument assembly and setting up the production area. This will ensure rapid start-up once the transition phase is complete. Production test equipment should also be validated during the pilot-build phase to ensure that test requirements have been implemented correctly. This process validates the functionality of the test equipment to be sure that it accurately meets its design specifications. Test equipment assures the manufacture of properly functioning modules that meet all performance requirements once the instrument has been moved into full-scale production. A validation report should be issued for each piece of test equipment.

4. Implement Staged Reviews

Continual checkpoints should be held throughout the product design and development process, including critical design, pilot production readiness and manufacturing readiness reviews. A critical design review should occur at the completion of the product prototype phase and prior to the release of documentation for the procurement of pilot material. This review must assess

product design to ensure that the hardware and software meet system requirements prior to pilot production.

The readiness of a product design to begin transition to manufacturing can be determined with a pilot production readiness review. The PPRR verifies that all appropriate design and program activities are completed satisfactorily and that the program team is prepared to build pilot production units. The review will ensure that the system design meets all applicable specifications and customer requirements, and is mature enough for pilot production units to be built by operations. During the review, team members will record findings, deficiencies, and technical issues. An action items list will be compiled, and individuals responsible for resolving them will be identified.

A final manufacturing readiness review (MRR) will be conducted after pilot production units are built and design validation is complete, to verify that the product is ready for full-scale manufacturing. A designated review leader should identify and request personnel from appropriate departments and functions to act as reviewers. Ideally, a review team includes representatives from engineering, operations, strategic sourcing, and quality assurance. The review will verify that all appropriate design, validation, and manufacturing preparations are complete and the program is adequately prepared to move to the production phase.

Because the MRR should be stringent and thorough, KMC Systems [1]employs an MRR checklist to understand the status of the design and associated documentation and ultimately prioritize outstanding tasks that needed to be completed to meet schedule and production requirements. During a recent product transition of an automated microbiology system, KMC Systems used its MRR checklist to prioritize remaining development/transition tasks prior to production. Each task was then delegated to either the engineering or manufacturing team for efficiency. The proven process was able to help the OEM meet its product launch date.

5. Train the Manufacturing Team

For a seamless and speedy manufacturing ramp-up, begin the training and knowledge transfer to the production team during product development and provide detailed assembly instructions. An effective training path will minimize wasted time and faulty products. Along with measures that increase and maintain morale and team spirit, the manufacturing team needs to be in tune with current Good Manufacturing Practices (cGMPs) as well as other FDA guidance regarding medical device manufacturing.

Conclusion

Whether an OEM plans to outsource manufacturing or not, the transition from design to manufacturing can either be a path to success or a roadblock to final product launch. Getting products to market on-time and within budget is highly dependent on the transition stage. Manufacturers that take manufacturability into account early and implement a proven process with cross-functional teams will reap rewards of condensed development cycles and larger profit margins.

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