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Design for Manufacturability: From Concept to Reality

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Design for Manufacturability (DFM) is a well-established practice, essential in realizing the transformation of new product concepts into mass-produced medical devices. And yet, all too often, issues that could have been avoided are identified very late in the process, impacting production costs and schedules. This suggests that key DFM principles are often underutilized in practice and not applied consistently, or to the degree necessary, to avoid these negative implications.

In this white paper, we will discuss three DFM-based best practices that will help create the conditions for success as manufacturing partners work with device designers towards a common goal. Engaging key stakeholders in an organized team from the inception of a project, conducting a thorough feasibility study, and implementing the proper quality tools will ensure that a device design is reliable, manufacturable, and acceptable to the physician or end user.

Integrated Product Development: One team, Multiple Disciplines

The first and most important element of DFM is a truly integrated multi-disciplinary product and design development team. Effective collaboration can help ensure that elegant engineering solutions are practical to manufacture from a cost or materials standpoint, and suit the end user. An integrated team also helps reduce the risk of a "silo" approach and an overemphasis of any one element, and design considerations being overlooked.

A senior staff engineer from one device manufacturer said the level and degree of the DFM teams vary, but may involve representatives from product management, quality and design engineering, regulatory, packaging, purchasing, calibration, prototyping, post-market, and others, as required. All critical customer requirements must be clearly established during initial team meetings, as total project lifecycle costs and speed to market are often dictated early on in the process. A solid interdisciplinary team considers important details such as performance characteristics, cost, timeline, clinical needs, and regulatory requirements. Consulting with key suppliers early can avoid costly rework later down the line.



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The Feasibility Study: Charting the Course for Success

A comprehensive feasibility study examines the key specifications throughout the life of a project and requires the team to thoroughly review and consider all potential design issues from the project's beginning. This type of study will provide information on a number of aspects that are crucial to the success of a product. Some aspects to consider include:

- **Materials Selection.** This step is critical because biocompatibility issues often combine with metallurgical and process challenges to impact manufacturing techniques downstream. The need for biocompatible materials may require changes in manufacturing approaches. For example, titanium screws for a prosthesis, while biocompatible, are difficult to injection mold and may require machining that adds complexity and cost. Hip and knee replacements require both costly high-grade materials and complex post-machining processes such as coatings or polishing. Ceramics are biocompatible, but may be more expensive in high volumes. The grade of ceramics can also make a difference, as in a recent case of a cardiac rhythm management device that had a high failure rate because cracks appeared during post-fabrication brazing. Substituting a higher, more heat-tolerant grade proved to be more cost-effective in the long run because of higher throughput.

A feasibility study should also consider the tolerance of materials for post-fabrication treatments, such as deburring and brazing. Materials, such as titanium, can cause laser markings on surgical instruments to smear or be rubbed off. Keeping them legible may require additional processes such as coating or embossing. Choosing the right material can also reduce fabrication steps.

- **Manufacturing Processes.** Alternative manufacturing processes are almost always available, but the trade-offs need to be weighed between speed and cost. For example, multiple machining steps might be replaced by ceramic or metal injection molding for some components. Machined components can be used for initial design and the proof of concept phase with injection molding substituted during production.

Application demands often determine the processes used. Injection molding may be the most economical way to produce gears in volume, but if the device requires high torque, machined gears may be required to maximize durability. Similarly, designs can be changed early in the process so that parts are produced by off-the-shelf tooling instead of using more costly specialized machinery or tools.

- **Finishing Processes.** A component's finish can have a substantial impact on durability, service life and clinical performance. Poorly-finished parts are a



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frequent cause of rejection and production delays. Some clinicians demand a pristine-looking reflective mirror finish, which may require specialized metals, surface treatments, polishing or blasting. Other instruments need duller finishes to reduce glare during surgical procedures.

The need for easy sterilization is another design factor that often guides DFM teams in selecting materials and processes. Where instrument life and durability is an issue, the team may recommend electropolishing or the use of anodized metal. The look and feel of a device or instrument may make the difference in acceptance by end users.

- **Application Considerations.** End users have widely varying requirements. Some applications such as cardiac ablation emphasize accuracy above all, while others focus on dexterity and speed. While adequate torque is often a key factor in developing surgical power tools, attention to ergonomics early in the design phase can reduce stress and manual effort for surgeons. One recent feasibility study for a surgical tool revealed that the peak static load on a clamping screw could be nearly twice the maximum clamping force indicated by the initial design. This information helped guide the team's recommendations for the tool's connectors and other components.

Of course, these are just some of the many important factors that a comprehensive feasibility study should include. Collaborating with partners that have both high-precision manufacturing capability and design services to conduct feasibility studies throughout product development lends itself to a more successful product launch.

Using Established Quality Tools to Support DFM

Quality initiatives, such as Six Sigma and lean manufacturing, are critical to reducing variation and removing waste from the manufacturing process. Other quality tools are essential to mitigating risk in the production of medical devices.

- **Risk Management.** In its various forms, risk management focuses on all of the critical-factor project elements at the onset. The Design of Experiment (DOE) is critical in evaluating or validating a component or process to be able to introduce it with assurance into use in a design and manufacturing system. This helps ensure that a product functions as intended. The DOE can prevent the need for costly testing to determine why a problem has arisen, or worse, ending up with worthless product. The DOE, despite its high value, is often overlooked in the rush to get a project moving.

Another key risk management document is the Failure Mode and Effect Analysis (FMEA). This should always be done as part of the planning phase to help guide



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the team in troubleshooting and in working their way through worst-case scenario factors during the design process.

When possible, device designers should provide their suppliers and partners with an overall system FMEA, in order to identify the most important product features and design tolerances, to determine how to control them and document the process including all changes. This system FMEA provides the direct inputs for the supplier's design failure mode and effect analysis (DFMEA).

The DFMEA will provide the basis for critical decisions from the end-user's perspective. For example, if a surgical tool design feels awkward, or is difficult for the surgeon to hold during a long procedure, the time to address this is at the DFMEA stage.

- **Continuous Improvement.** A continuous improvement approach can thrive in an environment where processes are often "frozen" after FDA approval or the production part approval process (PPAP). "Frozen" processes can be observed, evaluated and documented – especially by supplier-based DFM teams with a focus on improvements. Proposed changes are then shared with the device manufacturer to show the impact on production.
- **Kaizen.** This tactic, involving cross-disciplinary initiatives to improve processes, lends itself well to DFM. Its success requires an "on-the-floor" presence by designers, engineers and other team members. Design engineers should participate in multi-disciplinary discussions and observe production processes, then incorporate their lessons learned into the design. Kaizen initiatives may involve cross-training, workplace organization, mistake-proofing, eliminating redundant steps, setting takt times for individual steps, and fine-tuning or even replacing older machines with newer technology.
- **Six Sigma.** These practices keep the focus on minimizing variation and maximizing documentation. Device manufacturers must have a commitment to verifiable data to demonstrate how well processes are working based on the DOE, FMEA and other documentation.
- **PPAP.** Automatically applying PPAP principles to every manufacturing process from the beginning, gives manufacturers a benchmark to measure processes and maximize consistency.



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Conclusion

A sound DFM plan recognizes that successfully and efficiently manufacturing a product depends on more than features, marketing appeal or even ergonomics. Ultimately, the best-designed product in the world will only be successful if it can be produced within the given parameters. Consistently applying DFM principles and best practices will allow for a successful product that may be mass-produced cost-effectively and brought to market with minimal delays.

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About the Authors

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About Precipart

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