Device Development Excels in Rapid Development Centers

The manufacturing process all starts by partnering at the design stage and consulting with the supplier's RDC team to create a product that provides the best quality and patient outcomes.

Design and material choices can have a long-term impact on manufacturing costs and efficiencies for medical device manufacturers. When they work together with experienced component manufacturers from the start of a project, they can save time, reduce costs, and produce premium quality products, while keeping an eye on the goal of a smooth transition to serial production.

In addition, adherence to design for manufacturing (DfM) principles ensures efficient and cost-effective processes at high volumes (see the sidebar, "Defining DfM"). This article addresses the challenges medical device manufacturers face when it comes to designing a product and bringing it to market quickly and how a dedicated team of experts at a rapid development center (RDC) can improve this process.

THE DISCREPANCY BETWEEN DESIGN COST AND DEMAND EXPECTATIONS

DEFINING DfM

Design for manufacturability (also sometimes known as design for manufacturing or DfM) is the general engineering practice of designing products in such a way that they are easy to manufacture. The concept exists in almost all engineering disciplines, but the implementation differs widely depending on the manufacturing technology. DEFINING DFM

DfM describes the process of designing or engineering a product in order to facilitate the manufacturing process in order to reduce its manufacturing costs. DfM will allow potential problems to be fixed in the design phase which is the least expensive place to address them. Other factors may affect the manufacturability such as the type of raw material, the form of the raw material, dimensional tolerances, and secondary processing such as finishing.

Depending on various types of manufacturing processes, there are set guidelines for DfM practices. These DfM guidelines help to precisely define various tolerances, rules, and common manufacturing checks related to DfM. While DfM is applicable to the design process, a similar concept called DFSS (Design for Six Sigma) is also practiced in many organizations.

Source: Wikipedia

To remain competitive and offer affordable therapies to patients, medical device manufacturers are constantly looking to reduce the manufacturing costs of devices in development, as well as those already in market. Studies indicate that between 70 and 90 percent of manufacturing costs are linked to basic product design.

In the race to get new medical devices to market, speed is critical. According to *Industry Week,* manufacturing customers are demanding greater customization and faster speed to market at ever-lower costs. One area in which manufacturers are finding ways to meet this challenge is in product design. Innovation in complex product design techniques can deliver significant benefits in cost reduction, speed to market, product quality, and customer satisfaction.

Additional challenges arise regarding access to design verification. Device manufacturers want their manufacturing partners to offer design validation, including different configurations and high- and low-end samples (see the sidebar, “Design V&V”).

Finally, unrealistic expectations often exist during the handoff from design to manufacturing. Many device manufacturers work with design firms that have no manufacturing experience. When designs are handed off to the component manufacturer, they cannot be built “as is,” often requiring significant design changes, which impacts cost and time to market.

Additionally, many manufacturers are not equipped to scale up from prototype to production volumes. Producing millions verses hundreds of parts requires planning and a different approach to manufacturing.

CORE COMPETENCIES

When medical device makers partner with component manufacturers in the design phase, they can ensure cost control and scalability. Simple changes to a component’s design can have a huge impact on the tool and part cost, even affecting the device that it is assembled into. To navigate these challenges, many RDCs offer core competencies suited for medical device and pharmaceutical parts, including design, tool-making, high-precision machining, silicone and thermoplastic molding, secondary operations, automation, and assembly.

A Dedicated Team. RDCs offer a relational environment as opposed to a transactional one. RDC experts help medical device manufacturers discover what they need and how to get there. With a dedicated team of experts and quality tool-making equipment, RDCs can support medical device manufacturers throughout the development process, from device and component design to prototyping, testing, scale-up, and long-term supply of components and annuity production.

RDC experts can often design and create certain prototypes in as little as 24 hours, delivering sample parts right out of the tool while retaining additional samples for potential future analysis.

In addition to prototyping, rapid development teams collaborate with device manufacturers on component design and material selection to ensure superior quality of the finished device.

ACCESS TO QUALITY RESOURCES AND TECHNIQUES

DESIGN V&V

Design validation and verification are established and defined in the Quality System Regulation 21 CFR 820.30. Each manufacturer of any Class III or Class II device and certain Class I devices must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

Design Verification. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the design history file.

Design Validation. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the design history file.

Source: FDA 21 CFR 820.30

RDCs also bring value to customers by providing proven quality control processes. A good component manufacturer with rapid development capabilities gives customers access to raw material traceability, Class 7 cleanrooms, and established validation processes. Facilities are typically ISO 13485:2016 and ISO 9001 certified and meet requirements from the Food and Drug Administration (FDA) and European Medical Device Regulation (MDR).

Perfect Combination of Capabilities. Many component manufacturers specialize in only one of three critical development stages: design, prototyping, or production. Few offer expertise in all stages and, therefore, do not understand how design and material choices can impact long-term manufacturing costs and efficiencies. It's critical for medical device manufacturers to partner with

component manufacturers that understands the design, material, and production implications and has the dedicated experts to execute on every stage of the process.

A CASE STUDY: ACCELERATING TIME TO MARKET

A diabetes device manufacturer wanted to be first to market with an innovative technology that would change how diabetes patients track their glucose levels. Speed to market was essential, as the company's competitor was working on a similar innovation. The device manufacturer partnered with Trelleborg Healthcare & Medical to utilize Trelleborg's rapid prototyping and scale-up capabilities, ensuring the manufacture of the millions of parts per year required for a global launch.

Trelleborg created prototypes in just days, testing multiple design iterations ensuring feasibility of scale-up of each option, if chosen by the device manufacturer. This holistic design approach also included DfM and assembly testing, which led to bridge tooling and automation, quality control testing, and high-volume fully automated production. The diabetes device manufacturer achieved the desired launch date and quality expectations, delivering to market a device that will positively impact patients' lives.

CONCLUSION

With the demand for the rapid manufacturing of medical device components at a lower cost, it is critical for device manufacturers to partner with suppliers that have rapid development capabilities. Since RDCs often have a dedicated team of veteran engineering, process, and materials experts, they are often able to take device development ideas from design to serial production.

The process all starts by partnering at the design stage and consulting with the supplier's RDC team to create a product that provides the best quality and patient outcomes.

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