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Contract Manufacturing: Accelerating Product Development

Unlocking the full potential of materials science is one of the most efficient ways of elevating product performance and value while creating product differentiation.

Design and material choices can have a long-term impact on an original equipment manufacturer's (OEM) production costs and product quality.

When an OEM works together with an experienced contract design manufacturer (CDM) from the start of a project, many negative impacts to cost and quality can be avoided.

Design for manufacturing (DfM) principles implemented into a component or product helps ensure efficient, cost-effective processes, premium quality products, and a smooth transition into serial production (see the sidebar, “DfM Principles”). This article addresses the challenges medical device manufacturers face when designing and launching a product, and how a CDM’s dedicated team of material, engineering, and process experts can improve this process.

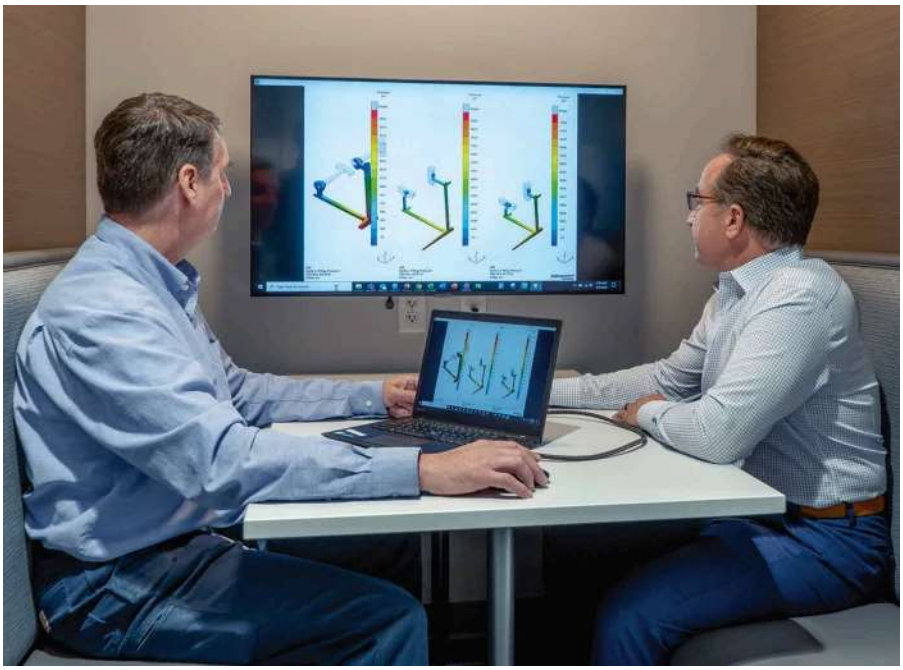
INNOVATIVE DESIGN: BALANCING OEM COSTS AND DEMANDS

With a designated team of experts and quality tool-making equipment, CDMs can design and create many prototypes in as little as 24 hours, delivering sample parts right out of the tool while retaining additional samples for potential future use.

To remain competitive by offering affordable products to customers, medical device OEMs are constantly looking to reduce the manufacturing costs of devices in development, as well as those already in market.

OEMs are also demanding greater customization, better product quality and seeking faster speed to market. One area in which manufacturers are finding ways to meet these challenges is through innovative product design. Device manufacturers also want their manufacturing partners to offer design validation, including different configurations and high- and low-end samples.

Design firms that have no manufacturing experience can create unrealistic expectations during the hand-off from design to manufacturing. When designs are handed off to the manufacturer, they often cannot be built “as is” and require significant changes, which increases costs and time to market.



Adherence to design for manufacturing (DfM) principles ensures efficient and cost-effective processes at high volumes.

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

UNMATCHED VALUE

When medical device OEMs partner with innovative and experienced CDMs in the design phase, they can balance cost control with the challenges of complex customized components, quality, scalability, and time to market. Simple changes to a component’s design can have a huge impact on the tooling, part and final assembly costs.

To navigate these challenges, some CDMs, such as Trelleborg Medical Solutions, have dedicated spaces offering core competencies suited to medical device and pharmaceutical manufacturers. These spaces include design, toolmaking, high-precision machining, silicone and thermoplastic molding, secondary operations, automation, and assembly.

ACCESS TO EXPERTS

Dedicated centers offer immersive engineer-to-engineer experiences where experts help medical device manufacturers achieve the best solutions with a focus on value and cost-effectiveness. With a designated team of experts and quality tool-making equipment, CDMs can support OEMs throughout the development process, from device and component design to prototyping, testing, scale-up, and long-term supply. They can design and create many prototypes in as little as 24 hours, delivering sample parts right out of the tool while retaining additional samples for potential future analysis.

MATERIAL SCIENCE INSIGHTS AND QUALITY RESOURCES

CDM teams can also collaborate with device manufacturers on material selection to optimize the finished device. Unlocking the full potential of materials science is one of the most efficient ways of elevating product performance and value while creating product differentiation. A CDM with the expertise and ability to formulate new materials can enhance product designs. This capability provides customers with highly accessible collaborations to develop breakthrough product designs. It also provides an opportunity for OEMs and manufacturers alike to continually expand their knowledge and mastery of materials science.

Another way CDMs bring value to customers is with quality control processes. Some CDMs can give customers access to raw material traceability and established validation processes. Facilities are typically ISO certified and meet requirements of the Food and Drug Administration (FDA) and European Medical Device Regulation (MDR).

Many component manufacturers specialize in only one of three critical development stages: design, prototyping, or production. Few offer expertise in all stages, thus lacking an understanding of how design and material choices can impact lifetime product costs. It is critical for medical device manufacturers' partners to understand all the critical development stages of a component and to provide dedicated experts to execute on every stage of the process.

THE MODEL IN ACTION

A diabetes device manufacturer wanted to be first to market with an innovative technology that would change how patients track their glucose levels. A competitor was developing a similar product, so speed to market was essential. The OEM partnered with Trelleborg Medical Solutions to take advantage of 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 to ensure the feasibility of scale-up of each option. This holistic design approach also included DfM and assembly testing, which facilitated bridge tooling, quality control testing, and high-volume fully automated production. The manufacturer achieved the desired launch date and quality expectations, delivering to market a device that positively impacts patients' lives daily.

DFM PRINCIPLES

Minimize Part Count

Rationale: Fewer parts generally lead to reduced assembly time, lower material costs, and decreased inventory management requirements.

Approach: Consolidate functions to eliminate nonessential components and create multifunctional parts wherever possible.

Standardize and Simplify Parts

Rationale: Standard parts are easier to source and replace, often resulting in cost savings and fewer unique setups.

Approach: Use readily available, off-the-shelf parts when feasible and design parts that can be manufactured with standard processes and tools.

Design for Ease of Assembly

Rationale: Simple assembly processes reduce the time, labor, and potential errors associated with product assembly.

Approach: Use modular assemblies, ensure easy access, and design parts with alignment features to facilitate assembly.

Design for Manufacturing Processes

Rationale: Ensuring that parts are compatible with common manufacturing processes (e.g., injection molding, CNC machining, stamping) reduces costs and enhances production feasibility.

Approach: Consider the specific manufacturing method during the design phase to avoid processes that are overly complex or require specialized machinery.

Tolerances and Fit

Rationale: Loose tolerances generally reduce costs and make manufacturing easier, while tight tolerances increase complexity and cost.

Approach: Specify tolerances only where necessary for the function of the product and allow for looser tolerances in noncritical areas.

Optimize Materials

Rationale: The choice of material affects durability, manufacturability, and cost.

Approach: Choose materials that meet the functional requirements of the product but are also easy to machine, mold, or form and are cost-effective.

Design for Quality and Reliability

Rationale: Products need to meet quality standards consistently to reduce waste, rework, and customer dissatisfaction.

Approach: Implement design features that simplify testing and quality control, and ensure robustness in design to withstand production variances.

Design for Automation

Rationale: Automation can reduce labor costs and increase consistency.

Approach: Design parts and assemblies that are compatible with automation processes, such as robotic assembly or automated inspection.

Design for Sustainability and End-of-Life

Rationale: Sustainable design reduces waste and can make disposal or recycling easier, benefiting the environment and potentially lowering costs.

Approach: Use recyclable materials, design parts that can be easily disassembled, and consider the product's life cycle from manufacturing to disposal.

Consider Cost-Effectiveness Throughout

Rationale: Cost considerations are central to DfM to keep manufacturing within budget while meeting quality standards.

Approach: Continuously evaluate each design decision for its cost impact, balancing functionality with manufacturability and cost.

CONCLUSION

The expertise of CDMs that have dedicated space for innovation are focused on accelerated development cycles, DfM, and the optimal application of materials science for their OEM partners. The demand for rapid design and manufacturing of products at a lower cost means it is critical for device manufacturers to collaborate with suppliers that demonstrate all these capabilities. It all starts by partnering at the design stage to create the best quality product and patient outcomes with a focus on value and cost-effectiveness.

This article was written by Chris Tellers, Innovation Center and New Product Development Director, Trelleborg Medical Solutions, Plymouth, MN. For more information, visit here [https://www.trelleborg.com/en/medical] .

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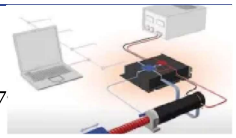

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