CASE STUDY

Donatelle®
A DuPont Business

Smoothly transferring a legacy program for a global cardiovascular OEM

Challenge

When a supplier shifted business strategies, a globally leading cardiovascular OEM needed to find a new contract manufacturing partner – and fast – for one of its legacy Class II cardiac devices. The medical device components comprised dozens of intricately molded and overmolded parts and sub-assemblies with tight tolerances.

Importantly, the legacy product's in-motion supply chain could not be interrupted. The incumbent supplier owned the capital equipment used to manufacture the product and would be in full production during the transition. The OEM could share the initial CAD drawings and specifications and some existing molds, but historical information pertaining to the molds, processes, qualification details and quality-related issues was sparse. Consequently, the new team would need to adapt the existing molds and quickly design, develop and validate new tooling and manufacturing processes. The new team also had to ensure production could meet ongoing demand before the existing inventory ran out.

Recognizing the significant challenge, the global OEM asked Donatelle to take over the program. Already a preferred contract manufacturer, Donatelle offers the deep expertise, rigorous processes and quality needed. Donatelle develops and manufactures similar ablation technologies for several industry leaders. The vertically integrated in-house capabilities help ensure continuity and consistency, while saving time compared to using multiple vendors. In addition, Donatelle's processes and procedures harmonized with the global OEM's production part approval process (PPAP).

Action

Understanding what was at stake, the Donatelle team created and implemented a thorough plan with aggressive-but-realistic timelines and built-in contingencies to manage the transfer.

Because the Donatelle team implemented its robust, proven development and validation processes, potential production issues were identified and resolved early on. Initial testing revealed the existing molds would require too many modifications to meet requirements efficiently and effectively. As such, the OEM and Donatelle agreed to develop new tooling for the majority of the parts. This involved:

- Designing and developing precise tooling to create molds and fixtures.
- Undergoing a rigorous design for manufacturability (DFM) process to determine which materials and geometries consistently achieved the required tight tolerances for each of the molded and overmolded components and sub-assemblies.
- Performing scientific engineering experimental studies, collecting data and analyzing it to identify optimal process conditions.
- Developing and performing all inspection processes required and validating manufacturing processes.

Result

With clear communication throughout the design and development processes and scope shifts, the Donatelle team worked closely with the OEM to successfully transfer the program. The legacy product continues to meet the needs of customers around the world. And the new tooling, rigorous inspection and efficient manufacturing production processes ultimately make the legacy product less expensive to manufacture for the global OEM.

Capabilities used

- Tool building
- Design for manufacturability (DFM)
- Injection molding
- Prototyping
- Process validation
- Packaging

Deliver your medical device promise

At Donatelle, we make products that sustain – and save – lives.

We manufacture medical devices and components. That's all we do. And we do it with the utmost precision, consistency and rigor, because for you – and your customers – quality is essential. Reliability is a must. And delivering on what's promised is vital.

Learn more about how we can help bring your medical devices to market – with confidence.

- Contact **+1.651.633.4200**
- Visit **donatellemedical.com**

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