CASE STUDY

SPECTRUM PLASTICS GROUP
A DuPont Business

Getting fast-tracked complex Class III orthopedic device to market on time – and in spec

Challenge

After working for 10 years on prototypes for a novel orthopedic device, a globally leading biotechnology company earned Breakthrough Therapy designation for fast-track status from the U.S. Food and Drug Administration. The product was designed with a challenging implantable material to mold and very tight tolerances. It also would be available in many sizes and SKUs.

Eager to manufacture the game-changing device and meet an accelerated launch timeline, the biotech needed to find a contract manufacturing partner with deep expertise in implantable materials sensitive to batch-to-batch variation, tightly controlled processes and complex bills of materials. They also preferred a U.S. partner to better support the needs of customers in North America.

The biotech's program leadership team chose us, anticipating the contract manufacturer's vertically integrated capabilities and rigorous processes would help increase the reliability and accuracy of the product from design through delivery – and reduce overall cost. As part of the program scope, they planned to lean on our proven design for manufacturability (DFM) processes, efficient program and tool management, consolidated resources and lean processes. They also trusted our impeccable track record for regulatory compliance and on-time delivery, and experience collaborating across global geographies.

Action

As the biotech and our engineering teams began collaborating, the DFM process revealed additional product design issues that needed to be mitigated before the product could be produced repeatedly with high quality. In addition, they knew any changes made to one element inversely affected another element. Furthermore, the manufacturing process for the product entailed more than 25 manufacturing steps over several days from start to finish, making it difficult to quickly assess the impact of any changes.

All that being the case, the engineers needed to work together to find a critical balance among the product's size, form and functional product requirements. They also had to develop and implement secondary finishing, sterilization management, and assembly, product labeling and packaging operations. And they had to do everything effectively and efficiently to meet an accelerated product launch timeline.

Together, they swiftly updated the project scope, and got to work redefining tolerances, redesigning necessary tooling, fixturing and automation needed, all while testing prototypes against approved product requirements.

Result

With the support of our dedicated engineering team, vertically integrated facilities and quality management systems, the biotech successfully produced the Class III novel orthopedic device in spec – and on time to go through the final FDA approval stages.

Capabilities used

- Design for manufacturability (DFM)
- Prototyping
- In-house design and tooling
- Injection molding
- Secondary operations
- Assembly, kitting, sterile packaging and product labeling

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SPECTRUM
PLASTICS GROUP
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Deliver your medical device promise

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.

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