CASE STUDY

Vention Technical Support Boosts Launch Readiness

CUSTOMER SITUATION

A small company in the minimally invasive cardiac surgery space was developing a novel first-generation laparoscopic device in preparation for a limited commercial launch. This complex, single-use device was facing reliability challenges, manufacturing issues, and inconsistent performance in preclinical testing.

The customer called in Vention to help. They had consulted with Vention before and had been impressed with Vention's deep knowledge of complex, single-use medical device development. The customer felt Vention could bring an outside perspective to help identify areas needing improvement and explore potential solutions.

VENTION SOLUTION

For 2 days onsite, a small Vention product development team embedded with the customer's product development team for a full-immersion look into the challenges of product design, manufacturing, and quality. Team members contributed root-cause analysis tools; expertise in Design for Manufacturing, Assembly, and Reliability (DFM, DFA, DFR); and proficiency in supply chain management.

The Vention team then created a "report card" rating the product in 3 categories:

- *Design for Reliability*
- *Component Manufacturability & Supply Chain*
- *Assembly Process & Manufacturing Quality Controls*

This report card gave the customer a top-level "dashboard" for prioritizing resources to solve the most pressing issues. The report also provided detailed observations and recommendations to put in place – including design change solutions, alternative manufacturing process methods, supplier options, and Statistical Process Control.

OUTCOME

Vention's involvement injected objective feedback at a critical time in development when the project needed a technical boost, at an affordable cost. The customer was very pleased with the report, which enabled them to prioritize actions to pursue their goals of increased reliability, reduced manufacturing scrap, and reduced manufacturing cost. The product received 510(k) clearance several months later and was on its way to a limited commercial launch.

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