CASE STUDY

MEDICAL DEVICE NPI: FROM DESIGN TO MARKET IN 10 MONTHS

A company had developed a much better device to treat a common ailment, but needed help bringing the product into production. The company's future depended on this product, and its executives came to Sanmina. Sanmina redesigned parts of the product, helped with documentation and FDA approval, and brought the product to market in ten months.

THE OPPORTUNITY

Many people suffer from a condition while not life-threatening, significantly impacts their quality of life. A company developed a new product to treat this condition much more effectively. Unlike medication, it was a one-time treatment, and unlike surgery, it required no hospitalization.

The market was large and growing, but the company's entire success rested on the redesign and manufacturing of the device, and especially on FDA approval.

THE CHALLENGE

Despite the promise of the new device, the company faced major obstacles in bringing it to market. These challenges included:

- **Strict FDA requirements.** The Food and Drug Administration (FDA) had to approve this product, evaluating not only the device, but also its design history, production parameters and even the tools and methods that affect its performance in clinical use. This company's documentation also did not meet FDA standards.
- **Critical engineering challenges.** They involved not only the documentation but also system testing and certain critical components.
- **Partial redesign.** Several sub-systems needed to be redesigned.
- **End-to-end solution.** The customer required support at all stages, from design through repairs and returns.

WHY SANMINA?

For over 20 years, Sanmina has designed, built and serviced a broad range of medical devices and products.

- **Sanmina has extensive experience meeting FDA documentation requirements.** The protocols of the FDA are exacting, and Sanmina has a separate team of regulatory personnel to assist with meeting FDA requirements.
- **Deep manufacturing expertise in twenty-one ISO 13485-2003 facilities worldwide.**
- **Sanmina minimizes costs.** Collaborating early with Sanmina on design and Supply chain reduced costs. DFx workshops helped improve production yields and made the design more robust.
- **Collaboration.** Sanmina's design and supply chain personnel worked alongside the customer's product team to develop the best overall solution for a number of subsystems.

- **Sanmina's vertical integration greatly increases supply chain efficiency.** Sanmina was able to design and vertically integrate several key components, significantly simplifying the supply chain for the customer.
- **Sanmina provides an end-to-end solution.** Sanmina provides a complete solution, from design through product validation, new product introduction, test systems development, volume manufacturing and repair.

THE APPROACH

The customer visited Sanmina's manufacturing and medical design center in Alabama. Working closely with the customer over the next ten months, Sanmina:

- **Created a documentation package that met FDA requirements.**
- **Re-designed certain subassemblies and implemented alternate components.** The revised designs were less expensive and the alternate components resulted in a more agile and robust supply chain.
- **Upgraded an obsolete display.**
- **Enhanced the quality of the plastics and base casting.**
- **Improved the customer's test protocols and re-designed test fixtures for more complete test coverage and higher product quality.** Revised test programs and procedures were based on field failure data.

RESULTS

- **FDA approval.** Sanmina's regulatory personnel knew what the FDA looks for in new medical products and documentation. FDA approval came swiftly, with no delays.
- **Rapid time-to-market.** Sanmina brought the project from initial kick-off to production in ten months.
- **Cost effective development.** Based on Sanmina's experience with medical product design, supply chain and new product introduction, development and validation costs were minimized.
- **Quality and regulatory discipline.** Laboratory, animal and clinical studies confirmed the effectiveness and safety of the device. Sanmina's quality and regulatory management systems gave the customer high confidence with the FDA.

ABOUT SANMINA

Sanmina Corporation is a leading electronics contract manufacturer serving the fastest-growing segments of the global Electronics Manufacturing Services (EMS) market. Recognized as a technology leader, Sanmina provides end-to-end manufacturing solutions, delivering superior quality and support to OEMs primarily in the communications, defense and aerospace, industrial and semiconductor systems, medical, multimedia, enterprise computing and storage, automotive and clean technology sectors. Sanmina has facilities strategically located in key regions throughout the world.

More information regarding the company is available at www.sanmina.com