

IEC Helps Medical Device Company Ramp Production 10-Fold in 3 Months

As a manufacturer of critical, high-reliability medical products, it is imperative that your EMS provider can scale quickly while maintaining the high level of quality control and product reliability required for medical devices. One medical device manufacturer was faced with a dire situation that left them in need of such an EMS provider.

Medical device manufacturers are responsible for protecting public health and well-being from products that present a risk of injury or are defective. When a product creates a risk of injury or is defective, manufacturers are required by 21 CFR 7 to issue a voluntary recall. Under a voluntary recall, the company can remove the product from the market or correct the issue.

Quality Struggle Results in Voluntary Recall

The medical device company's current EMS provider struggled with providing a quality product, resulting in several rejections and missed delivery dates. An FDA hold was placed on the product, and the company was facing a voluntary recall. Thousands of products were involved in the recall, so a decision was made to replace them instead of repairing them.

To quickly replace the defective product in the field, they purchased an emerging medical device company that manufactured a similar product. However, to meet the demand, production levels needed to be scaled up 10-fold.

IEC Ramps Up Production to Meet Customer's Needs

IEC Electronics was the PCBA supplier for the acquired company and found itself having to quickly ramp up from several hundred assemblies to several thousand in a few short months.

As an FDA-registered manufacturer with years of experience supporting class II and class III medical devices, IEC's customer base demands expertise and flexibility in the manufacturing process to support their critical supply chain needs.

IEC invested millions of dollars in people and equipment to meet the challenge, buying brand new SMT lines and dedicating a focused team and square footage to help the customer meet the demand. In only three months, IEC fulfilled its objectives, allowing the medical device company to meet its obligation to its customers.

A Long-Term Partnership

Since this time, the relationship has grown with IEC designing and building multiple PCBAs and full system assemblies for the company. As the manufacturing volumes continued to increase, IEC Electronics also re-engineered and scaled the in-house functional test capabilities, allowing them to quickly identify and correct quality defects before they leave the facility.

As a vertical manufacturer, IEC has consistently proven itself a valued partner to the medical device company. Utilizing its inhouse precision metalworking, wire and cable solutions, and advanced laboratories, combined with its lean manufacturing practices and engineering expertise, IEC has minimized the medical manufacturer's supply chain risk while reducing lead time and cost.