

COST REDUCTION IN PRODUCT REPLACEMENT

CHALLENGE

A major medical device OEM was interested in reducing costs of replacing returned devices from customers. The OEM experienced issues with space and material delays from overseas. This did not allow for the OEM to perform the work in-house in an appropriate turn-around time. In addition, the age of the unit caused issues in finding suitable replacement parts to manufacture new units. In the meantime, customers were asking for an entire replacement product despite the possibility that only a part of the whole needed replacement. The OEM needed to identify an ISO 13485 3rd party provider to handle the repair and return program instead of continuing to increase the capital costs associated with such a project.

SOLUTION

Stratosphere Quality established two isolated work stations with appropriate tools and ESD equipment. The OEM customer provided software/printers for return product labels at the facility. Stratosphere Quality worked closely with the OEM on the SOP, and implemented the appropriate instructions for both training and execution of the project. Proper GDP, GMP, Blood Born Pathogen, and ESD training was facilitated. The OEM and Stratosphere Quality established systems for custom communication and for delivery flow of incoming product. These systems were put in place to reduce any further delays within the repair and return process. The OEM's Customer Care Team evaluated the need for replacement, and the product was shipped directly to Stratosphere Quality's work stations for repair and return. Stratosphere Quality's inspectors administered the part replacement, and then returned the product to the appropriate location. Utilizing a bar code system and a proprietary software system, Stratosphere Quality was able to track and report all repair and replacement data to the OEM.

RESULT

Turn-around time of hospital meters was reduced from 4-6 days to 24 hours. In addition, the OEM was able to reduce over 45% of their cost compared to that of a new product replacement. The program recognizes almost 3 million dollars in savings for the customer with a 98% approval rating for reworked versus new equipment.

STRATOSPHERE QUALITY IS THE LEADER IN QUALITY ASSURANCE



ISO 13485 Certified



Expansive geographic footprint allowing us to quickly assist OEMs, Tier 1 and Tier 2 suppliers



Superior technology for data tracking and analysis



Recognized by OEMs and suppliers for outstanding performance and achievement



WHEN YOU NEED A TEAM THAT STANDS WITH YOU, WORKS FOR YOU, AND UNDERSTANDS CRITICAL ISSUES WITHIN YOUR BUSINESS, LOOK NO FURTHER THAN STRATOSPHERE QUALITY.





CHALLENGE

A major medical OEM had grandfathered components at a Tier 2 contract manufacturer of which were not validated.

SOLUTION

Stratosphere Quality was contracted to provide validation contract support for hand loaded components. With the customer's goals in mind, our team was responsible for all three phases of IQ/OQ/PQ. Our lead engineer developed the protocol and facilitated the IQ/OQ/PQ runs, while our operations team was utilized for the PQ portion during the inspection of 1,000 production parts.

RESULT

The OEM customer had satisfied the FDA requirements around validating the product, while eliminating the need for hiring additional internal staff or a new vendor in eliminating the product completely. The validation was completed at the contract manufacturer, and did not interfere with normal operations.

Stratosphere Quality has a deep commitment to bringing value to our clients, solutions to their quality issues, and results to their bottom lines.

Whether you need us for a few hours, days, or weeks, we're here to help – **24 hours a day, 7 days a week, 365 days a year.**

**TO START A QUALITY PROJECT CALL 1-877-224-8584
OR VISIT OUR WEBSITE AT STRATOSPHEREQUALITY.COM**

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