## StratosphereQuality

### CASE STUDY A RESOURCE DEDICATED TO EFFICIENCY



### ARE YOU UTILIZING YOUR STAFF IN THE MOST EFFICIENT WAY?

#### THE CHALLENGE: COST OF PRODUCT VALIDATION PROJECTS

A major OEM Medical Manufacturer was experiencing staffing issues because of a high volume product of newly installed manufacturing equipment for purposes of IQ/OQ/PQ inspections of the validation.

The sporadic timeline for validation projects caused various internal staffing and scheduling issues, and the validations were becoming too costly to utilize FTE's from other departments. Subsequently, utilization of other departments impacted budgets and productivity.

The major challenge for the OEM was to figure out a way to ensure that the product met all of the requirements, but do so in a manner that did not add to the already-present internal scheduling conflicts.

#### THE SOLUTION: OUTSOURCED, TRAINED VALIDATION TEAM

Stratosphere Quality provided a consistent crew of trained inspection personnel at various times of the year as required. Inspectors were trained to the project's SOP, Stratosphere Quality's Basic Medical Training and the customer's safety program. The project data was tracked and maintained by Stratosphere Quality, an ISO:13485 certified partner, as required by the SOP.

Stratosphere Quality's consistent workflow process enabled the client to realize significant cost reductions affiliated with product replacement while eliminating the need for dedicated internal resources.





### **THE RESULTS**

# **QUICKLY IMPROVED RESPONSE TIMES**

WITH STRATOSPHERE QUALITY'S ADAPTIVE STAFFING SOLUTION, NOTIFICATION TIMES WENT FROM WEEKS TO DAYS, RESULTING IN SIGNIFICANT COST SAVINGS.

Stratosphere Quality's flexible staffing resource has reduced the need for customer notification from weeks to days by improving response levels for the numbers of inspectors needed. This has allowed for larger windows to resolve equipment and/or documentation issues.



IMPROVE RESPONSE TIMES







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