FROM START TO FINISH

ALKU Case Study
Medical Device

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Project Overview

Large Medical Device Manufacturer

EU MDR Technical File Remediation Project

Project Duration: June/July 2019 - December 2020

The large Medical Device manufacturing company reached out directly to ALKU in May of 2019. Within two to three weeks, ALKU had 21 contractors hired and ready to be onboarded for an immediate start date. ALKU Contractors supported this project almost entirely and successfully remediated and updated all technical files and design dossiers to meet EU MDR standards over the course of about 18 months.

ALKU Provided

ALKU proactively had relationships established with the Regulatory Affairs Department at the Medical Device company. The client requested to review resumes and schedule 30 minute phone interviews. This company had a specific dollar amount allocated to each of the open positions. ALKU was able to provide the best talent possible to fit within their tight budget. The client hand selected 21 out of the 24 candidates they had interviewed for highly specialized functions within their project. Each of these candidates had a minimum of 5-10 years of hands-on regulatory affairs experience. ALKU maintained communication with the managers and contractors on this assignment on a monthly basis to ensure timelines and deliverables were being met. The project itself was managed by the full-time management team at the company. ALKU's contractors were looked at as team-leads and individual contributors in their respective therapeutic areas. The product areas supported were primarily class 2a, 2b, and class 3 medical device equipment. In just over the course of a year, the technical files/design dossiers were entirely remediated and submitted to the notified bodies for successful approval.

83k

Employees Globally

21

ALKU Consultants Hired

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2017-2021 BEST of Staffing CLIENT SATISFACTION DIAMOND AWARD 5

Inc. 5000