

ALKU Case Study

Medical Device



Project Overview

Multinational Medical Device Technologies Corporation
June 2019–Present

Medical device products include Endoscopic products, Laparoscopy, Respiratory Therapies, Thoracic Navigation Systems, 3D/Diagnostic Imaging Systems, Orthopedic Implantables, Surgical Energy, Tissue Management used in a variety of medical specialties. EU MDR Technical File Remediation Project, Post-Merger & Acquisition Integration Project, DHF Remediation Project, FDA 483 Remediation & Global Regulatory Center of Excellence Project.

ALKU Provided

In mid-2017 ALKU Medical Device division leaders proactively identified the immense burden the EU 2017:745 Medical Device Regulation put on many of our active and potential new clients. We sought to work with companies engaging in their EU MDR compliance initiatives earlier than others and were able to establish a strong network of consultants with direct EU MDR experience.

In mid-2019, ALKU established relationships with key decision makers at a global Medical Surgical Device Manufacturer. Project planning discussions began between the ALKU Account Manager and client stakeholders within Quality, Regulatory, Engineering, Project Management and other areas affected by the new regulatory change. ALKU visited over ten of our client's US sites, regularly engaging in resource planning meetings to proactively identify critical areas of need and associated timelines. Through our proactive, collaborative approach, ALKU has been able to establish direct relationships with key stakeholders and gain an understanding of each of their unique needs. This has rendered a 100% fill ratio on all job requests at this client to date, and now exclusively supports all the above staffing needs for this client.

Since late 2019, ALKU has provided resources for numerous projects including EU MDR Technical File Remediation, Post M&A Integration, DHF Remediation, Global Rebranding, Regulatory Center of Excellence Development, New Product Development, FDA 483 Remediation and Manufacturing/Technology Transfers. ALKU's has provided resources in Project Management, Quality Engineering, Global and Domestic Regulatory Affairs, Post Market Surveillance, Microbiology, Sterilization, Biocompatibility, Packaging/Labeling, to name a few. ALKU maintains regular communication with stakeholders to track project milestones and consultant production/performance. As the industry and its regulations evolve, ALKU continues to adapt to changes, and stay ahead of our client's needs.

85

Placements

1:1

Job Order to Fill Ratio



2021

Best Staffing Firms to Temp For



2020

Largest Life Sciences Staffing Firms in the US



2020

Fastest Growing US Staffing Firms



2020

Largest Staffing Firms in the US

