MEP National Network™

TEXAS SUCCESS STORY

API - USING ISO:13485 FOR MEDICAL DEVICE MANAGEMENT

ABOUT ADVANCED PAPERWORKS INC. Advanced Paperworks, Inc. is a minority-owned Texas-based converter of products using die cutting, laser cutting, routing, slitting, laminating, coating addition and more. Advanced Paperworks (API) services the El Paso – Cd. Juarez border region and is certified in ISO:9001 and ISO:14001. Not only are they suppliers for consumer goods and electronics industries, but they have begun producing medical components for the medical device industry.

THE CHALLENGE. The medical device industry is growing fast in the region due to on-shoring of overseas components and the investment in medical device manufacturing in the United States. Due to the location of API they are expanding their market to capitalize on the growing sector and the investment in health related industries. Advanced Paperworks has been certified in ISO:9001 Quality Management System and ISO:14001 Environmental Management System for over 15 years. However, in order to enter the medical device market potential customers have requested that API be certified to ISO:13485 Medical Device Management System in order to receive the go ahead to produce medical components. API contacted TMAC, part of the MEP National Network™, for help.

MEP CENTER'S ROLE. The implementation project phase lasted for nine months and entailed adding the ISO:13485 requirements to the existing quality management system infrastructure - document and records control, training and competence. There was special emphasis placed on the statutory and regulatory requirements of the ISO:13485 medical standard, as there was little experience within the organization working with FDA and COFEPRIS (Mexican counterpart agency to FDA) requirements. TMAC assisted API in finding the applicable requirements of their product, along with the reporting and labeling requirements that are the key to regulatory compliance.
The medical device management system was implemented and completed and is pending Phase II certification in the fall of 2022. The potential medical customers have accepted the Phase I audit results and have begun issuing purchase orders for converted sub-components, in addition to the medical device files for manufactured components that are to be produced. This has opened up a new market to API, which has allowed them to begin scouting new business opportunities in both the United States and Mexico.

RESULTS

- **19** new or retained jobs
- **$1,500,000** in retained sales
- **$704,500** in cost savings
- **$250,000** in new sales
- **$145,000** in new investment

CONTACT US

7300 Jack Newell Boulevard South
Fort Worth, TX 76118

(800)625-4876

www.tmac.org

TMAC

"TMAC has helped us identify the areas and methods of improvement while assisting us implement our medical device management system. We look forward to the potential growth this can bring our organization in the coming years and look forward to continuing our longstanding relationship with TMAC."

-Pedro Betacourt, Manufacturing Manager