MEP National Network™

NEW JERSEY SUCCESS STORY

CASE MEDICAL, INC., COMPLIES WITH EU'S NEW STANDARDS FASTER AND MORE EFFICIENTLY WITH NJMEP'S EXPERTISE

ABOUT CASE MEDICAL. Case Medical, Inc., is a 'MADE in New Jersey' manufacturer that produces and offers high-quality, cost-effective instrument processing products and services. They were originally founded in 1992 as a supplier of custom graphics trays to medical device manufacturers. In their 30 years of business, they've become a leader in the medical device space and are best known for the DIN-sized, SteriTite(R) universal sealed container and modular customizable MediTray(R) inserts that are regarded as the gold standard in instrument protection and organization. This local manufacturer prides itself on providing customers with products of the highest level of safety and effectiveness, using a universal design providing long-term cost savings and a high return on investment.

THE CHALLENGE. In May of 2017, the European Union adopted Medical Device Regulations MDR 2017/745 to replace both Medical Device Directive MDD 93/42/EEC and Active Implementable Medical Device Directive AIMDD 90/385/EEC. Issues with specific medical devices in the European Union forced them to add devices that were not regulated under the original directives. All medical device manufacturers and suppliers had 3 years to implement the changes required under the new regulation.
The challenge for manufacturers like Case Medical is when reviewing the language of the regulations, it is not necessarily written for their business. Understanding what exactly a manufacturer must do to comply is a full-time job and requires a working knowledge of exactly what auditors review during the audit process.

MEP CENTER'S ROLE. Case Medical reached out to their NJMEP account manager, Peter Russo, for assistance in complying with these new regulations. They needed an expert that understands all the nuances involved in meeting these high standards and to find out exactly where the gaps were in their current documentation and quality process. Peter Russo is a former auditor and has done extensive research into the new EU regulations to provide manufacturers with a more concise and easier to understand process. The first step to help Case Medical meet these new standards was to review the current QMS system and compare it to MDR 2017/745 compliance and audit current documentation and records. Peter Russo helped assess the MDR 2017/745 technical requirements and current Post Market Surveillance (PMS) vs. MDR CE Mark Classification Review.
Next, Russo provided the results of the gap analysis. The NJMEP team outlined all non-conformances to the new MDR and provided options to rectify these issues. Additional training was needed to help Case Medical meet its goals of being MDR 2017/745 compliant. Case Medical then went on to take advantage of the CARES Act funding to help offset that future training.

RESULTS

- 2 created or retained jobs
- $1,500,000 in new investment
- $200,000 in increased or retained sales
- $50,000 in cost savings

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NJMEP

"Thanks to Peter Russo we were able to meet these standards in a much more lean fashion without hitting dead ends. When he was helping us, we would navigate the regulatory pathways at a much better pace. We are definitely happy with the service we received."

-Michael Polozani, Microbiologist