MEP National Network™

TEXAS SUCCESS STORY

AMPCARE, LLC GAINS GLOBAL MARKET INDEPENDENCE THROUGH ISO 13485 AND CONFORMITE EUROPEENNE MARKING

ABOUT AMPCARE, LLC. Ampcare, LLC is a pioneering FDA-registered medical device and services company located in the United States. It specializes in designing, manufacturing, and training on its innovative neuromuscular electrical stimulation (NMES) therapeutic devices, cutting-edge electrodes, and restorative posture systems for treating dysphagia, a swallowing disorder that affects one in 17 people worldwide, according to estimates from the World Health Organization.
With a commitment to improving patients' lives, Ampcare delivers clinically effective, non-invasive therapies that promote muscle re-education and rehabilitation. Ampcare's solutions are trusted by healthcare providers across the U.S., Japan, Europe, the UK, Brazil, Hong Kong, and the Middle East.
The company's flagship product, the ESP Therapy System, has gained recognition for assisting patients in regaining swallowing function, preventing complications such as aspiration pneumonia, and enhancing their quality of life.

THE CHALLENGE. Ampcare recently faced a potential business continuity challenge as EU and UK authorities introduced new requirements to update compliance with regulatory standards. Simultaneously, the FDA issued its final rule to align its Quality Management System Regulation (QMSR) with EU standards (ISO 13485), requiring full compliance by February 2026. These developments necessitated swift action to realign Ampcare's quality systems and regain regulatory control over its global operations.
TechFW arranged the initial meeting between Ampcare and TMAC to discuss Ampcare's needs and whether TMAC was the appropriate organization to assist with these regulatory challenges.

MEP CENTER'S ROLE. To tackle these challenges, Ampcare partnered with TMAC, led by one of its business advisors, Mona El-Khatib. Mona played a crucial role in the development and implementation of a comprehensive quality and regulatory compliance strategy, which included key initiatives to:
Develop a strong Quality Management System (QMS) that complies with 21 CFR Part 820, ISO 13485:2016, and EU MDR 2017/745 standards.
Engage a direct EU-authorized representative and UKRP to restore regulatory access.
Submit applications for Conformité Européenne (CE) marking and ISO certification directly to a notified body.
A joint Memorandum of Understanding regarding rates between TMAC and TechFW, of which Ampcare is a member, made her efforts possible.
Additionally, with Mona's advice and assistance, MedMMAP provided a grant covering 75% of the QMS development effort in accordance with FDA requirements.

"This transformative journey underscores Ampcare's dedication to innovation and patient care. The exceptional strategic focus and execution by everyone on our team - Mona El-Khatib, TMAC, TechFW, MedMMAP, and Ampcare – was exceptional. I am a better CEO, and we are a better company from the advice given, direction offered, example set, and lessons learned, and I will be forever grateful."

-Russ Campbell, President & CEO

RESULTS

- Secured ISO 13485:2016 certification under EU MDR Annex IX for muscle stimulators
- Obtained CE Marking for cutaneous electrodes and restorative posture devices
- Top tier EU MDR applicant - Only 3766 QMS and 2177 product certificates issued from 27,357 applicants
- Regained and expanded global market access independently

CONTACT US

7300 Jack Newell Boulevard South
Fort Worth, TX 76118-7115

(800)625-4876

www.tmac.org

TMAC Texas Manufacturing Assistance Center