CASE STUDY

CAPA Remediation for Device Accessory Reliability

Objective

A medical device manufacturer of Class III life-saving devices had two Corrective and Preventative Actions (CAPAs) that had been outstanding for over a year and a half. The company needed to have the CAPAs resolved to ensure that product elements in question were compliant with all pertinent regulations and allowed to continue shipping.

Challenges

Internal teams in both cases believed they had electromagnetic compatibility issues and had spent 17 months working to identify the root cause without success. In one case, a power adapter redesign was already underway.

Solution

A Base2 Advisory Systems Engineer with decades of expertise in medical regulations and electrical engineering thoroughly examined design history files, product requirements, and testing documentation against the IEC 60601 suite of standards. After assessing actual test performance and resulting data, it became clear that both products actually met the required specifications and did not require any modifications. The Base2 engineer wrote root cause analyses for both CAPAs and secured cross-functional agreement on her assessments.

Outcome

Both CAPAs were closed about two months after Base2's engagement, allowing both products to continue to ship without any costly design changes.

Base2 assists companies across heavily regulated industries, such as aerospace, defense, transportation and medical devices give form to Digital Innovation. Our expert software and systems engineers deliver the processes and practices to speed up product development and accelerate time to market for develop complex interconnected systems.

To learn more about Base2, please visit www.base2s.com.