CASE STUDY

Ensuring Safety Compliance for a Medical Device Manufacturer

INDUSTRY	SOLUTION	APPLICATION
Medical	CEC - Safety consultancy and compliance support for Medical Devices	Infusion Pumps

CHALLENGE

A leading global medical device manufacturer encountered a critical regulatory hurdle during the safety evaluation of its latest system. The system failed to secure approval from the safety agency due to the absence of a required fire enclosure. The issue stemmed from the integration of Advanced Energy's CoolX CX18M power supply, which the agency determined necessitated additional fire containment measures.

The manufacturer had relied on the power supply's compliance with sub-clause 13.1.2 of IEC-60601 and did not incorporate a fire enclosure into the system's design. This misalignment between regulatory interpretation and design assumptions has delayed market entry and underscores the importance of proactive risk assessment in component-level compliance.

SOLUTION

Upon identifying that the CoolX CX18M documentation did not specify a fire enclosure—based on its compliance with sub-clause 13.1.2 of IEC 60601-1—the engineering team conducted a thorough review of the standard. This confirmed that the power supply's compliance was sufficient to negate the need for additional fire containment.

To address the safety agency's concerns, Advanced Energy's engineering team engaged directly with UL's lead engineer. Following a detailed technical review, UL issued a revised report affirming that the fire enclosure was not required, citing the power supply's adherence to the relevant IEC sub-clause.

Leveraging their strong regulatory expertise and established relationship with UL, the AE team ensured the report comprehensively addressed all safety considerations. This expert intervention was instrumental in securing a favourable outcome for the medical device manufacturer and advancing the system's path to market approval.

RESULT

The safety agency was convinced by AE's justification and UL's buy-in, ultimately passing the AE power supply as a component in the manufacturer's system. This approval was a significant milestone for the medical device manufacturer, as it ensured that their new system met all necessary safety standards without requiring a redesign.

The successful resolution of this issue demonstrated the effectiveness of AE's engineering team and their ability to navigate complex regulatory requirements. The team's thorough documentation and strategic engagement with UL played a crucial role in achieving this positive outcome.

Furthermore, the approval of the AE power supply allowed the manufacturer to proceed with their planned release schedule, avoiding delays and additional costs. This not only saved the company months of redesign effort but also hundreds of thousands of dollars in extra expenses.

The result also highlighted the value of the Customer Experience Center (CEC) service in Cork, which provided dedicated support and expertise to resolve the issue. This built customer satisfaction and positioned AE as a trusted advisor in the medical device manufacturer's engineering management.

CONCLUSION

The Customer Experience Center (CEC) demonstrated exceptional dedication and expertise in addressing the safety concerns of the medical device manufacturer's new system. By thoroughly understanding the issue, championing the customer's case, and securing buy-in from subject matter experts, the CEC was able to deliver the best possible outcome for the customer. This successful resolution not only saved the manufacturer significant time and costs but also reinforced the value of the CEC's services and solidified AE's position as a trusted advisor in the medical device industry.

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