

Ensuring quality electrical components in medical manufacturing

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Oshri Cohen, CEO of Cybord, delves into the medical device vertical's specific challenges and the complexities they pose to medical original equipment manufacturers (OEMs).



Supply chain concept

Even as demand for semiconductor chips continues to soar across diverse sectors, the medical device industry still faces significant hurdles and is often overshadowed by larger

industries like automotive. Representing a mere 1% of the total chip supply, medical devices encounter unique problems that hinder smooth operations.

Why do medical OEMs need a more intelligent supply chain?

The medical device sector is highly regulated due to the critical, life-and-death nature of many of its products. Consequently, medical devices must undergo extensive qualification processes to ensure their safety and efficacy. The stringent regulations make it exceedingly difficult to modify electrical components or introduce new chips into existing medical devices, resulting in prolonged development cycles and limited innovation.

A significant challenge for medical OEMs lies in the short lifecycle of semiconductor components, particularly memory chips. These components often have a lifespan of merely two to three years, necessitating frequent requalification of medical devices. Such frequent updates disrupt the supply chain, leading to increased costs and potential delays in the availability of critical medical equipment.

Additionally, the medical device industry's relatively smaller size compared to other sectors, such as automotive or consumer electronics, presents a notable disadvantage for medical OEMs. This disparity in market share translates into limited bargaining power when negotiating with major component manufacturers. As a result, medical OEMs may struggle to secure favorable terms and agreements, leading to increased costs and reduced availability of essential components.

Medical device manufacturers may be compelled to maintain substantial component inventories to ensure a seamless production process, tying up valuable resources. But in light of last year's unpredictable chip supply chain, medical OEMs are still struggling to face the challenge of managing component inventory effectively. Moreover, the volatility in the chip market necessitates establishing alternative sourcing strategies, ensuring a consistent supply of components even during periods of scarcity.

Moving forward, medical OEMS will need to make their supply chain more sophisticated by adopting AI smart tools, to improve their position and bolster the quality and availability of medical devices.

Amplifying medical exposure: The impact of multi-board systems

The medical industry is distinct from others in that it predominantly deals with complex multi-board systems rather than simple single-board products. This complexity poses a unique challenge – if a defective chip enters the supply chain, it can be distributed across numerous boards, making recalls an especially arduous and costly endeavour. Recalling intricate medical devices is near impossible and would likely result in substantial financial losses and severe reputational damage.

Indeed, within the ever-evolving landscape of the medical device industry, the significance of controlling traceability – the ability to track any given component or product along any given point in its supply chain life cycle – has reached unprecedented heights. While medical OEMs may trust their manufacturers to utilise cutting-edge traceability systems, the reality often presents a different scenario. Relying solely on assembly logs collected during the assembly process is no longer sufficient for medical OEMs. The stakes are too high, and any inaccuracies in the traceability system could lead to severe consequences. However, a silver lining emerges as AI and big data technologies pave the way for a new level of traceability, wherein every discrete component is meticulously tracked as a unique entity. Embracing these innovative methods promises to safeguard medical OEMs against potential risks.

Understanding the challenges

The medical device industry confronts many challenges in the face of increasing chip demand. Regulatory complexities and lengthy qualification processes impede innovation and adaptation to new technologies. The short lifecycle of semiconductor components adds strain to the supply chain, leading to increased costs and delayed device availability. Limited bargaining power due to the industry's relatively smaller size impacts negotiations with major component manufacturers, resulting in higher expenses and lower availability. And managing component inventory and establishing alternative sourcing strategies using advanced AI tools have become crucial for maintaining a steady supply of essential components.

Additionally, the complexity of multi-board systems heightens the risks associated with faulty chips, making recalls difficult and potentially detrimental to medical OEMs. Understanding

these challenges is vital for the medical device industry to address its limitations effectively, ensuring the continuous supply of life-saving devices to those in need.

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