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Adherence to IEC62366 may not ensure a successful FDA review: A case study

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Compliance to ISO/IEC 62366 ensures the medical device manufacturer has performed due diligence in the design and development of the product so as to minimize the risk of harmful use error. This standard also lays out a user centered design process that should enhance the product's general usability once market released. It has expanded the scope of its preceding standard, which was solely for electrical medical devices (ISO/IEC 60601-1-6: Medical electrical equipment - part 1-6: General requirements for safety - Collateral standard: Usability), to include all medical devices. The 62366 standard is often used when applying for a product's CE Mark. In essence, the device manufacturer may choose to show that activities have been performed for the specific product of interest or demonstrate that their overall product development process adheres to 62366. And it has become common for manufacturers to submit such compliance to the FDA for US release; especially for those attempting to enter the US market after CE mark. However, for a successful market release in the US, adherence to IEC62366 may be necessary but definitely not sufficient for a successful FDA review. In fact, the FDA has pointedly responded to the industry due to new product and 510 k submissions that tout such compliance as evidence use error has been investigated. They explicitly state they will not accept compliance alone as evidence that the design of the product would minimize the occurrence of use error. Through a case study, this presentation will detail the common FDA review comments concerning IEC62366 compliance. Details will be presented on how these discrepancies were successfully addressed and, ultimately, how to avoid initial obstacles all together by outlining the FDA human factors review guidelines currently in effect.

Biography

Dean Hooper is Principal at HE Consulting. He provides user-centered design expertise to all phases of product development, from initial needs gathering to final product validation. His strength lies in being proficient at simultaneously providing human factors input for optimal product design while contributing to successful regulatory submissions. He has provided human factors input to software and hardware development projects for over 18 years; the past 13 applying and directing user-centered activities to deliver safe and easy to use medical devices and associated peripherals; from Cardiac Rhythm management to robotic surgical systems. He has been awarded design patents and produced several publications; most recently on the evaluation of medical device use error and building user-centered programs to meet regulatory pressure to demonstrate safe design before market release. He received an M.S in Cognitive Science from New Mexico State University where he studied cognitive processes involved in word and speech recognition.

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