



ISO 13485-accredited medical device design

Managing creative risk

Lucid is one of the few UK product development businesses accredited to design medical devices

Why an accredited design team?

Accreditation to the European standard for the design and manufacture of medical devices makes Lucid's creative team a ready-made fit for healthcare businesses. We already follow and document the processes that any organisation planning to develop medical devices legally needs to maintain.

Development on a solid foundation

Our focus is on creative effectiveness.

We use an evidence-based approach to innovation, grounded in thorough analysis of options and informed risk management. It's an approach that encourages questioning and creative collaboration - the pre-requisites of demonstrably safe, sustainable medical product design.

We took 10 years to develop Lucid's ISO 13485 system, including 10 years of delivering ISO 9001 accredited brand, product and pack development. The time has enabled our team to carefully strip out waste, duplication or activity that could stifle innovation or collaboration.

The benefits

The earlier that ISO 13485 is considered in development, the more informed and efficient your design process will be. We can evidence that this approach makes sense, with an unambiguous design decision trail from project start to end.

Working to ISO 13485 from project conception to completion won't just demonstrate statutory compliance. The process can make design decisions that involve risk significantly more reliable and justifiable, whether or not medical devices are involved.

Working with a team accredited to develop medical devices is a worthwhile investment in getting the right product to market first time.