Usability Engineering to IEC 62366-1

User Research
Human Factors
Usability Testing
Compliance

Future-proofing medical devices
Usability Engineering to IEC 62366-1

Understanding your intended users to create usable medical devices.

THAY Medical are a natural choice of partner when developing medical devices, where ease of use, efficiency, effectiveness and user satisfaction is required. We specialize in collaborating with medical device developers to provide the usability and human factors engineering elements that are now critical in maximizing device safety, and in particular—use safety.

The usability engineering process aims to provide objective evidence of use safety through research and testing. This process works in a similar manner to other parts of device design (specification, research, development, testing, iteration and finalisation), but also works very closely to the risk management process defined in ISO 14971. The minimisation of risk—in this case, of use errors, maximizes the use safety of the device expected in real life.

Working together on usability

Developing devices efficiently.

THAY Medical are focused on effective device development, and to do this we work within project schedules to the medical device developer requirements. We focus on working closely with key development staff to provide the research, design, testing and documentation elements required by IEC 62366-1 to either internal quality system requirements or to our own.

The good news is that we are able to work globally in countries such as France, Spain, Portugal, Italy, Ireland, Sweden, Denmark, Holland, Germany, Brazil, Mexico, Australia, New Zealand, South Korea, India, Israel, South Africa, Canada, the USA and the UK. We can perform usability testing in all of these countries and since IEC 62366-1 does not specify where to test, it can be performed where the device is most frequently expected to be used, or to match a sales launch strategy.

Creating usable devices

Where a good product can become a great product.

Usability engineering is a method of developing a medical device with focus on the intended users. With focus on the user, the risk of use errors can be minimised and the use safety maximised. This can be the difference between a good device, and a great device. For more details, please visit our website or contact us.