

Medtech Masterclass

Making it Work: The Human-Centred Approach to Medtech Development

LEADING INDUSTRY EXPERTS

Sento Solutions – Making people’s lives easier.

<https://sentosolutions.com.au>

Sento Solutions (Sento) are a Usability Engineering (UE) and user experience consultancy. They are industry-leading experts, working with both local and global medtech start-ups and medical device manufacturers on over 20 medtech development projects.

Sento support the compliance of all human factors and usability engineering and risk management standards and guidances for Class I, II and III regulatory submissions across US, EU and AU regions. We conduct early user research to identify stakeholder needs, develop detailed use-related risks analyses, requirements and deliver all phases of formative and summative usability studies.

Usability engineering is a patient and user-centric form of risk mitigation, where we specialise in delivering safe and effective products and services to patients, healthcare professionals and lay users (for in-home devices). We also partner with Australian and US-based recruitment teams and test facilities to offer a 'one-stop-shop' of planning, executing and reporting early formative studies right through to late formative and validation (summative) studies.

In addition to ISO14971, IEC62366 and FDA guidance on applying Human Factors (HF) and UE to medical device design, our experts also have a wealth of knowledge and experience in complying with ISO13485 and FDA QSR, 21 Part 820.

