



IMPACT

ISO 13485

Xtra-med is based in Cheshire, England specialising in helping healthcare practitioners solve what is considered to be the Achilles Heel of haemodialysis –vascular access.

With 30 years of experience in the healthcare industry, they are on a mission to help find resolutions to vascular access. Xtra-med understands the issues they are trying to solve and aim to provide education as well as bringing innovative products to healthcare practitioners and patients. Xtra-med understands the difficulty and importance of solving these issues and are committed to finding and providing new solutions.

As a highly specialist company, Xtra-med required ISO 13485 to operate within new markets in their industry. Therefore the decision to implement ISO 13485 was a “strategic benefit of good quality management” as it allows Xtra-med to “supply the NHS” with their innovative products.

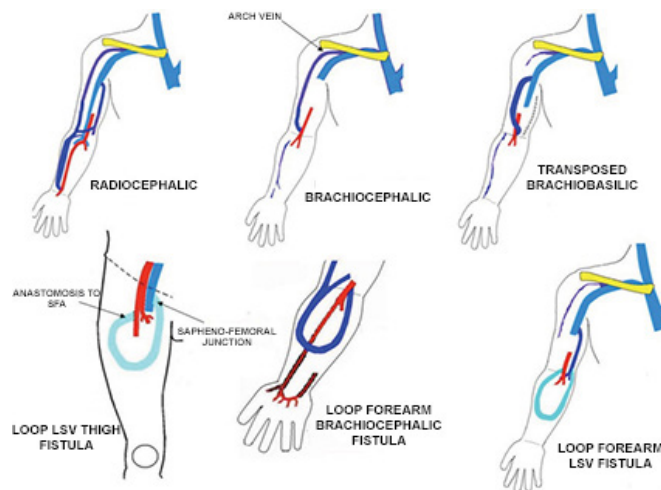
International Manager, Paul Jeffrey, decided to work with IMSM after an in depth online search through different ISO 13485 companies. After calling over 20 companies Paul valued the experience of having 1:1 guidance from a dedicated Area Manager to help answer questions and make this important business decision. “Our Area Manager’s initial support and advice was great and instrumental in us choosing IMSM.”

By working with an IMSM assessor, Xtra-med received a road mapped implementation process to create

an experience that was smooth, “I cannot fault our Assessor’s work and support.”

IMSM ensures possible non conformances are noted so that as a company you can be confident with the certification process. IMSM noted three nonconformances which is part of the process of implementation, enabling Xtra-med to solve these as required for successful accreditation. This ensured things “moved rapidly and all in all was a good experience.”

Implementing ISO during COVID-19 may have seemed like a daunting task, however IMSM and Xtra-med were able to do the process remotely with the help of their dedicated IMSM assessor. The experience was “helpful and supportive during our Risk Assessment for the remote audit and our initial Document review.”



Paul was able to work from home with no issues, and noted that “Everything else has been done remotely. Our assessor has been very good.” Even with UK wide lock down, Paul found that “communication was very good, so by the time we went to audit there was a very clear understanding of the company.”

Paul Jeffrey, was completing a lead auditor training course for both ISO 13485 and ISO 9001, and therefore understood the importance of having an experienced auditor and working with a reputable ISO consultancy.

IMSM auditors are not only ISO specialists but industry experts bringing their experience and knowledge to your business.



BENEFITS OF ISO 13485

- Competitive advantage through improved customer satisfaction and stakeholder relationships
- Increase business growth - win more contracts and attract larger customers
- Full ISO 13485 compliance - a prerequisite for regulatory authorities everywhere
- Reduced operating costs through continual improvement and optimized efficiencies
- ISO 13485 will also help you to monitor your supply chain so that you are always in control
- Legal compliance - be confident that your company has a quality system that meets legislation demands in every corner of the global market
- ISO 13485 will establish robust development, manufacture, distribution and control processes
- Improved risk management - greater consistency and traceability