KERSHAW TECHNOLOGY SERVICES

Regulation - Quality - Product

Who are we?

Kershaw Technology Services is a consultancy based in Cheshire, with clients across the UK. We specialise in regulatory compliance and product development for medical devices particularly during product development.

What is our business?

Successful product development requires the integration of regulatory compliance, quality management and product development.

Compliance with the requirements of the directives and regulations is critical to getting the product CE marked and on to the market quickly. Our business is hands on support for clients meet the regulatory requirements and creation of compliant documentation for the CE marking of their products. This support extends into the organisation and planning of the product development process if the client requires it, because compliance with the Regulations is more than having a Quality Management System.

It is important to bear in mind that to bring a medical device or IVD to market in Europe requires that the product is CE Marked and that you must be able to demonstrate how you have complied with all the relevant Regulations and their supporting standards. These documents must be sufficiently detailed to satisfy requirements of the notified bodies and competent authorities.

What do we offer?

Kershaw Technology Services provides services to deal with the nitty gritty of Regulatory Compliance, Quality Management and Product Realisation/Development. The service integrates Regulation, Quality and Product Development.

Examples of some of the services we offer.

Regulation

- Identifications of the relevant regulations
- Identification of the different options for CE marking your product, your route to compliance.
- Identification of the activities required to demonstrate compliance with the directive
- Creation of Technical Files for CE marking submissions and supporting documents.

Quality Management Systems

- Structured processes and documentation for product realization including product design, development and manufacture including design verification and validation.
- Risk Management processes and documentation.

Product Development

- Planning of product development/realization.
- Integration of ISO compliant product development with commercialization process
- Structured procedures and documentation for validation of manufacturing processes and test methods.

Although we cannot CE mark the product for you, we can make your life easier by helping with the creation of compliant submissions and bringing the product to market.

Contact

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