Visit: redmedtech.co.uk

Book: https://calendly.com/redmedtech/meeting

Services Summary

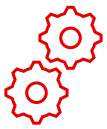
Red Medtech Ltd. is a management consultancy company specialising in the medical devices sector.
This niche specialism is technically complex and highly regulated, with our clients needing management consulting advice, guidance and practical support for their projects in order to achieve and maintain the certification and/or approvals needed to market their devices in various countries internationally.
Our client base is broad from micro start-ups, spinouts and SMEs to large global health tech companies.
We assist medical device designers, developers and manufacturers directly and also provide sub-contracted support to other medical device quality and regulatory compliance consulting firms.
Drawing on extensive professional experience in healthcare technology, engineering and manufacturing we provide a range of services to accommodate the diverse nature of client projects, medical device types and technologies in this sector. Red Medtech deliver management consulting in the following key areas of expertise:

Project Guidance: Management support for development, quality and regulatory medical device projects



Helping with strategy, project planning, implementation, and post-completion activities.
Consulting support from identifying resourcing needs and managing teams, to monitoring project performance, providing stakeholder updates and executive progress reporting.
Supporting projects to improve quality, productivity and compliance, scale-up and transfers.
Assist in supplier and service partner identification, including testing and certification bodies.

Product Development: Technical documentation for assessment by Notified Body and other regulatory authorities



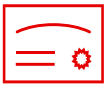
Applying design and engineering qualifications and first-hand experience to assist clients with new and existing product development projects, including innovative healthcare technology applications.
Advise and support technical aspects of medical device projects, throughout the total product lifecycle.
Provide development and innovation expertise for a wide range of device types and classifications.
Engineering consulting support including but not limited to design, materials, manufacturing, processes, software lifecycle processes, verification & validation testing, risk management, usability human factors.

Quality: Documentation for product and management system assessment by certification bodies



Help the planning, implementation, and maintenance of Quality Management Systems, including digital conversion projects from paper-based to electronic eQMS software solutions.
Assisting clients with internal, external and supplier audits, identifying certification partners, preparing for Notified Body and Approved Body audits, managing post-audit activities and remediation work.
Supporting quality investigations and compliance projects including delivering QMS training.
Consulting for ISO 13485 and MDSAP- Medical Device Single Audit Program certification projects.

Regulatory: Documentation demonstrating compliance for assessment by regulatory authorities





Provide information, advice and guidance so that clients can understand the requirements, their obligations, and the processes involved in getting their medical devices developed, assessed, and certified/approved to legally place on the intended market(s).
Help identify applicable regulations, directives, guidelines, horizontal and vertical standards.
Support to maintain in-market compliance including transitioning from EU Medical Device Directive to MDR Medical Device Regulations for CE marks, UK Medical Device Regulations for UKCA, and FDA for USA.
Provision of UKRP - Responsible Person and EU PRRC - Persons Responsible for Regulatory Compliance support for Clients including device registrations and consultation with applicable regulators, authorities, Notified Bodies and Approved Bodies on the Client's behalf.

Note on Labelling & Instructions For Use: A medical device includes its labelling and IFU - Instructions For Use, and so these are subject to the same compliance requirements and assessments stated above; legal manufacturers need to demonstrate compliance prior to market.

Note: Red Medtech Ltd. do not provide medical diagnosis or treatment services as a healthcare professional. Red Medtech Ltd are not the Legal Manufacturer of medical devices. Red Medtech Ltd are an independent contractor company, not part of the client organisation or management team. Red Medtech consulting services cover development and compliance for medical devices, in vitro diagnostics (IVD), health technology, combination devices, wellness products, healthcare-related consumer products and applications. Exclusions*: Red Medtech consulting services do not include hardware/firmware electronics engineering, software coding or device cyber security. Red Medtech does not perform clinical investigations, provide clinical assistance, clinical trial design, study endpoint, clinical controls, or statistical analysis. Client is responsible for conducting trials and collecting clinical data as needed for submissions. Red Medtech does not provide consulting services for industries outside the healthcare sector. *Red Medtech collaborates with trusted providers to enable, coordinate and facilitate the delivery of these specialist services as part of our Project Management services.

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