company profile

MEDICAL TECHNOLOGY promedt CONSULTING

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MT Promedt Consulting GmbH is a Germany based regulatory consultancy providing analytical and strategic services to the international healthcare market focusing on medical devices and in vitro diagnostic products. The company supports manufacturers worldwide in the medical device certification and clearance process, international product registration and in the development and implementation of quality management systems. Founded in 1995, the company is centrally located in Europe with a German office in St. Ingbert/Saarland and is represented in the USA with an office in Salt Lake City, Utah. In January 2021 MT Promedt Consulting Ltd. was founded with an office in Oxford, UK. MT Promedt Consulting GmbH provides the services as a European Authorised Representative (EC REP) for non-European medical device manufacturers according to the European regulations. Furthermore the company provides the services as an UK Responsible Person (UK RP) according to the current UK regulations via the office in Oxford, UK.

The objective of our company is to provide excellent and hands-on assistance for our clients. Considering the sponsor's perspectives, we tailor our competent services to meet the customer's needs in a cost-effective manner and within a clear timeline. We understand and enjoy the entrepreneurial spirit inherent in the small and medium sized companies. Benefitting from years of experience in the fields of design and development, production, quality assurance and regulatory affairs, MT Promedt Consulting offers full-service packages in order to speed up the process from product development to market clearance. Our commitment is to help our clients to obtain a remarkable advantage in these markets by gaining faster market access.

team

Our team consists of experts – pharmacists, microbiologists, chemists and biomedical engineers – with an extensive medical, scientific, regulatory, technical and business background who are well-respected by international notified bodies and competent authorities. We are specialised in the fields of medical technology, pharmaceuticals and regulatory affairs. We have profound knowledge in the areas of quality management systems, international regulatory requirements, CE conformity assessment procedures, product safety assessment and testing, planning and performance of production processes, product validation and post-market surveillance activities.

partners

By accessing a global network of subsidiaries and partners in Australia, Brazil, India, Israel, Japan, Korea, Saudi Arabia, Singapore, Taiwan, Turkey and USA, MT Promedt Consulting provides in-depth knowledge across the lifecycle in medical technology from product development to the post-market period.

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