

Providing Effective, Efficient and Affordable Solution to Medical Devices Industry

Sushvin Consultancy Services Ltd supports its clients with the ever-changing regulations in the medical device industry. We spoke to its Founder, Aditya Kulkarni, to find out more since its recent recognition in the Global Excellence Awards 2022.

Compliance plays an important role in the medical device industry as safety and efficacy of the product is the key for its entry to the market. The regulators and competent authorities are always looking for non-compliance in medical device industry which can affect our rights to market the product.

There are challenges that medical device companies need to address to ensure their success, due to it being a fast growing and competitive field. Sushvin Consultancy Services Ltd, is a Global Medical Device Consulting Firm and a ruling provider of strategic Regulatory and Quality Compliance Services for Medical Device and In-vitro Diagnostic (IVD) devices. It was founded in 2011 to support with the ever-changing regulations in the medical device industry for its clients in the UK, EU, US, the Middle East, South Asia, and the rest of the world. Sushvin Consultancy Services is a proud member of ABHI (Association of British HealthTech Industries).

Recently, a challenge that companies in the medical device industry have faced is regulatory compliance for transition from Medical Devices Directive (MDD) to Medical Device Regulation (MDR), the introduction of MDR is led to delays in the grant of CE Certificates to medical manufactures.

That is where Sushvin Consultancy Services comes in to guide its clients through such challenges. The Founder, Aditya Kulkarni, explains, "Our Regulatory Services cover regulatory strategy and compliance, quality assurance and compliance, technical file preparation and regulatory submissions, clinical evaluation reports, guidance and support for the MDR/IVDR Regulation, drug/device combination and borderline products, vigilance and post market surveillance, provision of UK Rep Services, labelling, and staff training." These areas of expertise mean it can offer its clients a variety of high-quality services that are also affordable.

The team at Sushvin Consultancy have the education and experience needed to be able to provide effective services that ensure its clients are up to date with the applicable regulations in the Medical Device industry worldwide. They are praised by clients for their "persistence and dedication towards solving clients problems and be readily available whenever needed", shares Aditya. Their efforts to support all clients is then seen as their products successfully make it out into the market, Aditya highlights, "Our team of experts have been helping our clients navigate the complex regulatory landscape and ensure that their products meet the highest standards of safety, quality, and performance."

Sushvin Consultancy Services values creativity, open communication, and a commitment to excellence. "This culture of collaboration has enabled us to develop innovative solutions for our clients that have helped drive our success", says Aditya. This is seen reflected in the company's goals for 2023. It is expected to enter global regulatory markets to enable faster registration and QA/RA compliance for its clients – especially through partnerships with local partners. It is also registering for ISO 13485 Quality Management System for Medical Device Service Providers and growing its team with SMEs from different fields of medical devices and IVD's. Giving back is in the team's sights for this year as Aditya highlights "Sushvin Consultancy Services is also keen and dedicated towards social causes to help create a better world for everyone."



It is clear that through their dedication to provide quality and up to date services Sushvin Consultancy's recent recognition in the Global Excellence Awards 2022 is well deserved, as it now holds the title of Best Medical & Pharmaceutical Regulatory Services Provider – UK. We look forward to seeing what 2023 has in store for it.

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