Fact Sheet

Dedicated European Regulatory Solutions for MedTech Companies

Reliable partner covering regulatory and quality compliance from initial product definition and registration to post marketing activities

MedTech companies continue to face the ever-increasing demands of regulatory authorities, disparate requirements in different geographies, amplified scrutiny and growing demands for verification, validation and supervision. The rapidly escalating complexity drives companies, large and small, to seek greater support for their teams to keep up with the demanding workload and complex requirements.

Implications of an evolving landscape

The MedTech regulatory affairs arena is constantly being reshaped by the regulatory authorities around the world, with even more significant changes in taking place in Europe. Following years of discussions, the European Union has adopted a new regulatory policy formulated in the **Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).** These new Regulations are nothing less than a total upheaval of the field, changing accountability and responsibility at all levels. The withdrawal of the United Kingdom from the European Union (EU), known as Brexit, poses new challenges for the regulatory MedTech industry.

The policies create an entirely new regulatory environment that will have to be learned and applied by the entire medical device value-chain, from developers, through manufacturers to importers, distributors and local regulatory representatives. The radical changes in the regulatory environment generate an enormous demand for support services from skilled personnel and educational activities.

The pressure that the new regulations create is not limited to Europe. They impose a new dimension of complexity for all non-European manufacturers that do or want to do business in Europe.

Benefits

IQVIA MedTech regulatory solutions conducts works with MedTech companies according to clear principles of high-level performance and timely delivery. We offer comprehensive consulting services for MedTech, including Regulatory Affairs in Europe and Quality Management System (QMS) services.

Continuous compliance - Obtain clearance to market your products across Europe and remain compliance over the long term.

Trust - Management of confidential business and product information with complete discretion.

Expertise - Over 20 years of regulatory and quality experience working with European regulatory and certification authorities.

Personal attention - Get your products past regulatory hurdles with innovative, responsive and pragmatic solutions.

IQVIA MedTech offers dedicated highly skilled regulatory affairs and quality assurance consultants that help MedTech companies navigate the regulatory and quality maze.

Support across the product lifecycle

One of the key strengths of **IQVIA MedTech** is the broad offering of services, encompassing the entire spectrum of regulatory, and quality management activities that satisfy clients' needs throughout the product life cycle. The core of this offering stems from the team's intrinsic expertise, providing knowledge, solutions and execution for its clients' needs while managing the process efficiently.

The team have extensive D&D, engineering, techno-regulatory backgrounds and have experience with a wide range of medical device technologies. We know how to get products past the regulatory hurdles by providing pragmatic solutions. We understand the needs of the vibrant high-tech medical device industry and the dynamic regulatory environment.

Early regulatory involvement minimizes the risk of potential re-engineering, thereby saving precious time and resources.

Regulatory solutions principles of IQVIA MedTech

Multi-disciplinary experts in the field of mechanical, electronic, chemical, bio-medical and bio-technology engineering, life sciences, medicine, computer sciences, statistics and technical writing

Proven experience with meeting specific technological and clinical requirements, complying with international standards, European Union (CE Mark) and the UK (UKCA and UKNI)

Extensive knowledge and guidance through the entire development process, from initial concept to regulatory plan, verification and validation, clinical studies, pre-marketing clearance and post-marketing compliance

Robust services allow clients to begin marketing their products and ensure they remain in compliance

Regardless of your company's size, through partnering with IQVIA MedTech you can realize several benefits:

- Highly skilled regulatory and quality consultants supporting your project
- Creative and innovative solutions to minimize product registration timelines
- Targeted approaches to maintain compliance throughout your product lifecycle

IQVIA MEDTECH

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