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MED TECH OUTLOOK

MEDICAL DEVICE CONSULTING EDITION

Awarded By

MEDTECH OUTLOOK

We develop a sustainable project management cadence that ensures our clients´ regulatory quality standards are maintained

GLOBAL

The Full-Service Clinical Research Organization

As a full-service clinical research organization (CRO), GLOBAL is a "one-stop-shop" which specializes in providing writing and consulting services to medical device, in vitro diagnostic, complex biologics, and pharmaceutical companies.

One of their primary services is helping medical device manufacturer comply with EU MDR, which came into force in 2021. EU MDR has brought forward strategy changes across the industry when releasing a device to market. For example, when developing a new medical device, large manufacturers today are now applying for US-FDA clearance first instead of the previously more forgiving EU CE mark. Navigating and implementing EU MDR is a complicated and resource-intensive task, one that GLOBAL is equipped to handle.

The company's EU MDR consultants help determine the appropriate regulatory and clinical remediation needed to achieve EU MDR compliance. Further, they can develop a document and process remediation plan that ensures clients' regulatory quality standards and compliance is achieved.

Additionally, GLOBAL provides clinical operations support focused on developing and executing cost-effective PMCF studies and surveys. Its consulting support assists with determining the appropriate remediation plan and clinical strategy, which in turn helps clients save money in the long term.

"We develop a sustainable project management cadence that ensures our clients' regulatory quality standards are maintained," says Emily Stephens, Founder and CEO of GLOBAL.

When GLOBAL kicks off a project, they assess clients' needs and build a team of subject matter experts to meet their demands. The company builds a blended team to achieve project goals on a large scale, as needed, leveraging talent from consultants, project managers, and subject matter experts. Apart from its large team of medical writers, GLOBAL has a robust recruiting and training pipeline. Every GLOBAL client receives quality products on time, which were prepared by experienced professionals. Further, they have the highest quality standards, which include an internal quality review and a two-stage data verification process.

To assist clients in meeting regulatory requirements, GLOBAL provides consulting, gap analyses, regulatory/clinical writing, and EU MDR remediation expertise. The company also offers training and consultation services to help internal teams better understand the regulatory requirements and share best practices based on its extensive experience of working with notified bodies.

For underestimated project timelines and inefficient workflows, GLOBAL offers management of regulatory documents and can build schedules to optimize compliance and avoid unnecessary revisions or updates. This can, in turn, reduce resources due to new streamlined processes and efficient timeline management. In a project management role, GLOBAL can also provide training and supervision for regulatory/clinical department members.

As a one-stop shop, GLOBAL's range of services and solutions is unique and impressive. They started with a small expert Clinical Evaluation Report (CER) writing team and evolved into a full-service CRO. This evolution came from a clever and agile reaction to clients' needs for clinical evidence generation and regulatory support.

GLOBAL now supports medical device and pharmaceutical manufacturers with clinical research development, clinical writing, publishing, and submission management for eCTD submissions, CMC (Chemistry, Manufacturing, & Controls), regulatory strategies, advanced regulatory automation assistance, and life science and technology staffing services. Its most exciting industry disruptive element comes from GLOBAL Exponential Technologies (GxT), a recently created partner company of GLOBAL. GxT provides software-based tools and services to improve regulatory submission efficiency and quality through automation and advanced intelligence software.

GLOBAL was founded in 2014 with a unique vision that offers employees an environment where they can perform at their best, an employee-friendly CRO. They are the first medical writing company to offer unlimited PTO, flexible schedules, company-paid medical benefits, quarterly bonuses, and a generous profit-sharing plan for employees.

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MEDTECH OUTLOOK

The annual listing of 10 companies that are at the forefront of providing Medical Device Consulting services and impacting the industry

Medical Tech outlook

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