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ЦЕНТР СЕРТИФИКАЦИИ И РЕГИСТРАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ

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A Trusted Partner Offering Streamlined and Expert Services for Medical Device Registration

The medical device registration process plays a pivotal role in ensuring the safety and efficacy of healthcare products in the market. However, this seemingly straightforward procedure comes with a myriad of challenges that can pose significant hurdles for manufacturers seeking approval for their medical devices.One persistent challenge that keeps cropping up is the issue of incorrect paperwork and reports submitted by applicants. The persistent errors in these essential materials, coupled with manufacturers' frequent inquiries, contribute to a cumbersome and prolonged review process. The inaccuracies in the documentation not only complicate the evaluation of the dossier but also extend the overall timeframe for approval, potentially delaying the availability of crucial medical innovations for patients. Thus, recognizing the critical need for a streamlined and error-free medical device registration process, Regmeddevice (CCRMD, Ltd) came into existence as a trusted partner for manufacturers navigating the complex regulatory landscape.

CCRMD traces its roots back to the passion and perseverance of its CEO, Elena Zarubina. Initially, Elena worked as an operating nurse in an oncological medical center. Later, she transitioned to a role as a specialist-expert, meticulously scrutinizing documentation and protocols for medical devices within the Federal health service registration framework. This is when she noticed a recurring issue – her department often encountered incorrect documents, reports and

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protocols from applicants. These errors in the documents, regular questions from manufacturers - all this complicated and increased the timeframe for reviewing the dossier and the process as a whole. This experience and the desire to establish productive work in the field of registration of medical devices prompted specialist Elena to quit her job and start her own company, Center of Certification and Registration of Medical Devices in 2011. At the heart of it all was a simple goal –to create a platform where any medical device manufacturer could avail support in preparing precise documents, conducting essential tests, and seeking expert consultations. Every year, as new regulations for the medical device industry were introduced and demands

for compliance increased, the company evolved, expanding its team of experts and acquiring new capabilities. Today, after almost 13 years, CCRMD stands tall as a living testament to Elena's vision – a powerhouse of competence, featuring a dedicated team, steadfast partners, and over a decade of expertise in the intricate field of medical device registration.

Making Advanced Medical Technologies Available to Millions

CCRMD help developers, manufacturers, and distributors to quickly bring new medical devices to the Russian market, increasing the availability of advanced medical technologies for millions of people. The company is engaged in the registration of medical devices of the widest range. This includes managing the registration process, handling official notifications, and facilitating collaboration with federal executive authorities responsible for regulating the circulation of medical devices within the Russian Federation. It is also deeply involved in addressing issues related to the application of norms and legal requirements, streamlining procedures for medical device circulation, and optimizing information exchange.

Moreover, they excel in creating essential document packages required for notification registration, leading to the acquisition of an authorization document for the medical device. Their services also encompass the meticulous formation of registration dossiers, amendment of registration documentation, preparation of Technical and Operational documentation, and the development and registration of technical specifications and risk management files. In addition to the above, the company undertakes the development of regulatory documents, facilitates the creation of applications, and provides various services related to the registration of medical devices. This includes organizing tests such as technical, toxicological, clinical, and electromagnetic compatibility, as well as aiding in the acquisition of permits for importing medical devices. The company actively engages in addressing and rectifying detected violations during scheduled inspections by the State Control over the circulation of medical devices. “We value the trust of our clients, so we

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maintain a consistently high level of quality of our work, expand the list of services offered and look for new solutions to meet the challenge of external factors," opines Elena.

CCRMD participates in obtaining Registration Certificates for the most significant and important medical devices in treatment. "Millions of people are waiting for delivery of the latest products as Treatment planning systems, Treatment delivery systems, proton therapy systems, medical ventilator devices, which are so necessary nowadays. And our company is very proud to take part in the realization of these tasks," adds Elena.

Embracing Ethical Values in Business Operations

CCRMD adheres to a set of core business principles that reflect its commitment to safety, regulatory compliance, professionalism, and customer-centricity. These principles not only serve as guiding values but also shape the company's identity as an industry leader in medical device registration. At the forefront of CCRMD's ethos is a robust emphasis on safety and meticulous adherence to management and control systems. This commitment extends to ensuring strict compliance with legislation, regulations, rules, and standards set by supervisory bodies. By prioritizing these elements, the company establishes itself as a reliable partner dedicated to maintaining the highest standards in the industry.

Through the continuous development and implementation of new formats and technologies, CCRMD not only keeps pace with advancements but also sets the benchmark for others to follow. With a team boasting extensive expertise in medical device registration, it goes beyond typical registration services to offer a comprehensive suite of services, including legal advice, testing, corporate consulting, and innovative solutions to address clients' unique challenges.

It saves clients' time by providing effective solutions in the sphere of rendering services on

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the Russian market in the field of registration of medical devices. They specialize in preparing the required documents for both domestic and foreign medical devices and equipment. Every year the services of the company are used by subjects of economic and foreign economic activity and every day, its dedicated team works relentlessly to ensure the Company's worthy position in the Russian market of medical devices circulation. At the same time, the Company is always faithful to its mission, which is to provide services at an increasingly qualified level.

Yet, what truly sets CCRMD apart is its unwavering commitment to a set of core values and ethical standards that guide every action they take. The company recognizes that its reputation hinges not solely on compliance with Russian laws and the upholding of human rights but equally on its commitment to social responsibility and the unwavering adherence to moral and ethical norms. It is committed to combating corruption, upholding legality, protecting the rights and freedoms of employees and customers, and holding individuals accountable for corruption offenses. This commitment is woven into the fabric of the organization, reinforcing the values of doing the right thing, focusing on innovation and high quality, accountability, continuous learning and improvement, and mutual assistance among employees. Regmeddevice's commitment to ethical conduct is underscored by a comprehensive Code of Conduct. While the mission and values guide the company, the Code of Conduct provides practical guidance on how to implement these principles. “We do business with a variety of medical device companies from countries around the world. That is why it is also important for us to comply with the rules and requirements of international regulations. Compliance with these laws reinforces

our reputation for fairness, honesty and integrity," affirms Elena. By upholding these principles, Regmeddevice seeks to build and maintain its reputation as one of the leading companies in the market for consulting and advisory assistance in the registration of medical devices, while contributing to the development of medicine.

Proactively Addressing Global Challenges

At the heart of CCRMD's mission lies a relentless pursuit of advancements in health. This pursuit permeates every aspect of its operations, from the meticulous preparation of precise dossier documents to the impartial testing of products and the collection of accurate information. In the dynamic landscape of the medical device market, global challenges emerge for manufacturers, including supplier changes, modifications in product instructions and configurations, new logistical issues, labeling adjustments, and updated certifications. Recognizing the complexity of these issues, CCRMD actively studies all new emerging issues and helps its clients to carry out all necessary activities in a short time.Working simultaneously with companies from different countries and with different problems or situations, it is able to offer its clients professional assistance and different solutions.

Despite the ongoing complexity of medical device regulations worldwide, CCRMD remains proactive, continually learning and adapting to offer innovative problem-solving approaches to clients and manufacturers. "Unfortunately, the requirements for medical devices and the rules of their circulation in the countries are not simplified, which means that more and more new questions and problems will arise for our customers and manufacturers of medical devices. All these problems and difficulties push our company and employees to develop, to study new rules and information, to offer new options for solving problems to our partners," shares Elena.

CCRMD's commitment to a comprehensive approach, timely service delivery, and a high degree of responsibility has earned trust and credibility, positioning the company as a valued and active participant in the process of bringing cutting-edge medical devices to the market. This dedication ensures long-term sustainable success for CCRMD and all stakeholders involved.