Medical Regulations Gate

The Bridge To Your Success

Saudi Arabia (Head Office)
P.O.Box: 5998,
Phone: +966 11 2934961
Fax: +966 11 2937695
E-mail: info@mr-gate.com
Riyadh 11361, Kingdom of Saudi Arabia

Egypt
Phone: +20 22 7295574
Mobile: +20 12 74006050
E-mail: info@mr-gate.com
Degla View- Memaar Al Morshedy- Ring Road
Cairo, Egypt

UAE
Phone: +971 4 2449270
Office: 913 C
9th Floor
Ibn Battuta Gate Tower
Dubai, UAE

About MRG

Business Solution

Medical Regulations Gate is a leading Medical Devices consultancy company with its headquarters in Riyadh, Saudi Arabia working closely with various Regulatory Authorities all over MENA and Asia region such as Saudi Food and Drug Authority (SFDA), Ministry of Health Egypt (MoH), Ministry of Public Health Lebanon (MoPH), Ministry of Health & Prevention UAE (MoHAP) & Ministry of Health Pakistan (MoH)

MRG is honored to cooperate with over 300 successful Healthcare Organizations that include; Medical Devices/ IVD Manufacturers, Medical Devices/ IVD Distributors & Hospitals. MRG proudly continues to lead its markets by working alongside our clients as one team with a mutual ambition to accomplish extraordinary results in regulatory compliance.

We are always pleased to be part of your success, by assisting you to simplify your business process with a high-level of Commitment by guiding and advising you on all the pre and post-marketing requirements for medical devices, in-vitro diagnostic devices, contact lenses, and laser surgical equipment in MENA and ASIA region.

With 20+ years of experience and extensive knowledge of medical devices markets and regulations, MRG has registered 100,000+ medical products covering all classifications and various jurisdictions

Our Services

Consultancy and Regulations

KSA:

- Registering Manufactures site for Medical Device Establishment License (MDEL) with the Saudi FDA.
- Registering Medical Device Marketing Authorization (MDMA) with the Saudi FDA on behalf of the Manufacturers.
- Communicating with Saudi FDA of any changes in the product or any information about the Manufacturers.
- Assisting manufacturers with their post-marketing and vigilance reporting.
- Classifying products with the Saudi FDA
- Assisting local companies to register with the Medical Device National Registration (MDNR) with the Saudi FDA.

Egypt:

- Assemble and Submit the product registration file to CAPA.
- Submit documentation to the scientific committee for review, if needed.
- Notifying CAPA of any changes/ variations in the product or any information about the manufacturer.
- Assisting manufacturers with their post marketing and vigilance.
- Assist with preparing responses to additional information requests from CAPA.

Our Services

Consultancy and Regulations

UAE:

- Represent the manufacturer in its dealings with the U.A.E authorities.
- List each medical device category or generic device group intended to be supplied to the U.A.E market,
- Arrange a meeting with the Authorities to provide the Product Registration supporting documentary evidences,
- Cooperate with the manufacturer and the MOH on evaluations and actions taken during market surveillance and/or vigilance procedures in U.A.E.
- Make the following information available to the MOH when so required in relation to its market surveillance activities
- The marketing authorization issued by the MOH for the listed medical devices in U.A.E.

Lebanon:

- Assisting overseas manufacturers with the registration of Implantable Devices and Para-Pharmaceutical Products with MoPH (Ministry of Public Health).
- Assisting local companies with registering their Medical devices with MoPH.
- Working closely with local companies for Post-Marketing requirements.

Pakistan:

- Submitting and obtaining a Medical Device Establishment License with the Medical Device Board (MDB).
- Submitting and obtaining Certificate of Enlistment or Registration of Medical Devices from MDB.
- Working closely with MDB for Post Marketing Requirements.

Our Partners

MEDICAL TECHNOLOGY promedt CONSULTING

MT Promedt consulting is a German-based regulatory consultancy providing analytical and strategic service to the international healthcare market (medical devices, in-vitro diagnostics, pharmaceutical, and biotechnical industry) the company supports manufactures worldwide in the medical device approval and clearance process, international product registration and in the development of quality management systems.
MT promedt consulting provides services as European Authorized Representative for non-European device manufactures according to the European Regulations, Founded in 1995, the company is centrally located in Europe with Two German office in St. Ingbert/Saarland and Tornesch/Schleswig-Hostein and is represented in the USA with an office in Salt lake city, Utah, USA.

MASSON INTERNATIONAL
WE STRIVE TO HELP YOU THRIVE

Masson Internal Sàrl is a company specialized in Export Sales and International Business Development. It helps manufacturers around the world growing their export sales in foreign countries: market study/competitors analysis, market-entry strategy, distributor/importer search, in-country sales & business development, setting-up subsidiaries.

Some of MRG's International Clients

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