MEDDIDIA®

MEDICAL ▪ DIGITAL HEALTH ▪ DIAGNOSTICS

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Don’t Let Regulations hold back your Innovations!

Launching Medical Devices in the EU

www.med-di-dia.com

MEDICAL DEVICES IN INDIA

MEDDIDIA®

IBEF
INDIA BRAND EQUITY FOUNDATION
www.ibef.org

Based on IBEF publications

Market Size in India is among the **top 20 markets** for medical devices worldwide. India's medical devices market stood at US$ 11 billion in 2020 and is expected to reach US$ 65 billion in 2024.

India has a **75-80% import dependency on medical devices,** with exports at Rs. 14,802 crore (US$2.1 billion) in 2019 and is expected to increase at a CAGR of 29.7% to reach Rs. 70,490 crore (US$10 billion) in 2025.

To increase export of medical devices in the country, the **Indian Ministry of Health and Family Welfare (MOHFW) and Central Drugs Standard Control Organisation (CDSCO)** implemented the following initiatives: re-examination and implementation of Schedule MIII (a draft guidance on good manufacturing practices and facility requirements); system for export labelling; clinical evaluation and adverse reporting clarification; state licensing authority to extend free sales certificate validity from 2 years to 5 years to allow exports; create a list of manufacturers with export licensing for easy access by regulatory authorities worldwide.

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WE SEE AN OPPORTUNITY!

GRS®
Global Regulatory Services

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ABOUT US

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Med-Di-Dia is a regulatory and quality compliance consultancy firm supporting **Medical Device, In-Vitro Diagnostics and Digital Health companies** from our base in Galway, Ireland.

We will cut through the maze of regulations and be a risk partner on the journey to the market ensuring complete regulatory support for companies so that clinicians and patients can benefit from the commercialisation of innovative devices.

Med-Di-Dia was spun out of Global Regulatory Services to provide the key services of:

EU Authorised Representative
EU Person Responsible for Regulatory Compliance
EU Legal Representative for Clinical Trials
EU MDR and IVDR Regulatory Compliance
US FDA Regulatory Compliance

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THE OPPORTUNITY

Innovation Hub

Manufacturing Hub

Business Booster

Since India is becoming a global leader in Innovation and Manufacturing and with the Government's vision to increase Medical Device Exports, Europe and Ireland serve to be optimum markets.

Business and Trading relations between Ireland and India have a strong foundation. Being the only country in the European Union where English is the first language, Ireland has a strong potential to help Indian companies enter the European Union!

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THE CHALLENGE

Language Barrier

The European Union has a very strict policy towards regulations. With the application of MDR and Incoming IVDR, Medical Device innovators must develop a strong regulatory pathway to navigate through the maze of mandatory requirements.

Strict and Different Regulations

With the new regulations, the definition of Medical Devices has made the classification process even more complex which has had a direct impact on most medical software (SaMD - Software As a Medical Device).

Requirement of Representatives

Apart from the Regulations, non-EU Companies must have an EU Authorised Representative (EU AR) who will represent them to the European Commission and the Regulators.

European Union
Authorised Representative

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THE SOLUTION

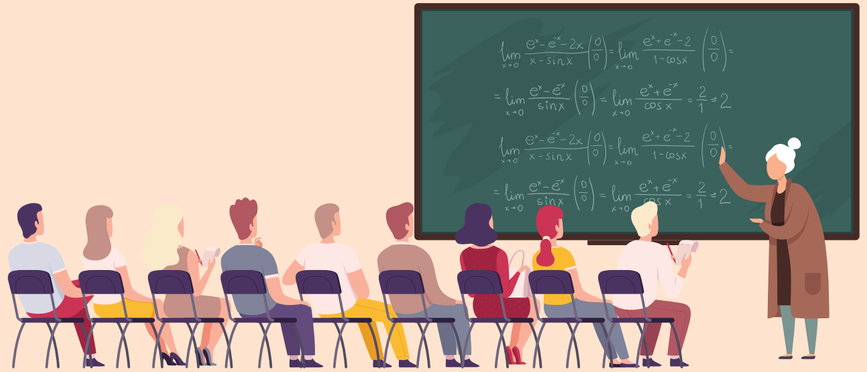
Med-Di-Dia is perfectly placed to help Indian MedTech Companies by providing:

Regulatory Clinics

One-to-One Consultation Clinics for Indian MedTech Innovators (free-of-charge)

Vouchers

Negotiated Vouchers to create Regulatory Market Entry Strategy and Regulatory Roadmap to EU



University BootCamp

Specialised Training Sessions for Universities, University Startups and graduates focusing on EU MDR/IVDR CE Mark etc...

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INTERESTED ?

Contact Us Now!

Visit - www.med-di-dia.com

and connect with

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Your Regulatory Partners for Devices, Diagnostics and Digital Health!

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Other Services

Review and approval of all elements of Medical Device and IVD submission data (CE Mark & US FDA) including the following:

Product Regulatory Strategy

Liaison with Notified Bodies

Design File Compilation

Clinical Evaluation

Sterilisation Validation Report

Management of Product Recalls

Risk Management Analysis

Internal Audits,Vendor Audits,

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