VOL.NO. 02 | ISSUE-10 | DECEMBER-2024

REGUVEDA

YOUR MONTHLY REGULATORY UPDATE

We provide turnkey services spanning from product design and development, manufacturing unit design up to achieving the regulatory approvals of national as well as international level.

OPERON STRATEGIST

Transforming Thoughts In To Reality

LATEST NEWS & UPDATES

REGUVEDA
YOUR MONTHLY REGULATORY UPDATE

OPERON STRATEGIST

VOL.NO. 02 ISSUE-10 JANUARY-2024

MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

'MedTech Mitra': A Strategic Initiative to Empower MedTech Innovators and Reduce Imports

The Indian government recently launched the 'MedTech Mitra' initiative, a strategic program aimed at empowering MedTech innovators and significantly reducing the country's dependency on medical device imports. This visionary move is poised to revolutionize India's healthcare landscape by fostering indigenous innovation and self-sufficiency in the MedTech sector.

'MedTech Mitra' serves as a robust platform designed to nurture and support budding MedTech talents across the nation.

READ MORE

Medical Device News

Parliament to Introduce Proposed New Drug Law

The government is poised to introduce the Drugs, Medical Devices, and Cosmetics Bill of 2023 during the current session of Parliament. This bill aims to replace the 80-year-old Drugs and Cosmetics Act of 1940, consolidating and amending regulatory requirements for drugs, medical devices, and cosmetics across India. Notably, the proposed legislation will encompass a distinct section dedicated to setting regulatory standards specifically for medical devices. This move will not only establish separate guidelines for these devices but also institute a dedicated team of regulatory officials equipped with specialized skills to oversee the approval and monitoring of all types of medical devices.

READ MORE

TO KNOW MORE

IVD CE Marking: Compliance Certification for In Vitro

In the realm of in vitro diagnostic (IVD) devices, obtaining CE marking for European market access is pivotal. Compliance with the European Union's stringent regulatory standards ensures the safety and efficacy of these devices. With the introduction of the In Vitro Diagnostic Regulation (IVDR 2017/746) in May 2022, the landscape for IVD compliance has undergone a significant transformation.

At Operon Strategist, we offer specialized expertise in European IVD CE marking services, providing tailored support to navigate this intricate regulatory journey.

READ MORE

Understanding the Significance of FORM MD-3, MD-5, MD-7, and MD-9 in CDSCO

In India's stringent medical device regulatory landscape, FORM MD-3, MD-5, MD-7, and MD-9 play crucial roles in obtaining licenses for manufacturing and selling medical devices. MD-3 initiates the process for low to moderate-risk devices, while MD-5 signifies final approval for these classes. MD-7 and MD-9 relate to moderate to high-risk and high-risk devices, respectively. This entails a meticulous process involving scrutiny, documentation, compliance checks, and premises audits overseen by CDSCO.

READ MORE

TO KNOW MORE

A Guide to FDA eSTAR Submission Template

The introduction of eSTAR revolutionizes the FDA's 510(k) submission process for medical devices, mandating electronic filing starting October 1, 2023. It offers an interactive PDF platform, ensuring comprehensive submissions and efficient responses to FDA inquiries. The goal is to elevate submission standards, requiring detailed data for pre-market reviews. The process involves accessing the eSTAR template from the FDA, registering online, and submitting through designated portals. Despite larger submission sizes and increased user fees, eSTAR promises improved transparency, enhanced submission quality, and a streamlined process.

READ MORE

Medical Device CDSCO Import License for Testing Purpose

In the ever-changing healthcare realm, importing medical devices for testing in India demands strict compliance with regulatory norms. The Central Drugs Standard Control Organization (CDSCO) oversees this process and grants MD-16 import licenses, ensuring adherence to stringent safety and quality standards.

This blog delves into the significance of these licenses for testing medical devices, highlighting their role in maintaining regulatory compliance in the country.

READ MORE

TO KNOW MORE

Revolutionizing Healthcare: Medical Device Industry Report 2023

The 2023 medical device industry report showcases dynamic advancements, regulatory updates emphasizing safety and efficacy, and government schemes incentivizing research and manufacturing. Notably, the establishment of upcoming medical device parks promises revolutionary production capabilities and collaborative opportunities

In this blog, we will explore the transformative landscape of the 2023 medical device industry, delving into its dynamic advancements, safety-focused regulatory updates, and initiatives driving research and manufacturing. Highlighting the pivotal establishment of forthcoming medical device parks, we aim to uncover their potential to revolutionize production and foster collaboration, underscoring their role in propelling imminent industry growth.

READ MORE

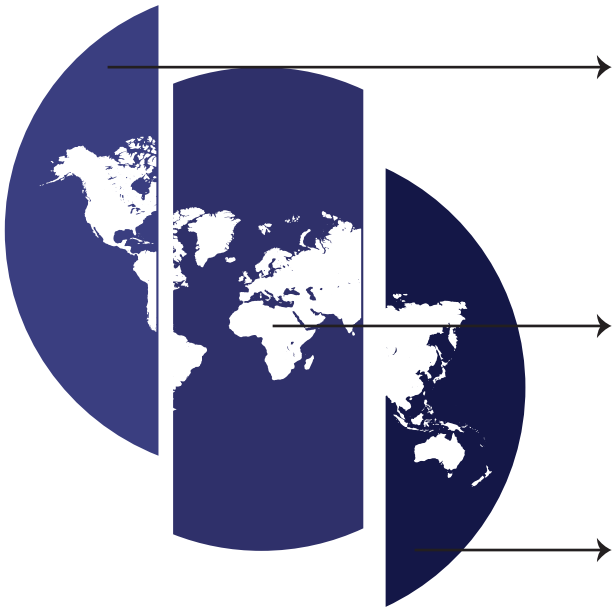
2024 Medical Device Trends and Global Market Outlook

The blog by Operon Strategist explores 2024's medical device trends and globle market outlook, highlighting technology's impact on patient care. It discusses wearables, 3D printing, IoT, AI diagnostics, minimally invasive techniques, and 5G's role in revolutionizing healthcare connectivity. Predicting a $595 billion market in 2024.
The blog also addresses industry challenges like regulations while spotlighting opportunities in advanced technologies like generative AI.

READ MORE

Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

OUR SERVICES



- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **Regulatory Approvals:**
- FDA 510(K)
- CDSCO Registration
- CE Marking
- UKCA
- SFDA

- **Medical Device Design Development Documentation:**
- Drug Device Combination Product
- USFDA 21 CFR 820.30 Design Control Requirements

CONTACT US

For more details regarding licence process and regulatory services .

enquiry@operonstrategist.com

+91-9370283428

Office No.14, 4th Floor, MSR capital, Morwadi, Pimpri, Pune 411 018