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YOUR MONTHLY REGULATORY UPDATE

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Driving Innovation in the Medical Devices Sector of India: What It Requires

India's Medical Technology Sector Projected to Surge to Rs. 2,177.9 Billion by 2026

FDA's Credibility Modelling Guidance for Medical Devices

MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Driving Innovation in the Medical Devices Sector of India: What It Requires

In India, fostering collaboration among stakeholders is seen as the linchpin for advancing the development of high-quality medical devices that can effectively address patient needs while ensuring sustainability. A recent report jointly published by KPMG in India and the Asia Pacific Medical Technology Association highlights the existing policies and initiatives that drive innovation in India's medical device sector, offering insights into the challenges and recommendations for overcoming them. This report aims to guide stakeholders through the transformation of the medical device industry in the country.

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Medical Device News

India's Medical Technology Sector Projected to Surge to Rs. 2,177.9 Billion by 2026

An industry report forecasts India's medical technology market to reach INR 2,177.91 Billion by 2026, indicating a robust Compound Annual Growth Rate (CAGR) of 23.87%. The report examines key players like Opto Circuits Limited, Philips India Limited, Siemens Limited, TTK Healthcare Limited, and Appasamy Associates, crucial in driving this growth. It analyzes market segments, growth drivers, global and regional dynamics, and the impact of the Russia-Ukraine conflict.

Explore the comprehensive news to delve deeper into India's burgeoning medical technology sector and gain valuable insights into the market landscape.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

FDA's Credibility Modelling Guidance for Medical Devices

The FDA's release of the "Credibility Modeling Guidance" is a groundbreaking framework for evaluating computational models in U.S. medical device premarket submissions. This comprehensive guidance introduces a risk-informed approach to enhance transparency and consistency in regulatory reviews, emphasizing critical factors like model risk and credibility evidence categories. It outlines steps for manufacturers to define questions of interest and identify evidence categories, and systematically assess credibility evidence. Operon Strategist highlights this as a crucial resource for navigating the regulatory landscape, offering insights to elevate standards in computational modeling for medical device development and regulatory compliance.

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A Guide to Medical Device Sterilization Methods

When it comes to medical devices, safety and hygiene are of most importance. Ensuring that medical devices are free from harmful microorganisms and safe for patient use is crucial. This is where sterilization comes into play. In this comprehensive guide, Operon Strategist will be shedding light on the various methods used to sterilize medical devices and the importance of clean room in medical device sterilization.

The article details various sterilization methods—steam, ethylene oxide, radiation, vapor phase, filtration, and liquid sterilization—highlighting their suitability based on the materials used in the devices. Additionally, it emphasizes the significance of clean rooms in maintaining sterility and offers guidance on selecting the optimal sterilization technique based on device composition. This comprehensive guide thoroughly covers essential aspects of medical device sterilization.

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Regulatory Budgeting for Drug Device Combination Products: EU MDR

The research, development and commercialization of drug-device combination products is gearing up in the pharmaceutical industry. These products offer unique therapeutic advantages and improved patient outcomes, but they also come with complex regulatory requirements and financial considerations for certain country approvals.

In this blog, we will explore the key cost and budgeting factors associated with drug-device combination products, focusing on compliances for device part, involvement of notified bodies, testing laboratories, and additional regulatory compliance.

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Understanding US FDA Renewal for Medical Device

The U.S. Food and Drug Administration (FDA) plays a pivotal role in ensuring the safety and effectiveness of medical devices in the United States. Medical devices, ranging from simple bandages to complex diagnostic equipment, must undergo a rigorous review and approval process before they can be marketed. Once a medical device is cleared or approved by the FDA, manufacturers must renew their registrations to maintain market access.

In this blog, we'll explore the intricacies of FDA renewals, why they matter, and how to successfully navigate the renewal process to keep your medical devices on the market.

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A Guide to FDA Communication for Medical Devices

In the ever-evolving world of medical devices, navigating the intricate regulatory landscape is essential for bringing your innovation to market. The United States Food and Drug Administration (FDA) plays a pivotal role in this journey. Effective FDA communication is key to ensuring that your medical device meets all regulatory requirements and reaches the hands of those who need it.

In this blog, we'll discuss how to communicate with the FDA for your medical device and provide you with valuable insights to make this process smoother.

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Guide to MHRA Medical Device Registration

Registering medical devices and in vitro diagnostic devices (IVDs) in the UK is a crucial step for manufacturers looking to market their medical devices in Great Britain. The Medicines and Healthcare Products Regulatory Agency (MHRA) oversees this process, ensuring compliance with stringent regulatory standards.

Discover the essential steps for registering your medical devices and IVDs in the UK, imperative for market entry into Great Britain. Learn why non-UK manufacturers need a UK Responsible Person (UKRP) to manage device registration on their behalf. Dive deeper into the process and gain comprehensive insights by exploring further details.

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A Guide to Getting a CDSCO Import License for Japanese Exporters of Medical Devices

Entering a new market holds immense potential for growth, especially for manufacturers of high-quality medical devices in Japan seeking expansion. India, with its thriving healthcare sector, presents a lucrative market ripe with opportunities. To navigate the regulatory landscape and facilitate entry into India, Japanese exporters can rely on Operon Strategist's expert regulatory consulting services to obtain the essential CDSCO import license.

Operon Strategist provides comprehensive regulatory consulting services tailored for Japanese medical device manufacturers aiming to penetrate India's burgeoning healthcare market. Our expert guidance ensures a smooth acquisition of the necessary CDSCO import license, streamlining entry and fostering growth opportunities in India's dynamic landscape.



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Navigating Access to USFDA 510(k) Database

The blog discusses the significance of the USFDA 510(k) Database as a centralized repository for information on medical devices undergoing the 510(k) premarket notification process. It highlights the database's role in providing crucial details such as device indications, technological specifications, safety profiles, and more. Operon Strategist is positioned as consultants offering expertise in navigating the FDA's 510(k) clearance process for medical devices in the United States.

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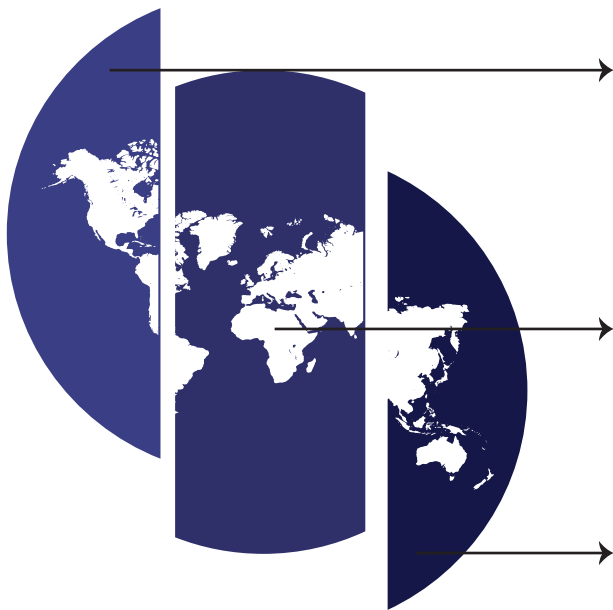
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Operon Strategist, A Leading Medical Device Regulatory Consultant.
Get Expert Assistance From Our Experienced Professionals And
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OUR SERVICES




- **Turnkey Project Consultant:**
 - Product Feasibility And Detailed Project Report
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 - Validation Documentation
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 - 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

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