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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

EU-Approved Medical Devices May Not Require Clinical Investigation

Indian Medical Device Industry Seeks 10-15% Customs Duty Raise

NEW

Upcoming Events this Month

- MEDICALL (Chennai)
- Medical Device Regulatory and Quality Summit 2024

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

EU-Approved Medical Devices May Not Require Clinical Investigation

The Indian government is considering eliminating the need for clinical evaluations of medical devices approved in the European Union (EU) to hasten the availability of innovative medical devices in India. Currently, clinical investigations are exempted for devices approved by regulatory agencies in the United States, United Kingdom, Australia, Canada, and Japan. The Drugs Technical Authority Board (DTAB), India's top drug advisory body, will soon review the proposal to amend Rule 63(1) of the Medical Devices Rules, 2017, to include the EU. The health ministry initially received this request in 2021 and referred it to the Central Drugs Standard Control Organization (CDSCO) for further evaluation. The matter will be re-discussed in the upcoming DTAB meeting to take necessary actions.

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Indian Medical Device Industry Seeks 10-15% Customs Duty Raise

The Indian medical device industry is calling for customs duties on medical imports to increase from 0-7.5% to 15% and for GST to be reduced from 18% to 12% in the 2022-23 budget. This aims to decrease reliance on imports, currently over 80% of the market.

Rajiv Nath of AiMeD argues that higher customs taxes won't greatly affect consumers due to already high retail prices. AiMeD also proposes a 2% infrastructure development cess on imports to support local manufacturing. Dr. Shravan Subramanyam of Wipro GE Healthcare highlights the need for investments in digital tools and local production to boost the MedTech sector and achieve self-sufficiency.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Government Targets 113 Home-Grown, Affordable Medical Devices to Reduce Import Dependence

The Indian government plans to boost local manufacturing of 113 affordable medical devices over the next five years, reducing import dependence and supporting both Indian and multinational manufacturers. Key segments include cancer therapy, imaging, implants, and diagnostics. The initiative aims to enhance export competitiveness and achieve an import coverage ratio of 1 within five years. Under the Production Linked Incentive (PLI) scheme, four medical device parks have been established, with 26 projects and an investment of Rs 1,206 crore. The goal is to cut import dependence from 75% to 50% in five years and increase exports.

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New Artificial Intelligence Act: What You Need to Know

On July 12, 2024, the EU's AI Act (Regulation (EU) 2024/1689) was officially published, establishing unified rules for AI systems, including those used in medical devices and in vitro diagnostics. Most AI medical devices are classified as "high-risk" and must comply with both the AI Act and existing regulations (MDR or IVDR), verified by a third party. The Act will be fully effective by August 2, 2026, with certain provisions starting from February 2, 2025. Operon Strategist offers expert guidance to ensure your AI medical devices meet these new requirements. Contact us for support.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Regulation (EU) 2024/1860: Extension of IVDR Transitional Period and New Provisions

Regulation (EU) 2024/1860, published in the Official Journal of the European Union, extends the transitional period for in vitro diagnostic (IVD) devices to ensure market supply continuity. This update revises provisions on EUDAMED usage and introduces mandatory reporting of supply disruptions. The phased rollout of EUDAMED and extended transitional periods address delays and capacity issues, aiming to prevent critical device shortages. Operon Strategist is ready to assist manufacturers with compliance and implementation of these new requirements.

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WHO Launches MeDevIS: Global Platform for Medical Device Information

The World Health Organization (WHO) has launched MeDevIS, an open-access online platform offering comprehensive information on medical devices. This global resource, featuring details on 2,301 devices across various health issues, aims to support informed decision-making by governments, regulators, and users. MeDevIS streamlines access to device information, replacing traditional paper-based methods and standardizing device naming with EMDN and GMDN systems. This initiative is particularly beneficial for resource-limited settings, enhancing access to critical medical technologies.

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EU MDR 2017/745 Requirements for Placing Your Device on the Market

Navigating the EU MDR 2017/745 for medical devices involves several critical steps to ensure compliance and market entry. Key requirements include determining the device's classification, adhering to General Safety and Performance Requirements (GSPR), implementing a risk management process, conducting clinical evaluations, and preparing comprehensive technical documentation. Manufacturers must also obtain CE marking, draft an EU Declaration of Conformity, and register on EUDAMED. Operon Strategist offers expert guidance throughout this process, providing tailored solutions to help manufacturers meet all regulatory requirements efficiently and effectively.

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How to Get CE Mark for Medical Devices

To obtain a CE mark for medical devices, manufacturers must classify their device, set up a quality and risk management system, prepare technical documentation, conduct clinical evaluations, and work with a Notified Body for certification. Key steps also include appointing a responsible person, preparing a Declaration of Conformity, and maintaining post-market surveillance. The CE mark ensures compliance with EU standards, facilitating market entry. Operon Strategist offers expert support throughout this process.

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Various Materials Used in Medical Device Manufacturing (Know About Some Common Medical Devices) | Operon Strategist

This blog highlights the key materials used in common medical devices: syringes and needles use polypropylene and stainless steel; blood collection tubes feature polypropylene and isobutyl rubber; IV sets include ABS and DEHP-free PVC; and gauze bandages are made from cotton. Each material is chosen for its specific properties like durability and biocompatibility. Operon Strategist assists manufacturers in selecting materials and ensuring regulatory compliance for high-quality medical devices.

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Upcoming Opportunities in the Medical Devices Manufacturing Segment

The medical devices industry is booming, offering exciting opportunities in active devices (electronic medical devices), disposable medical devices, and orthopedic and dental implants. Active devices are growing due to technological advances and rising chronic diseases, while disposable devices see increased demand for infection control and cost-effectiveness. Orthopedic and dental implants are expanding due to an aging population and advancements in materials and technology. Manufacturers who innovate and adapt to regulatory changes will thrive in this evolving market. Operon Strategist offers expert consulting to navigate regulatory and compliance challenges, helping manufacturers succeed in the competitive medical devices sector.

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Understanding ISO 13485 Resource Management: Key to Quality Medical Device Manufacturing

ISO 13485 mandates effective resource management to ensure high standards in medical device manufacturing. This involves managing human resources, infrastructure, work environments, and equipment to maintain product quality and regulatory compliance. Key practices include training, infrastructure maintenance, and equipment calibration. Proper resource management improves product quality, compliance, and operational efficiency. Operon Strategist provides support with gap analysis, training, and infrastructure optimization to help manufacturers meet ISO 13485 standards.

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Tips to Export Medical Devices Without CE Marking

Exporting medical devices without CE marking can be a strategic move for manufacturers targeting markets outside of Europe. While CE marking is typically required for medical devices sold within the European Economic Area (EEA), many countries outside this region have their own regulatory requirements. You can export your medical devices to non-European countries using ISO 13485 and local Free Sale Certificates (FSCs), bypassing the need for CE marking and its associated complexities. Here's a comprehensive guide on how to navigate exporting medical devices without CE marking.

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The Rise of Automation in Medical Device Manufacturing

The medical device industry is experiencing a transformative shift with the rise of automation. This evolution is enhancing precision, efficiency, and consistency in the production of medical devices. As automation continues to redefine the landscape, it brings forth numerous benefits and challenges that manufacturers must navigate. This blog delves into the impact of automation on medical device manufacturing, explores regulatory requirements, and highlights the role of Operon Strategist, a leading medical device regulatory consultant company.

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8 Important Steps to Achieving Medical Device Approval

Introducing a new medical device to the market involves navigating complex regulatory processes, but it can be managed with the right approach. This 8-step roadmap guides you through defining your product, identifying relevant regulations, establishing a test plan, and preparing necessary documentation. Key steps include submitting your device for testing, obtaining certifications, and seeking regulatory approvals in target markets such as India, the EU, Saudi Arabia, and the U.S. For seamless approval, partner with Operon Strategist, who offers expert consulting to help you meet global standards efficiently and ensure your device reaches the market successfully.

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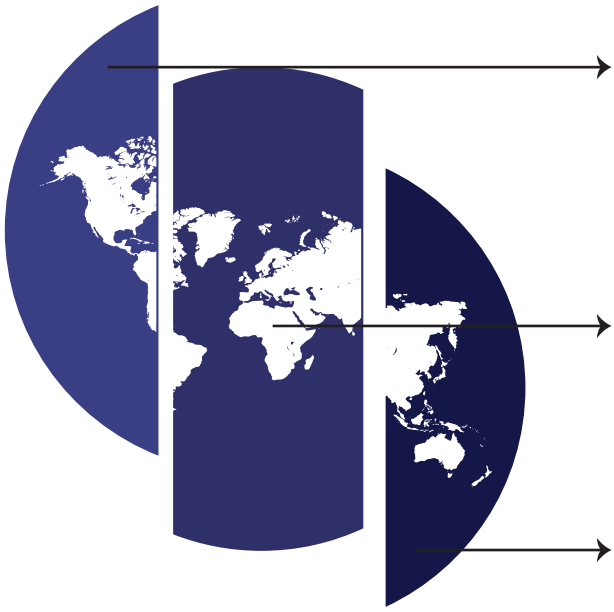
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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

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