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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.

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Transforming Thoughts In To Reality

LATEST NEWS & UPDATES

FDA Unveils Comprehensive Strategy for Integrating AI into Medical Products

Mandatory Online Submission of PSURs for Medical Devices Implemented

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analytica Anacon India | JEMS Today Indianapolis

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

FDA Unveils Comprehensive Strategy for Integrating AI into Medical Products

The FDA has unveiled a groundbreaking strategy for integrating artificial intelligence (AI) into medical products, aimed at advancing patient care, safety, and innovation within healthcare. The comprehensive plan emphasizes collaboration, regulatory clarity, promotion of best practices, and support for research initiatives. With a focus on responsible AI utilization, the FDA's initiative is poised to revolutionize the healthcare landscape, ensuring access to safe and effective AI-powered medical products while fostering an environment conducive to innovation.

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Medical Device News

Mandatory Online Submission of PSURs for Medical Devices Implemented

Operon Strategist reports on the recent circular issued by the CDSCO mandating the online submission of Periodic Safety Update Reports (PSURs) for medical devices and in-vitro devices. Effective March 19, 2024, this measure aims to simplify the submission process, enhance efficiency, and ensure prompt evaluation of safety updates. Operon Strategist stands ready to assist stakeholders in complying with this regulatory requirement and navigating the transition to online submissions.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Concerns Raised by Parliamentary Panel on Quality of Used Medical Devices

Operon Strategist reports on concerns raised by the Parliamentary Standing Committee on Chemicals and Fertilizer's regarding the quality of used medical devices in India. The committee highlights regulatory gaps and advocates for government intervention to ensure safety and efficacy. Operon Strategist stands ready to address these concerns, assisting companies in navigating regulations and promoting transparency in the healthcare sector.

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CDSCO Implements Compulsory Online Safety Reporting for Medical Devices

Operon Strategist reports on the recent mandate by the Central Drugs Standard Control Organization (CDSCO) requiring medical device manufacturers to submit safety reports online, effective April 1, 2024. This move aims to modernize India's drug regulation framework and enhance post-market surveillance. Period Safety Update Reports (PSURs) play a crucial role in pharmacovigilance, and transitioning to online submission will streamline processes and improve transparency. Operon Strategist stands ready to assist companies in navigating this regulatory change, ensuring compliance and transparency in the Indian medical device market.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Haryana's Medical Device Manufacturing Policy 2024 Targets ₹3000 Crore Investment

Operon Strategist reports on Haryana's bold vision to establish itself as a global leader in medical device manufacturing through the Draft Medical Devices Manufacturing Policy 2024. The policy aims to attract INR 3000 crore in investments and create 20,000 jobs, driving economic growth while reducing dependence on imports. It encompasses a diverse range of medical devices and components, emphasizing sustainability and global collaboration. Operon Strategist stands ready to assist companies in navigating regulatory compliance and leveraging opportunities presented by Haryana's visionary initiative, contributing to the advancement of the medical device industry.

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5 Companies Propose to Invest ₹176 Crore at Ujjain's Medical Devices Park

Operon Strategist reports on the latest developments at Ujjain's Medical Devices Park, where five companies have proposed a combined investment of ₹176 crore. These investments, facilitated by the Madhya Pradesh Industrial Development Corporation (MPIDC), aim to enhance healthcare infrastructure and create approximately 687 job opportunities in the region. Notable investments include initiatives in radiotherapy cancer treatment devices, blood collection systems, insulin syringes, ENT workstations, and orthopedic implants. Operon Strategist highlights its role in supporting regulatory compliance for companies capitalizing on these opportunities, contributing to the growth and advancement of the medical device industry in India.

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Global Opportunities for Medical Device Manufacturers: Insights into India, LATAM, and African Markets

Operon Strategist's latest blog explores the burgeoning opportunities for medical device manufacturers in key regions such as India, Latin America (LATAM), and Africa. Highlighting the growth prospects, regulatory landscapes, and market dynamics in each region, the blog offers valuable insights for companies aiming to expand globally. From India's thriving healthcare sector to LATAM's diverse landscape and Africa's unmet healthcare needs, manufacturers can capitalize on these markets with the right strategies and regulatory guidance. Operon Strategist, with its expertise in navigating global regulatory frameworks, stands ready to assist companies in seizing these opportunities and ensuring compliance in diverse markets.

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A Comprehensive Guide to Setting Up a Cleanroom for Your Medical Device Industry

Establishing a cleanroom in the medical device industry is crucial for maintaining product safety and effectiveness. Operon Strategist's guide outlines essential steps, including determining cleanliness requirements, selecting suitable locations, installing air filtration systems, and implementing best practices. By following these steps and seeking expert assistance, manufacturers can ensure compliance with industry standards and guarantee the quality and safety of their products. Operon Strategist offers comprehensive cleanroom solutions to guide facilities through this process, from assessment to implementation.

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A Comprehensive Guide to Obtaining CDSCO Loan Licenses for Medical Devices

Operon Strategist's latest blog offers a comprehensive guide to obtaining CDSCO loan licenses for medical devices in India, crucial for manufacturers seeking market entry. Exploring the regulatory framework, application process, and key forms required for loan license authorization, the blog provides valuable insights for navigating the complex landscape of regulatory compliance. By outlining the significance of loan licenses and the authorities responsible for granting them, Operon offers practical guidance to manufacturers aiming to streamline their entry into the Indian market. With expertise in regulatory consulting, Operon ensures compliance with all documentation requirements and provides ongoing support to facilitate successful license acquisition.

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Navigating the European NB Opinion Process for Drug Device Combination Products

Operon Strategist's latest blog post delves into the intricate process of obtaining a European Notified Body (NB) opinion for drug-device combination products. By highlighting key stages such as initial assessment, design and development, compilation of technical documentation, and evaluation by the NB, the post offers invaluable insights into navigating the regulatory landscape. Operon Strategist's expertise in this field ensures comprehensive support for clients, from inception to securing market approval. Read the full blog to learn how to streamline your path to success in bringing innovative combination products to market.

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Navigating the Complexity: Risk Analysis of Drug-Device Combination Products

Operon Strategist's latest blog delves into the intricate process of risk analysis for drug-device combination products, highlighting the challenges and complexities inherent in this innovative realm of healthcare. From interdisciplinary collaboration to regulatory compliance and patient safety considerations, the blog emphasizes the importance of a structured risk analysis framework. By outlining key steps in risk identification, assessment, mitigation, and communication, Operon offers valuable insights for manufacturers navigating the development, manufacturing, and regulatory approval processes of these transformative therapies. Partnering with Operon ensures compliance, prioritizes patient safety, and unlocks the full potential of innovative therapies to improve patient outcomes and enhance quality of life.

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Ensuring HIPAA Compliance and Cybersecurity for Software as Medical Devices

Operon Strategist's latest blog delves into the critical aspects of ensuring HIPAA compliance and cybersecurity for Software as Medical Devices (SaMD). Highlighting the significance of adhering to HIPAA regulations and implementing robust cybersecurity measures, the blog emphasizes the legal obligations and trust-building potential inherent in safeguarding patient data. From understanding HIPAA requirements to implementing cybersecurity best practices throughout the software development lifecycle, Operon offers expert guidance to SaMD developers. By prioritizing compliance and data security, manufacturers can uphold patient privacy, maintain regulatory compliance, and bolster trust in the digital healthcare landscape.

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5 Tips for Medical Device Registration Across Global Markets

Successfully registering medical devices across global markets requires meticulous planning and adherence to diverse regulatory frameworks. Operon Strategist outlines key strategies for navigating the complexities of registration in major markets like the US, EU, Canada, and Australia. From understanding specific regulatory requirements to leveraging quality management systems (QMS) for efficient documentation, the blog emphasizes the importance of long-term strategy, compliance prioritization, and expert guidance. By following these strategic pillars, manufacturers can streamline the registration process and ensure market success worldwide.

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Navigating the Medical Device Market Entry Gameplan: The EU and The US Analysis

Launching medical devices in the European Union (EU) and the United States (US) involves navigating distinct regulatory landscapes and market dynamics. The EU, governed by the Medical Device Regulation (MDR), prioritizes patient safety and quality with a streamlined CE marking process. In contrast, the US FDA oversees stringent regulations under the Federal Food, Drug, and Cosmetic Act, with variable pathways like FDA 510(k) and PMA. Key considerations for market entry include regulatory environment, market size, entry barriers, and competitive landscape. Understanding the differences between these markets is essential for successful market entry and expansion.

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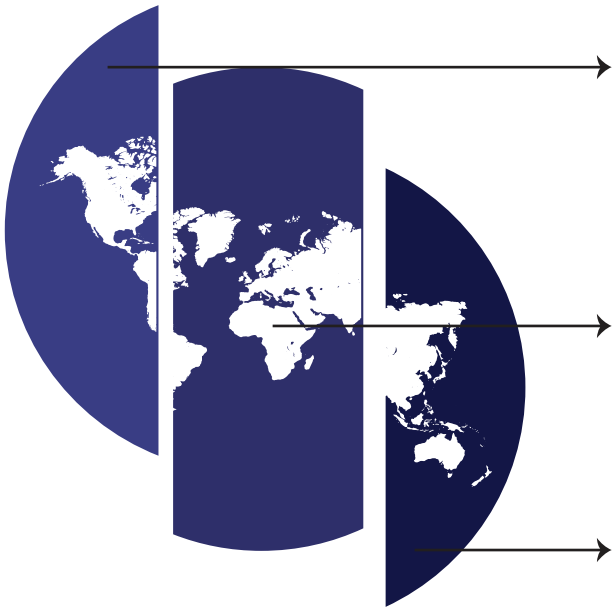
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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

CONTACT US

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