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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

Indian Government Launches Online Application System for Neutral Code for Medical Device Export Licenses

CDSCO Issued Regulatory Guidelines for Sampling of Medical Devices, Drugs and Cosmetics

EU MDR Cybersecurity Requirements for Medical Devices

NEW

Upcoming Events this Month

Medical Fair India | Nepal Medical Show

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Indian Government Launches Online Application System for Neutral Code for Medical Device Export Licenses

The Indian Government has introduced a simplified process for obtaining a Neutral Code, essential for manufacturing medical devices for export. Through the Directorate General of Health Services, Central Drugs Standard Control Organization (Medical Devices Division), applicants can now utilize the Online System of Medical Devices portal to apply for the Neutral Code, streamlining the process and eliminating paperwork. The Central Licensing Authority will issue the Neutral Code in accordance with the Medical Devices Rules, 2017. Stakeholders are encouraged to adhere to the new online application process, with Operon Strategist offering comprehensive support for navigating regulatory requirements in medical device exports.

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Medical Device News

CDSCO Issued Regulatory Guidelines for Sampling of Medical Devices, Drugs and Cosmetics

On February 9th, 2024, CDSCO issued regulatory guidelines for drug, cosmetics, and medical device sampling in India. Emphasizing quality and combating counterfeit products, the guidelines prioritize high-risk parameters, comprehensive monitoring, and prompt regulatory actions. They cover sampling plans, selection criteria, and testing laboratory roles, aiming for thorough analysis and compliance with GMP. Operon Strategist supports these guidelines and helps medical device manufacturers ensure quality and safety standards. For details, refer to CDSCO's circular.

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Parliamentary Panel Asks the Government to Notify More Bodies for Audit and Inspection of Medical Device Units

A recent report by a Parliamentary Panel has underscored concerns regarding the shortage of notified bodies available for auditing and inspecting medical device manufacturing units in India. With only 13 bodies currently operational, the panel, led by Dr. Shashi Tharoor, emphasized the urgent need to increase this capacity to maintain quality standards in the industry. The panel also highlighted the importance of providing adequate technical infrastructure and manpower to these bodies. Additionally, it emphasized expediting the licensing process for medical device manufacturers to ensure regulatory compliance and patient safety.

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EU MDR Cybersecurity Requirements for Medical Devices

The blog explores the critical role of cybersecurity in ensuring the safety and integrity of medical devices, particularly considering the EU Medical Device Regulation (MDR). It highlights key components of the EU MDR cybersecurity requirements, such as integrating cybersecurity into device design, adhering to general safety and performance requirements, and implementing post-market surveillance measures. The post also outlines best practices for achieving compliance, including conducting risk assessments, incorporating security-by-design principles, and providing user training. Operon Strategist is positioned as a trusted partner for navigating EU MDR cybersecurity requirements, offering expert guidance and support to manufacturers in meeting compliance standards and mitigating risks effectively.

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Guide to Navigating US FDA 510(k) Approval for IVDs (In Vitro Diagnostic Devices)

Navigating FDA's 510(k) approval process for In Vitro Diagnostic Devices (IVDs) is complex, but Operon Strategist offers specialized consulting to help. This blog outlines key aspects, including demonstrating equivalence to predicate devices and FDA classifications. Operon's services cover regulatory strategy, predicate device identification, testing support, submission prep, and post-submission assistance. Their expertise aids companies in achieving crucial approval for innovative diagnostic technologies.

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The Role of AI in Medical Devices: Insights from Operon Strategist

The blog explores how artificial intelligence (AI) is transforming medical devices and highlights the Operon Strategist's role in guiding companies through regulatory compliance and AI integration. It discusses AI's impact on diagnostics, personalized treatment, predictive analytics, and remote monitoring, citing examples of AI-based medical technologies. Operon Strategist's expertise in streamlining regulatory processes and AI integration is emphasized. The piece concludes by underlining AI's potential to enhance healthcare and the importance of trusted partnerships, like with Operon Strategist, in navigating this evolving landscape.

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Understanding SaMD and SiMD in Medical Device Regulation

The blog explores the distinction between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD), focusing on regulatory compliance, risk management, and development processes. Operon Strategist offers comprehensive regulatory consulting services to help companies navigate compliance frameworks and accelerate time-to-market for innovative medical technologies, ensuring adherence to quality standards and regulatory requirements.

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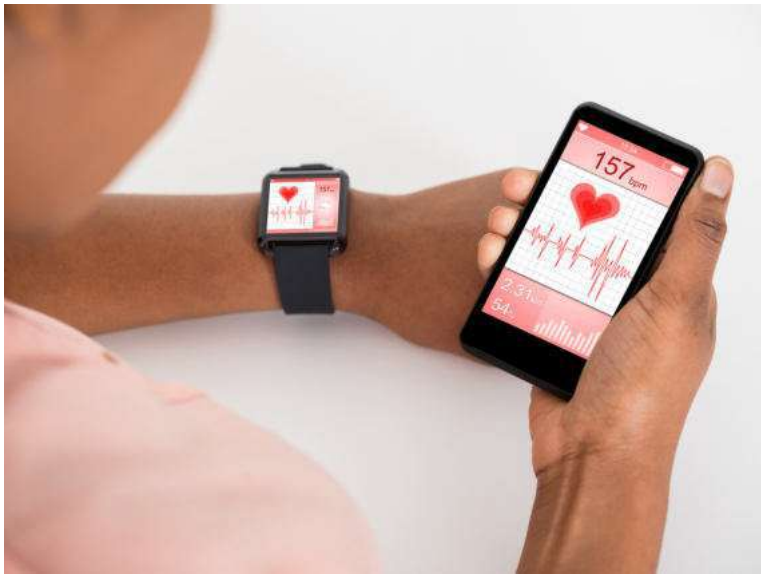

Impact of Generative AI in Healthcare: Navigating Regulatory Requirements for Medical Devices

The blog explores the transformative potential of generative artificial intelligence (AI) in healthcare, particularly in the realm of medical devices. Generative AI, including generative adversarial networks (GANs), offers advancements like personalized implants and enhanced diagnostic tools by analyzing large datasets. It streamlines the development process, accelerating innovation and improving patient outcomes.

Operon Strategist provides comprehensive services to ensure seamless regulatory compliance and product excellence, empowering companies to harness the full potential of generative AI in medical devices and revolutionize healthcare.

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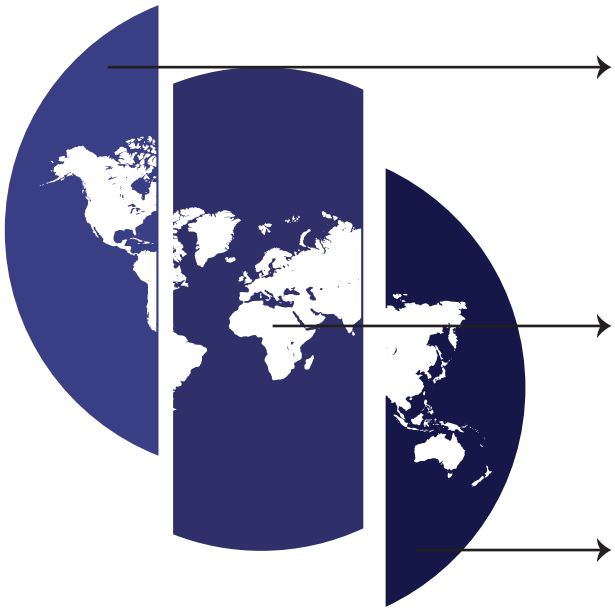
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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For more details regarding licence process and regulatory services .

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