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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

Ujjain Medical Devices Park Booming with Rs. 1,400 Crore Investment and 4,500 Job Opportunities!

NEW

Upcoming Events this Month

Medical Expo India, Indore | India Med Expo, Noida

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Ujjain Medical Devices Park Booming with Rs. 1,400 Crore Investment and 4,500 Job Opportunities!

Ujjain Medical Devices Park has attracted significant investment, surpassing Rs. 1,400 crore from 28 medical equipment and consumables manufacturers. This influx of investment is expected to create around 4,500 job opportunities, contributing to the growth of the medical device manufacturing sector in Madhya Pradesh. The park aims to increase domestic availability and affordability of critical care medical devices, addressing the current reliance on imports. With the industry valued at $11 billion and a promising growth rate, the development of this park signals a positive shift in India's medical technology sector.

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Medical Device News

India Streamlines Drug & Medical Device Approval Process

India is revolutionizing its drug and medical device approval process, aiming for faster access to life-saving treatments. With bold initiatives and closer collaboration between regulators and industry, the nation is paving the way for smoother approvals and groundbreaking innovations. Operon Strategist offers expert consultation to optimize regulatory journeys, accelerating market success for pharmaceutical and medical device innovations.

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MEDICAL DEVICES REGULATORY UPDATES

CDSCO Important Update: Mandatory Registration of Class C and D Medical Devices (Transition to Licensing)

CDSCO has issued an important update regarding the transition from mandatory registration to a licensing regime for Class C and D medical devices in India. Effective from October 1, 2023, manufacturers and importers are reminded to initiate the process of obtaining manufacturing/import licenses via the CDSCO online portal to ensure compliance with the Medical Devices Rules 2017. Operon Strategist offers expert consultation to facilitate a smooth transition, ensuring compliance with regulatory requirements and uninterrupted access to vital medical devices for patients.

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Performance Evaluation for In Vitro Diagnostic (IVD) Device: Step-by-Step Process

In vitro diagnostic (IVD) devices are vital in healthcare, aiding in diagnosis and management. However, before their use, thorough performance evaluation is necessary to ensure accuracy and safety. This blog outlines the steps involved, from establishing evaluation plans to compiling reports. It emphasizes compliance with regulations and involvement of key stakeholders. Operon Strategist offers expertise in navigating regulatory requirements and project management for successful IVD device development.

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TO KNOW MORE

How to Regulate Drug Device Combination Product

Combining drugs and medical devices in a single product holds great promise for healthcare innovation, but navigating regulatory hurdles is crucial. Operon Strategist's latest blog explores the complexities of regulating drug device combination products, covering key steps like determining regulatory pathways, pre-submission meetings, design controls, and post-market surveillance. By offering expert assistance tailored to individual needs, Operon Strategist aims to guide developers through the regulatory landscape and unlock success for innovative products.

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Navigating Medical Device Software Validation and Verification: An Extensive Guidance

Ensuring the safety, reliability, and regulatory compliance of medical device software is crucial for patient care. Operon Strategist's latest blog explores the intricacies of software validation and verification, covering key processes like requirements analysis, test planning, and documentation. By providing expert guidance, Operon Strategist aims to assist developers in navigating this critical aspect of product development, ultimately contributing to the delivery of safe and effective medical devices to market.

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Uzbekistan Medical Device Registration

Navigating the process of medical device registration in Uzbekistan requires a clear understanding of the regulatory framework and classification system. Operon Strategist's latest guide offers valuable insights and actionable steps for manufacturers looking to enter this burgeoning market. From understanding device classification to compiling essential documents and navigating the registration timeline, Operon Strategist aims to streamline the process and maximize market access for medical device innovations in Uzbekistan.

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CDSCO Test License for Medical Devices in India (Form MD 12, And MD 13)

In India, individuals can obtain a Test License (Form MD-13) from CDSCO to produce limited quantities of medical devices for specific purposes such as research or training. Operon Strategist simplifies the application process, guiding manufacturers through registration on the Sugam portal, document preparation, fee payment, and submission. With expertise in regulatory compliance, Operon Strategist ensures timely approvals, enabling manufacturers to focus on innovation while meeting standards for medical device safety and effectiveness.

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TO KNOW MORE

Deciphering US FDA Compliance for Medical Gloves: An Extensive Manual

Operon Strategist's latest blog delves into the complexities of achieving US FDA compliance for medical gloves, essential for ensuring patient and healthcare worker safety. Highlighting key requirements and considerations, such as adherence to Quality Systems Regulations (QSR) and biocompatibility testing, the blog underscores the importance of robust quality management systems and ongoing regulatory vigilance. By providing expert consultation and tailored strategies, Operon Strategist aids manufacturers in navigating FDA regulations and fostering a culture of safety within the medical glove industry.

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IVD Manufacturing

Operon Strategist's blog on IVD manufacturing offers a comprehensive overview of the processes, regulations, and machinery involved in producing in-vitro diagnostics. From classification of IVD medical devices to obtaining regulatory licenses like the CDSCO manufacturing license, the blog emphasizes the importance of compliance and quality assurance. It delves into the product development cycle and highlights essential steps like contextual inquiry and functional analysis. Moreover, it outlines the machinery used in IVD manufacturing, detailing each component's role in the production process. Operon Strategist, with over a decade of experience in medical device consulting, provides invaluable insights for manufacturers entering the IVD industry.

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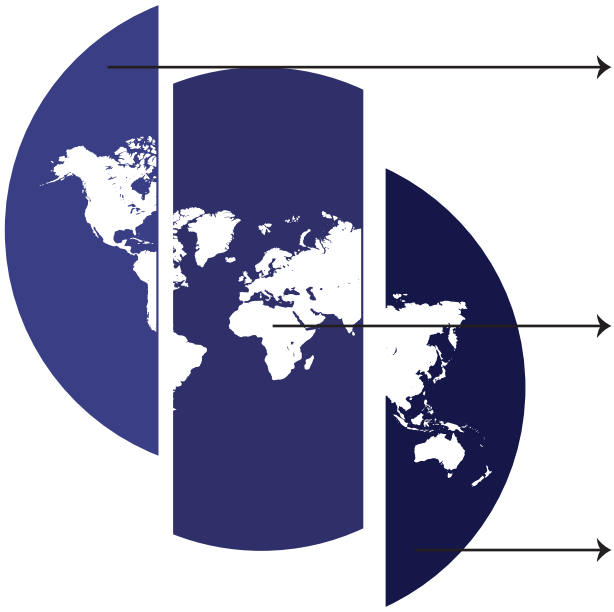
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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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